

Common Funding Sources Among Registered Dental Clinical Trials: A Descriptive Study

Patel P¹, Patel D², Kapadia U³, Belgal P², Nalliah RP^{4*} 

¹DDS Candidate, University of Michigan School of Dentistry, USA

²DDS, General Dental Practitioner, USA

³DMD Candidate, Tufts University School of Dental Medicine, USA

⁴Associate Dean for Patient Services, University of Michigan School of Dentistry, USA

*Correspondence author: Romesh P Nalliah, Associate Dean for Patient Services, University of Michigan School of Dentistry, USA;

E-mail: romeshn@umich.edu

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Abstract

Objective: ClinicalTrials.gov is a public database of clinical trials that provides details on clinical trials. Our study aims to identify primary funders for dental clinical trials.

Method: We searched the term "Dental" on ClinicalTrials.gov, identifying 634 studies as of September 2, 2023. Our inclusion criteria was trials still recruiting, not yet recruiting, enrolling by invitation or active but not recruiting which identified 113 clinical trials for our study. Each clinical trial was classified as either a clinical trial or an observational study. Two calibrated independent reviewers then categorized clinical trials into "Primary prevention," "Secondary prevention," "Tertiary dentistry," and "High-end dentistry." Disagreements were resolved through discussion with a third reviewer. According to the University of Michigan Human Research Protection Program operating manual part 4. V.A., this study is considered IRB-exempt.

Results: Of the 113 studies, 20 were observational and 93 interventional studies. Funders included Universities (42.5%), Industry (26.55%), Individual/Other Organizations (15.0%), National Institute of Health (NIH) (15%) and Other US Federal agencies (0.89%). Out of 113 clinical trials, 24 were primary prevention; 11 were secondary prevention; 33 were tertiary prevention and 25 were "high-end dentistry."

Conclusion: The study found that Universities were the primary funder of clinical trials in dentistry. This has implications for a dental research faculty's ability to gain sufficient funding to generate research to promote science and advance their careers. Universities with more money allocated to research will support more clinical trials.

Keywords: Dental Clinical Trials; National Institute of Health; Dentistry

Introduction

Oral diseases have a high global burden in terms of prevalence, impact and expenditures, with no notable decline in recent decades [1]. These conditions can affect one's physical, social and psychological health, impacting a person's quality of life [2-8]. According to the Centers for Disease Control and Prevention (CDC), over half of adolescents aged 12 to 19 have had at least one cavity in their adult teeth since 1999-2004 and similarly, about 1 in 4 adults aged 20-64 years had untreated tooth decay in 2011-2016 [2-32]. The United States (US) spends more than \$124 billion on costs related to dental care each year [2,31]. On average, over 34 million school hours and 92 million work hours are compromised due to dental emergencies requiring unplanned care and approximately \$46 billion dollars (2015 US dollars) of US productivity is lost each year due to untreated oral diseases [2,17,26,31]. Evidence suggests that dental care is currently more treatment-driven rather than prevention-driven [3,4]. Data suggests that regular preventive dental care has been associated with substantial savings in overall dental care costs when compared to dental care costs for those individuals who received no or few preventive visits during the study period [5].

Redirecting crucial resources such as finances, time and productivity towards preventive dental care and research could prevent the downstream consequences of disease such as unplanned dental emergencies that lead to loss of productivity, school hours and quality of life [6]. It is, therefore, imperative to view oral diseases as a critical public health concern that is worthy of prioritization in funding. The National Institutes of Health (NIH) and its oral health branch, the National Institute of Dental and Craniofacial Research (NIDCR), have funded various research studies [7]. As of the latest review in August 2018, these also include studies on salivary diagnostics, oral cancer, oral health and opioids and regenerative medicine, aimed at advancing knowledge and improving public health [7]. Clinical trials are necessary to prospectively evaluate preventative, diagnostic and therapeutic methods. They are essential for producing high-quality evidence that could be used to guide clinical practice and enhance community health. However, data suggests that it takes 17 to 23 years to convert original research findings into their use in clinical practice [9].

