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Need for an Ethical Framework for Testing for Systemic Diseases in Dental Clinics

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Abstract

Testing for systemic diseases in dental clinics is a potentially attractive avenue for oral health professionals and may be viewed as an opportunity to increase professional reach, expand practice, and improve financial returns. However, several ethical questions arise that must be addressed before such activities are adopted. (1) What should be the level of training dentists must acquire to deal with challenges associated with testing? (2) How well are dental practices aware of and compliant with the Health Insurance Portability and Accountability Act and procedures related to informed consent? (3) What is the evidence regarding acceptability and effectiveness of testing? (4) What should be the acceptable standard of practice for conduct of invasive and noninvasive tests? (5) What is the boundary delineating “testing” and “reporting” vis-à-vis counseling? (6) What is the value of testing without counseling? (7) What assurances need to be in place to ensure voluntariness of testing? (8) How would data from testing be used in “research,” especially with the growth of practice based research networks? and (9) Does the American Dental Association Code of Ethics need to incorporate guidance for practicing dentists? We discuss how ethical principles can be used to develop a framework of guidelines for potential testing for systemic diseases in dental clinics..

Keywords

dental clinic; testing; systemic disease; ethics

I. INTRODUCTION

Interest among dentists in adopting some preventive medicine practice measures in dental clinic settings to expand services offered through their practices has been growing.^{1–5} A key factor in this developing interest is expansion of the bottom-line business-driven model of dental practices. On the other hand, dental educators have advocated an “oral physician” model for dental education that incorporates a medical approach as opposed to a current dental “procedure-based” training model as the desired direction for oral health care training in the 21st century. Such a change in the philosophy of future dental training curricula is viewed by dentists as an opportunity to enable them to expand the scope of practice beyond an exclusive focus on procedures on the teeth and supporting structures.⁶ As the concept of integrating oral health with general health matures, the realization (albeit late) has set in that

there are perhaps common sets of risk factors that drive disease occurrences, pathophysiology, and outcomes that are shared across physiologic systems of the body and are not restricted by sectoral demands of anatomically defined clinical specialties. Although systems can be subjected to Cartesian reductionism for ease of understanding the individual processes; the body is a sociobiological entity that is more than the sum of the reduced parts and fits the definition of a system. The impact of this paradigm shift to a more holistic approach to healthcare is exemplified in the report “Modernizing NHS Dentistry: Implementing the Plan,” which outlines the UK government's strategy to emphasize dental health care workers’ involvement in multisectoral approaches to health promotion through a common risk factor approach.⁷

In general, the increase of the total economic burden on the health care system has led to a search for alternative opportunities for prevention and early detection of disease in an effort to establish a disease prevention-oriented model rather than a curative model. In one approach of such a model, to reduce costs is to make prevention and testing available easily and at low cost to the population. This approach provides the opportunity for established and new professionals and corporate entities to explore expansion of medical services that would not only expand their businesses, but also could argue in favor of increasing access to care for the population and decreasing overall health care costs.

From a dentist's standpoint, the argument for testing for systemic diseases (TSD) is based on the notion that dentists treat patients with or without signs and symptoms of systemic disease and are in a unique position to detect early-stage disease, especially among those patients who do not seek medical care,⁸ and therefore can help prevent and minimize therapeutic intervention needs at early stages, thereby also reducing health care costs. For dentists, TSD thus has been identified as an enormous opportunity for the “early detection and referral model” where diagnosis can be followed by timely treatment, which is beneficial to the community.³

Before dentists accept such a model of service provision expansion, there are several important aspects of this proposed health care environment that need to be assessed, especially from an ethical standpoint. We frame 9 broad questions that we believe must be addressed prior to rampant adoption of such a model of practice and service enhancement.