Fifty-six dental institutions received NIH funding and 55 received NIDCR awards between 2005 and 2014 [10]. Nine US dental schools currently listed by the American Dental Education Association, did not receive any grants from the National Institutes of Health (NIH) during this time [10]. Less is known about research funding from other sources such as universities and industry. Better understanding of funding sources and their funding patterns could help a junior faculty focus their grant application processes.

The capacity to examine ClinicalTrials.gov registration data has been made easier and better by the availability of the Clinical Trials Transformation Initiative Aggregate Analysis of ClinicalTrials.gov (CTTI AACT) database [11]. The CTTI AACT database underwent an upgrade in 2017 and is now housed on a cloud-based platform that makes the whole collection of trials registered in ClinicalTrials.gov available for download and analysis. Because of its relational and reorganized style, it is easier to analyze. It offers access to more fields not easily included in straight exports from ClinicalTrials.gov [11].

Since the inception of ClinicalTrials.gov in the year 2000, over 400,000 clinical trials have been registered [10]. Clinical trial metadata analysis can reveal crucial trends over time, such as the composition, size, design and types of studies being financed. To our knowledge, there is no literature available on what kind of dental research is supported by different sponsors such as the NIH, industry, universities and individuals or other institutions. The goal of our study is to describe the different types of research funded by the different types of sponsors. This information will be useful for faculty (especially tenure-track) as they begin or advance their careers and seek out institutions and sponsors that can support their work and career development. Better understanding of funding and sponsor patterns may also help mentors to early career scientists provide better feedback and guidance as they commence their research career.

Methodology

We took a snapshot of data on the Clinicaltrials.gov website on the second day of September 2023. Two independent calibrated reviewers searched clinicaltrial.gov for “dental” studies in the United States. We identified a total of 634 studies. Our inclusion criteria were active studies on that particular day which were either recruiting, not yet recruiting, enrolling by invitation or active but not recruiting participants. We excluded 521 that did not meet these eligibility criteria. This left 113 active studies for evaluation.

The two calibrated reviewers went through each study and collected data on study type and funder type and classified each study based on intervention. A third reviewer was available to resolve disagreements by discussion. Study types included interventional and observational studies. Primary funders included NIH, Industry, Other US Federal Agencies and All Others. “All Other” funder categories were heterogeneous and comprised non-US governmental agencies, organizations, universities and dental companies. So, we categorized “All others” into University-funded and Individual/Other Organizations to get more accurate information.

Funding sources were further categorized into sponsors and collaborators which included NIH-funded, Industry-funded, University-funded, Individuals/Other Organizations and Other US Federal agencies. Each registered dental clinical trial study was already classified as either an interventional (Randomized clinical trial or Non-randomized clinical trial) or an observational (Non-interventional) study. We further categorized clinical trials into four groups: “Primary Prevention,” “Secondary Prevention,” “Tertiary Dentistry” and “High-End Dentistry.”

We defined Primary Prevention as interventions that help prevent oral disease before it can occur, for instance, water fluoridation. Secondary Prevention was defined as the intervention to arrest a disease condition that has already occurred and prevent the disease progression and recurrence for instance dental restorations for primary dental caries. Tertiary dentistry was defined as affordable dental solutions that restore form and function-for example removable and fixed prostheses, simple tooth extractions, Scaling and Root planing. High-end dentistry was defined as the best available, evidence-based, solution in dentistry to restore form, function and esthetics such as veneers and surgical procedures such as implant placement.

When there was disagreement about the category, a third reviewer was available for group discussion to resolve the disagreement. According to the University of Michigan Human Research Protection Program operating manual part 4. VA, this study is considered IRB-exempt.

Results

As of September 2nd, 2023, we identified a total of 634 studies. There were 113 active studies which were included in our evaluation. 20 (17.7%) out of the 113 were observational studies with the remaining 93 (82.3%) being “Randomized/Nonrandomized clinical” studies (Table 1). These registered dental clinical trials were further segregated broadly by primary funder type as NIH, Industry, University, Individuals/ Other Organizations and Other US Federal agencies. 48 (42.5%) of 113 were funded by Universities, while 30 (26.55%) were Industry funded, 17 (15%) studies sponsored by Individuals/Other Organizations, 17 (15%) were funded by NIH and 1 (0.89%) by Other US Federal agencies (Fig. 1).

NIH

Out of the 17 NIH clinical trials, 8 were categorized as “Primary prevention” trials and 3 were “Secondary prevention”. So, based on the source of funding and the study category, out of all NIH funding, 64.71% (11 out of 17 studies) is allocated to primary and secondary prevention combined. Moreover, one trial was “High-end dentistry” and 5 studies were “Observational” (Fig. 1). Adults were the most commonly involved population in the studies, accounting for 13 out of 17 trials. The number of studies with a range of participants between 101-500 was 10 (Fig. 2).

Industry

Out of the 30 industry-funded studies, 10 were “Tertiary dentistry” trials, 6 were “High-end dentistry”, 6 were “Primary prevention”, 1 was “Secondary prevention” and 7 were “Observational” studies (Fig. 1). A total of 23 out of the 30 trials that were industry-funded were treatment-driven rather than prevention. 27 out of 30 research studies that received funding from the industry involved adult participants. Most of the studies with the number of 19 were done with a 1-100 participants range while two studies had a participant size of 501-5000 range (Fig. 2).

University

University-funded the majority of “Tertiary dentistry” trials, a total number of 19 out of 48 followed by 12 “High-end dentistry” trials, 9 studies of “Primary prevention”, 4 studies of “Secondary prevention” and 4 “Observational studies” sponsored by universities (Fig. 1). 30 university-funded studies had 1-100 participants size while two studies had a participants range of 501-5000 (Fig. 2).

Individuals/Other Organizations

Individuals/Other Organizations supported a total of 17 studies out of them 5 were “High-end dentistry” trials, 4 were “Tertiary dentistry” trials followed by 3 were “Secondary prevention” and 1 was “Primary prevention”. 4 of the studies funded by Individuals/Other Organizations were “Observational studies” (Fig. 1). 11 out of 17 studies funded had a participant size range of 1-100. Moreover, one secondary prevention study had the highest number of participants, involving over 5,000 participants size, with a total of 14,100 participants (Fig. 2).

Other US Federal Agencies

One study was funded by another US Federal agency that was interventional in nature and was categorized as high-end dentistry (Fig. 1). It involved 150 participants (Fig. 2).