II. WHICH TSD SERVICES AND TOOLS IN THE MARKET ARE BEING VIEWED BY DENTISTS?

A list of tests that currently are being considered for use in the dental clinic for TSD is presented in Table 1. These range from indices developed within epidemiologic studies to commercially marketed test kits. The Framingham risk score, a series of prediction equations developed from the Framingham Heart Study, is a widely used, validated tool to assess the increased risk of experiencing a coronary heart disease event within 10 years.^{9–13} Greenberg et al¹⁴ demonstrated its application by oral health care providers as a resource for identifying patients hitherto unaware of their increased risk. Commercial ventures such as the Healthy Heart Dentistry Program include the Diabetes Risk Assessment and C-reactive protein kits.¹⁵ Each kit contains a patient consent form and a professional report provided to the patient and dentist within 1 to 2 weeks.³ The Perio-Metabolic Profile blood screening test promoted by the same enterprise examines metabolic markers of periodontal inflammation.¹⁵ The package requires a few drops of blood and includes tests for total cholesterol, low-density lipoprotein, triglycerides, high-density lipoprotein, glucose, C-reactive protein, hemoglobin A1c, and fasting insulin before starting treatment for periodontal disease. A dentist subsequently can refer the patient to a physician for further clinical evaluation and diagnosis if test results are abnormal. In addition, rapid point-of-care

testing (POCT) with new Food and Drug Administration (FDA)–approved blood screening tests can screen for cancers (detection of tumor biomarkers secreted in saliva such as c-erbB-2 protein expression for breast tumor recurrence or response to therapy).^{3,4} With the rapid application of genomics to diagnostic tests, analysis of human DNA, RNA, or protein is now possible.¹⁶ Genetic tests can be used to detect gene variants associated with a specific disease or condition. In the clinical setting, genetic tests may confirm a suspected diagnosis, predict future illness, detect the presence of an unaffected carrier state with the possibility for expression in future generations, and predict response to therapy.¹⁶

In addition to the excitement about in-office blood testing, there has been considerable enthusiasm about the use of saliva as a diagnostic fluid. Currently, oral fluid- based tests exist or are being developed to detect a variety of conditions (Table 2). For example, research in salivary diagnostics have led to development of biomarkers for some cancers,^{20–22} autoimmune diseases,^{23,24} viral diseases,^{25–28} bacterial diseases,^{29,30} cardiovascular diseases,³¹ and HIV (Table 2).^{32,33} FDA-approved saliva kits also include kits to test for HIV and drug abuse (OraQuick ADVANCE, OraSure Technologies, Inc., Bethlehem, PA; Orasure HIV1 Western Blot, OraSure Technologies, Inc.; QED Saliva Alcohol Test, OraSure Technologies, Inc.; and Saliva Screen 5 Professional, Medimpex United Inc.), steroid use (ZRT saliva test, ZRT Laboratory, LLC, Beaverton, OR), and secretory immunoglobulin A and melatonin currently being considered for diagnostic testing.^{34,70}

III. WHAT ARE THE ISSUES RELATED TO TSD WITHIN THE DENTAL CARE FRAMEWORK?

Screening can be defined as “the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly.”³⁵ When screening is applied to populations, the principle aim is not to bring patients to treatment but to determine the prevalence, incidence, and natural history of the variable under study. *Case finding* is a term that is more appropriate to the form of screening where the chief objective is to detect disease and bring patients to treatment.³⁵ Thus, it is important to distinguish between “testing” and “screening”; the former targets at-risk individuals and the latter targets populations. TSDs are conceived to function more at an individual (“testing”) level.

The dental practice of the future is envisioned as a holistic, health-oriented dental office in which patients are offered a variety of services related to screening, testing, and monitoring of systemic diseases apart of regular dental services.^{8,14,36–42} Ethical complexities arise from this vision in a variety of dimensions and must be addressed before such practices are adopted. It is important to evaluate the types of TSDs offered and if and how dental practices may integrate TSDs into the delivery of care to their patients. The “one-stop shopping” model propagated by Glick⁴³ may reflect as concern for more than a patient’s oral health that may have a dramatic impact on the overall health of a dental practice, its patients, and the population.

We discuss the application of bioethics principles to TSDs in dental clinics to assess the appropriateness of such practices and to foster awareness of ethical dilemmas that could arise system wide and during the course of carrying out in-office testing by dental practitioners. Another purpose of this article is to assess the ethical preparedness of professional dentists, the dental education system, and the oral health care delivery system to conduct TSDs in dental clinic settings before its adoption in routine care. These issues are covered under the 9 questions that follow.

A. What Should Be the level of Training Dentists must Acquire to Offer TSD Services?

What level of knowledge and training about disease diagnosis, testing, and systemic health is required for dental practitioners to provide TSD services knowledgeably, efficiently, and effectively? What skills, attitudes, communication strategies, and evaluation approaches would need to be integrated in dental education so that dentists can provide TSD services and deal appropriately with test outcomes in a scientific, knowledgeable, ethical, and legal manner? Literature assessing dentists' training and capability in carrying out such tests, effectively communicating test results, and answering questions about potential consequences of test results is sparse. Previous studies have focused on examining dentists' knowledge and skills in oral cancer (OC) diagnosis, HIV testing, diabetes, and heart disease (summarized in Table 3).^{40,44–46} Evidence from this literature provides pointers toward dentists' preparedness for providing TSD services. Lack of adequate and current knowledge about systemic diseases often have been suggested to be issues regarding dentists' awareness of OC risk factors, common sites, prevalence, incidence, and mortality estimates. For example, a recent study suggested that 38% of nursing home dentists could not correctly identify the 2 most common sites of OC. Furthermore, only 30% of participants knew that majority of OCs were diagnosed in people older than 60 years of age. Also, 53% of respondents incorrectly reported that increasing age was least likely to be a risk factor associated with OC. Fifty-three percent of respondents had a low systemic disease knowledge score. Younger dentists have been reported to have better knowledge than older dentists.⁴⁷

Are dentists adequately trained in medical courses to interpret TSDs independently and confidently and to understand all implications of the test outcomes? If not, then to incorporate TSD services in practices as a part of the medical professional fraternity, the dental education system needs to be modified to enhance dentists' preparedness for such roles. It is known that for a larger medical role, training in the biological sciences and medicine for dental students is inadequate.⁴⁸ Probable reasons for the failure of US dental schools to provide dental students with practical training in general medicine could be linked to lack of need, increased costs, medical training not being a core component of dental education, too much required effort, and cause for anxiety among faculty members.⁴⁸ There is a definite direct relationship between what students are taught and what they will do in practice. The American Dental Association (ADA)'s annual Survey of Predoctoral Dental Education has only 2 subject listings integrating general medical training: general medical emergencies and hospital dentistry.⁴⁹ The Macy Study Report panel recognized the connection between systemic health, dentistry, and dental education,⁵⁰ and to incorporate the potentially changing role of dental professionals, they acknowledged that changes in the definition of dental practice could begin with changes to the dental school curricula and clinical education. It is, therefore, essential to explore if the proposed dental curricula changes are successful and adequate to equip dentists with the required knowledge to carry out TSDs. Some of these needed modifications are outlined in Table 4.

B. How Well Are Dental Practices Aware of and Compliant with HIPAA laws and Procedures Related to Informed Consent?

The Health Insurance Portability and Accountability Act (HIPAA) was passed in 1996 and required full implementation with all statutes by May of 2008. Overall, HIPAA security rule comprises 3 sets of regulations: (1) patient privacy; (2) electronic transmission of transaction codes between parties; and (3) the security of patient care data. Failure to comply with HIPAA may carry heavy civil and criminal penalties. How do incorporating TSD services in

clinical practice modify the need for HIPAA compliance of dental offices, especially since external entities then will be involved with sharing and moving personal data? It is essential to exercise caution with storage or transport of data obtained from TSDs. HIPAA requires administrative, physical, and technical protection of any identifiable information that can be linked directly or indirectly to an individual.⁵¹ There is a slow but steady shift in the storage of patient information from traditional hard-copy format to electronic health records (EHRs). The proportion of all dental offices with computers increased from 11% in 1984 to more than 85% in 2000,⁵² though the adoption of EHRs is low. Implementation and use of EHRs are considered scientifically reportable events and quality assurance guidelines draw from HIPAA.⁵¹ Data security is a major source of concern because of the possibility of stolen data, and security systems must be planned to limit access to backed-up patient records.⁵¹ Incorporation of TSDs in dental clinics will require tight protection of EHRs, notification of patients about rights to privacy, and training of dental staff in handling patient records. Practices that have both hard-copy files and EHRs will need multiple safeguards for protection that may also require some additional overhead costs that should be considered.

Furthermore, ethical concerns may arise about disclosure of test results to patients' families and relatives. Important questions faced by dentists that could affect their choice of action include:

1. Because a dentist's office acts only as a point of collection and dispatch of samples, should the dentist receive a copy of the report?
2. If they do, then what privacy protection and HIPAA procedures should be adopted and what kind of ongoing quality assurance steps for continued HIPAA compliance are required?
3. What choice would a dentist make when deciding whether to disclose a positive test result to a patient's spouse or family?
4. Who would decide the practice of legal and moral requirements of privacy and confidentiality for a dentist?
5. Would the dentist be responsible for making choices on a case-by-case basis?
6. Would the dentist be protected in the case of any lawsuits citing breach of confidentiality?