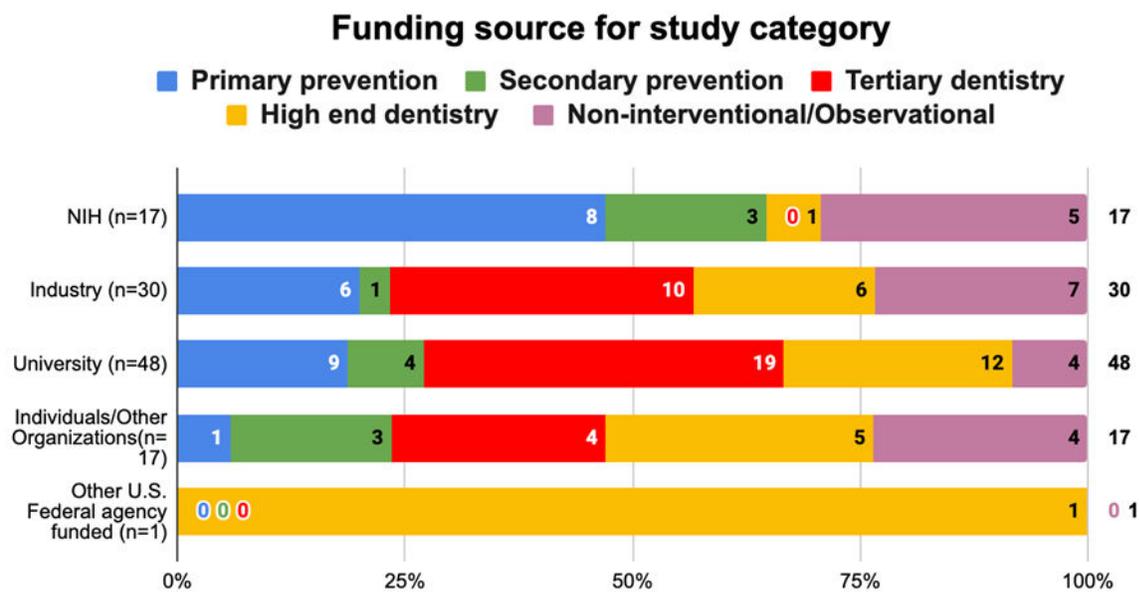


Figure 1: Funding source for study category.

Range of Participants in Different Funded Trials

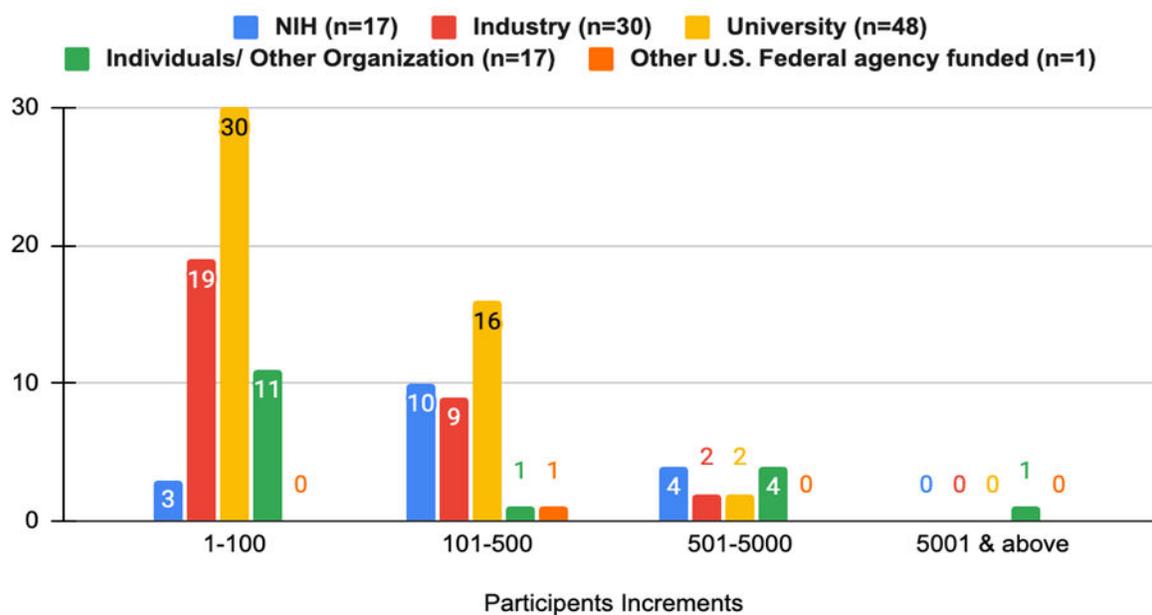


Figure 2: Range of participants in different funded trials.

	Observational (17.7%)					Interventional (82.3%)				
	NIH	University	Industry	Individuals or Other Organization	Other US Federal agency	NIH	University	Industry	Individuals/Other Organization	Other US Federal agency
Number (Percentage) of all studies	5(4.4%)	4(3.5%)	7(6.2%)	4(3.5%)	0(0%)	12(10.6%)	44(38.9%)	23(20.3%)	13(11.5%)	1(0.9%)

Table 1: Number of ongoing Observational studies and Interventional (clinical trials) studies.