In general, the current dental curricula do not train dentists to fulfill such a role. Therefore, a modification of the curricula to incorporate stronger jurisprudence and counseling experience will be required to prepare dentists address these issues as a professional.

Importantly, routine confidentiality and privacy issues take on added meaning when applied to genetic testing. Results of patients' genetic information may have major implications for the families because it may reveal genetic susceptibilities in parents, siblings, and children; thus, sharing information about one person can disclose risk about another person.⁵³ A 1998 position statement by the American Society of Human Genetics focused on the potential conflict within the health care professional--patient relationship. It stated that the legal and ethical norm of patient confidentiality should be respected: "Only exceptionally is a health care professional ethically permitted to breach confidentiality and as a legal matter ought to be privileged, that is, given a discretionary right to disclose genetic information to at-risk relatives without incurring liability provided certain conditions are met."⁵⁴ Dentists will encounter these situations and would have an ethical duty to inform patients about familial implications of the result. Genetic information may be used by insurers to deny, limit, or cancel health insurance and by employers to discriminate in the workplace. On May 21, 2008, then-President Bush signed into law the Genetic Information Nondiscrimination Act,

which protects Americans against discrimination based on their genetic information when it comes to health insurance and employment.⁵⁵ Therefore, dental education would not only require a firm grasp of genetic concepts but also ethical, legal, and social aspects unique to genetic testing.⁵³ In addition to HIPAA laws, dentists would need to be aware of procedures and implications related to informed consent. The dentist would be required to explain potential benefits and risks associated with TSDs thoroughly and clearly, taking into account cultural sensitivities, which also suggests a need for formal training and retraining in cultural competence.

Ethics and professionalism are core components of the curriculum in accredited dental programs.⁵⁶ However, “no one has ever done the right thing because of taking an ethics course in dental school.”⁵⁷ When asked about perceptions of primary learning outcomes from a course in ethics and professionalism, the most commonly identified topics among first-year dental students were confidentiality (21%), informed consent (21%), and obtaining assent from children and adolescents (19%).⁵⁸ Compliance with HIPAA is perceived as a challenge because of the lack of detail in its provisions;⁵⁹ however, the authors claimed results were inconclusive because of low response rates. Evidence reporting dentists’ adherence and compliance with HIPAA and adequacy of ethics training within dental schools is lacking and more research would need to be conducted prior to starting provision of TSD services.

C. What is the State of Evidence Regarding the Need, Acceptability, Usefulness, and Effectiveness of TSDs in Dental Settings?

1. Dentist Willingness

Few studies have assessed the acceptability and usefulness of TSDs within dental practice settings.^{14,36–39,41,60} Not unexpectedly, dentists are willing to incorporate TSDs in their practices. Greenberg et al⁵ assessed dentists’ attitudes toward chair-side testing for medical conditions. The majority of dentists thought it was important to test for hypertension (85.8%), cardiovascular disease (76.8%), diabetes mellitus (76.6%), hepatitis (71.5%), and HIV infection (68.8%). Respondents were willing to refer patients for consultation with physicians (96.4%), collect oral fluids for salivary diagnostics (87.7%), conduct medical screenings (83.4%), and collect blood via a finger stick (55.9%).⁵ Dentists’ attitudes toward involvement in health promotion and systemic disease prevention services ranged from a strong endorsement of screening for OC and hypertension as being part of a dentist’s role to moderate acceptance of their role in tobacco screening and cessation, with lower support for screening of nutrition, alcohol and recreational drug use, HIV risk, or referral for counseling and testing.⁴⁴ Dentists are usually not experienced in delivering diagnoses of potentially life-threatening conditions, with the exception of cases of rare diagnoses of OC, and may find the experience to be stressful.⁶¹ This may deter dentists’ acceptance of TSD. In 2005, Patton et al³⁹ identified major themes likely to affect the acceptance/implementation of a rapid oral HIV test in dental offices. The test itself was perceived as simple to implement, however, there were issues about the sensitive nature of conveying an HIV diagnosis. Other concerns identified were (1) feelings of inadequacy in responding appropriately to follow-up questions about HIV from patients who test positive; (2) the need for time investment to educate oneself about HIV issues; (3) ease of referral of the newly diagnosed patient to qualified providers for psychological and HIV care; (4) concern about the patient’s acceptance of preliminary testing in the dental office; (5) the need to conduct appropriate risk assessment for selective screening and associated legal implications if seen as prejudicial; (6) office signage or health history query for voluntary screening may be too passive to recruit participants; and (7) uncertainty regarding the dentist’s role in HIV screening and dealing with life-and-death issues.³⁹

2. Patient Willingness

More studies are needed to determine patient acceptance and willingness to participate in TSDs in dental clinics. Koka et al³⁴ assessed the preferences of adult outpatients in medical or dental settings for giving saliva, urine, or blood for clinical testing. Respondents perceived donation of saliva as more comfortable and convenient than that of blood or urine, and they reported that saliva and urine are easiest to collect at home compared with blood.³⁴ In a study evaluating the patient perspective on rapid HIV screening at an urban dental clinic, Dietz et al⁶² found that 73% (out of 150 respondents) reported willingness to take a free, quick HIV test during their dental visit. Factors such as low self-perception of risk (37%) and already having been tested elsewhere (24%) were the main reasons for not accepting a free, quick HIV test.⁶²

3. Population Impact Argument

In 2005, Glick and Greenberg³⁷ used the Framingham risk score to examine the potential role of dentists in identifying patients' risk of experiencing coronary heart disease events among those with no reported specific risk factors and who had not seen a physician during the previous 12 months but had seen a dentist. Eighteen percent of the male subjects had an increased 10-year global risk of experiencing a coronary heart disease event (>10% risk score).³⁷ In an evaluation of a counselor-based, rapid HIV testing in an urban, hospital-based dental clinic, Blackstock et al³⁶ found 19 previously undiagnosed individuals (0.53%) who confirmed HIV positive. Fifteen newly diagnosed patients (78.9%) were linked to care.

4. Impact on Access Considerations

It has been suggested that providing TSD services in dental clinics "would provide dentists with the opportunity to screen for significant systemic disease risks among a population that would not otherwise seek medical care."³⁷ This suggestion for being able to gain access to those people who would otherwise not visit a physician or who visit a physician infrequently also is based on the notion that these people visit dentists more frequently, and therefore dentists have a better opportunity to catch undiagnosed disease or screen for diseases/disease markers.

We examined this contention by assessing the 2007 Medical Expenditure Panel Survey (MEPS) data and data from several years of the Behavioral Risk Factors Surveillance System. From MEPS, we found that only 29.5% of those who did not visit a physician had visited a dentist in the past year! This population represented 9.81% of the total population. The odds ratio for visiting a dentist when not visiting a physician compared with visiting a physician was 0.48 (95% confidence interval, 0.46–0.50).

Furthermore, overall, per-capita dental visits over 1 year were 0.80. However, among those who visited a dentist on the past year, the mean dental visits were 1.95, and mean dental visits among those who *did not* visit a physician but *did* visit a dentist were 1.74. Similarly, overall, mean dental visits among those who visited a physician were 0.94; mean dental visits among those who *did not* visit a physician were 0.51. Therefore, because the mean dental visits among those who did not visit a physician was significantly lower ($P < 0.0001$) than even the total per-capita mean visits, it is difficult to understand how dentists will be able to improve access to TSDs in that population. As it is, access to dental care is a major problem in the United States, especially for poorer people; evidence-based assessments of assumptions perhaps would shed stronger light on the scientific credibility of such claims.

Those who visited a dentist but did not visit a physician had a mean total income (\$27,361) that was significantly lower than those who visited both a physician and a dentist (\$32,360; $P < 0.0001$). Similarly, mean expenditure was also less for those not visiting a physician

(\$571 vs. \$641). Overall, among those who did not visit a physician, 27% did not have any health insurance (only 57% had some private health insurance coverage). Behavioral Risk Factors Surveillance System data reveals that only 39% of those with less than \$25,000 annual income have some kind of insurance that pays for some or all routine dental care. In a study using MEPS data, it was noted that the per-capita unpaid charge of \$76.70 for low income group was significantly greater than for high income group (\$47.80; $P < 0.01$). More Medicaid recipients (52% vs. 12% for nonrecipients) incurred at least \$50 in unpaid charges ($P < 0.01$).⁶³ This brief analysis suggests that, from the point of bringing services to those who do not visit a physician, at best, the potential impact of TSDs in dental clinics would be on 3.8% of the population, most of whom are poor and evidently have a questionable ability to pay for even routine regular services.