Discussion

Our study showed that 17.7% of the 113 clinical trials we evaluated were observational studies and 82.3% were clinical trials that included randomized and non-randomized trials (Table 1). Evidence shows that there has been growth in the number of Randomized Controlled Trials (RCTs) in dental research during 1969-99 [12]. As RCTs provide a high level of evidence, they are valuable in clinical decision-making as a part of evidence-based dentistry [13].

Our study has shown that the NIH only represents 15% of funded studies - promotion and tenure committees must recognize that 85% of clinical trials are funded by other sources and, primarily, the universities. According to Table 1, We found that 42.5% of dental clinical trials were funded by Universities and there may be tremendous variation in the source of these internal funds. It is important for aspiring faculty and promotion and tenure committees to recognize that the most common primary funding source is not state or federal agencies but the universities themselves. While "Industry" (26.5%), Individual/Other Organizations (15%) and NIH (15%) represented the next most common funders. According to Gresham G, et al., From 2000 to 2019, 245,999 clinical trials were conducted, with 54.9% completed [11]. Among the completed trials, 3.8% were funded by the NIH or a US government agency, 36.0% by industry and 60.2% by other sources like universities, foundations, hospitals and others [11].

Additionally, funds from universities may not be readily available at some institutions and may vary from year to year at others. This may create disparities in research and career advancement opportunities at different institutions. According to Lipton JA, et al., their study from 2005 to 2009 showed that fifty dental schools received a total of \$974.393 million of funding - 69.3% from NIDCR while 30.7% from 21 other NIH Institutes/Centers (ICs) [14,15]. This indicates that some institutions may not have garnered any NIH funding. It may also be a reflection of the evidence that some dental institutions have various support mechanisms and incentives to help faculty acquire funding from NIH and NIDCR [15].

Evidence suggests that collaborations between universities and industry were more likely to be funded, primarily, by the industry [16]. Notably, our study showed that universities fund a larger portion of clinical trials compared to industry (42.5% versus 26.5%). Furthermore, data also revealed a direct relationship between the increasing number of institutions involved in the study and the probability of industry funding [16]. In fiscal year 2020, \$245 million was awarded to dental schools/universities from NIH, which has drastically increased by 22% from the last decade [18]. Ehrhardt, et al., analyzed trends in funding, focusing on NIH and industry-funded trials. They concluded that from 2006 to 2014, the number of newly registered NIH-funded trials decreased, while industry-funded trials increased [19]. In this way, the industry has emerged as a prominent contributor to academic research, contributing to the advancement of scientific knowledge and clinical research [20]. Based on these previous studies, our analysis is aligned with the fact that NIH-sponsored studies are of a lower amount than industry-funded. Once again, faculty and promotion and tenure committees must pay attention to the importance of industry as a funder of clinical trials.

Fig.1 demonstrates NIH-sponsored 8 primary and 3 secondary prevention studies which occupy 64.71% of total NIH funding. The NIDCR's mission is to focus on dental and oral health, turning research findings into strategies for prevention, early detection and treatment to improve overall health [21]. Cavities and the associated pain can negatively impact the quality of life and also lead to increased school absences for children [22]. The NIH has awarded \$3.6 million to New York University, College of Dentistry to study cavity prevention and cost-effectiveness in school-based dental programs [22]. This study, which began in 2017 and concluded in 2023, evaluated the use of silver diamine fluoride, fluoride varnish and sealants for caries prevention [22]. Moreover, A major clinical trial led by the University of Michigan School of Dentistry from 2018 to 2023 has shown that Silver Diamine Fluoride (SDF) effectively prevents tooth decay in young children and is sponsored by NIDCR [23]. These align with our study results that major funding for NIH is for prevention. Fig. 1 illustrates that the industry sponsored 10 out of 30 tertiary dentistry trials followed by 6 high-end dentistry trials. An article by Pereira, et al., discusses industry-sponsored studies in implant dentistry, highlighting a 6% increase in industry investment based on a 20-year bibliometric overview [16]. Studies from North America and Europe were more likely to receive industry funding than studies from other countries and regions [16]. High-end dentistry trials, including those on surgical procedures like guided bone regeneration and sinus lift, as well as tertiary dentistry trials on prosthodontics topics, were more likely to receive industry funding compared to other topics [16]. Moreover, the Industry also significantly funded 6 (20%) primary prevention. According to Reda S, et al., industry sponsorship often focuses on primary prevention procedures, such as fluoride varnish or gel for caries prevention [24].

Fig. 1 shows that the majority of trials funded by Individuals/Other Organizations focused on "High-End Dentistry" with 5 out of 17 trials, followed by 4 "Tertiary Dentistry" trials. For University-sponsored trials, the majority focused on "Tertiary Dentistry" with 19 out of 48 trials and 12 trials on "High-End Dentistry". Research in implant dentistry is growing, with thousands of scientific publications each year [25]. The list includes journals by the ISI Web of Science, PubMed, journals in periodontology, prosthodontics, oral surgery and clinical dentistry, which cover implant topics. Many national, European and international associations and dental meetings related to implants have a larger number of members and participants [25]. Implant dentistry is now more active scientifically and professionally than many established dental specialties. Additionally, there is a need for postgraduate education in this field because the undergraduate dental curriculum does not teach the knowledge and skills necessary for the practice of implant dentistry [25]. According to our results, 27.1% of the University-funded trials were targeted at either preventing the disease or stopping disease progression in the initial stages. Promoting oral health and behavioral modification such as motivational interviewing, parent targeted intervention were used. Secondary prevention studies included the use of silver diamine fluoride, dental fillings in initial dental caries and promoting smoking cessation.

Fig. 2 represents the participant sizes across various funded trials. The objective in determining the sample size for a randomized clinical trial is to ensure it's large enough to effectively detect a treatment benefit [27]. A smaller sample size may result in insufficient power, making it difficult to extrapolate findings and leading to inconclusive results [28,29,30]. Additionally, a large sample size can exaggerate statistical differences that might not be clinically relevant [28,29,30]. Participant size calculation is a very crucial aspect of any study [30]. The majority of research trials are conducted with participant ranges of 1-100 and 101-500. Specifically, for NIH-funded trials, 10 of 17 involved 101-500 participants and 3 involved 1-100 participants. Among industry-sponsored trials, 19 of 30 involved 1-100 participants and 9 involved 101-500 participants. In university-sponsored trials, 30 of 48 had 1-100 participants and 16 had 101-500 participants. Moreover, there were no participants in the group of 5001 and above for any type of funded trials except the Individuals/ Other Organization category with only 1 study. Notably, that secondary prevention study had the largest participant group, with over 5,000 participants category, totaling 14,100 participants. A recent study done by Gresham, et al., concluded that increased financing for larger randomized clinical trials may be necessary to guide future research and inform clinical decision-making [11].

Limitations

Although our study shines light on funding sources for dental research, there are limitations that should be considered when interpreting our findings. Firstly, in a registry such as clinicaltrials.gov, there could be classification subjectivity which introduces error. Similarly, our data is United States centric and this may be less applicable or not applicable for other dental research in other countries. Finally, there is no information about completed and withdrawn studies which may change our results and conclusions.

Conclusion

The purpose of this paper was to describe the trends in ongoing dental trials in the USA and their primary funding sources. Results of the current study showed that NIH predominantly funded primary and secondary prevention studies while the Industry more often funded tertiary dentistry. The most common category of research focus was tertiary dentistry and the majority of research studies were funded by the University category. The types of studies being funded and the funding sources have major impacts for dental schools and their tenure-track faculty.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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None.

Data Availability Statement

Not applicable.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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