5. Cost Considerations

The previous discussion begets an important issue that usually has been left out of the discussion about incorporating TSDs in dental clinics: costs! Assessment of ethical issue–related costs involved in establishing and providing TSD services in dental clinics stem from an economical premise encompassed by 3 important questions:

1. Do these services cost extra to the patient/consumer of the service or is the service included in what would otherwise be dentists' charges to the patient had the service not been offered (e.g., as a part of the initial examination/diagnostic work-up)?
2. Does this extra cost increase overall health care costs or is it neutral to an overall health care cost increase?
3. What is the overall cost–benefit balance of these services and how does this impact the health care system?

Schefdore³ stated that, “convenient, affordable, FDA-approved blood-testing kits are available to dental practices that wish to move into this area of assisting patients with early detection possibilities”. Would these “affordable” costs be passed on to the patients or would those be absorbed by the dentist with a “pro bono” intent or be written off as charity care? It is clear the intent is to charge patients for the TSD services though at a minimum margin, but for a small profit at least. If so, by how much would total health care costs increase? Based on our results cited earlier, if TSD services at dental clinics are able to reach 50% of the “impact argument” population, it would reach 1.9% of the population, that is, 5,866,465 people (US population = 308,745,538; US Census data 2010). For a most conservative estimate, assuming an improbable lowest of possible extra charges for TSD services at \$5.00 per test means an increase of at least \$29,332,325 to health care costs. So, what benefits would accrue on adding an extra \$29.3 million to health care costs by providing TSDs in dental clinics?

Schefdore³ further stated that, “these tests are mailed to the lab from anywhere in the country, and results are faxed to the dentist within 10 days, or more quickly if necessary. These screening tests are not performed for a dentist to diagnose a systemic problem. They are done to help the dentist, who, by taking into proper perspective the systemic health of a patient during complete oral diagnosis and treatment planning for dental procedures, should be concerned about patients' health and determine if any medical evaluations might be indicated.”

Apparently, the suggestion is to use the tests that can be implemented by patients at home. If these tests can be performed at home, what would be the purpose of adding the extra cost to the system by performing them at the dental clinic? Furthermore, dentists' robust traditional clinical training ensures that they take good medical histories and conduct thorough

examinations to note symptoms and elicit signs of potential medical problems. Upon suspicion of potential medical problems, the patient is referred to the appropriate medical colleague for examination and diagnosis. To add to this model TSDs in the dental clinic, the arguments have to be compelling. At this time, such evidence seems to be lacking.

D. What Should Be the Acceptable Standard of Practice for Conduct of Invasive and Noninvasive Tests?

Regulatory bodies such as the Office of In Vitro Diagnostic Device, Evaluation, and Safety of the FDA standardize medical devices “intended for use in the diagnosis of disease or other conditions”.⁶⁴ The US Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed.⁶⁵

The categorization of commercially marketed in vitro diagnostic tests under CLIA is the responsibility of the FDA. This categorization includes the process of assigning commercially marketed in vitro diagnostic test systems to 1 of 3 CLIA regulatory categories based on their potential for risk to public health: (1) waived tests; (2) tests of moderate complexity; and (3) tests of high complexity.

All point of care programs must apply for a CLIA certificate and choose an appropriate accreditation agency for their needs. POCT sites such as dentists’ offices must have their own CLIA certificates and a designated director, regardless of whether patients are charged for testing or not.⁶⁵ The director is responsible for setting quality standards, reviewing performance data, and guaranteeing adequate staff training and competency assessment, in addition to ensuring results are communicated to patients and entered into records.⁶⁵

Developers and manufacturers have an ethical obligation to make their devices as accurate as possible and to display prominently information about the level of accuracy of their diagnostic kits. Tests need to be performed without interruptions or distractions. For example, reading times for saliva tests may be narrow for some test methods.⁶⁶ Test kits should also not be outdated. Unfortunately, these standards of performance are not always met, leading to problems in the quality and reporting of results. That said, significant problems with the accuracy, reliability, and quality of many commercial diagnostic kits have been identified.^{67,68} For example, slightly more false-positive and false-negative results occurred for rapid HIV tests with oral fluid than with whole blood.⁶⁹ Dentists should, therefore, have adequate information to decide whether a test is accurate enough to warrant use within the clinic setting.

Dentists who want to provide TSD services have to deal with some important quality assurance questions in this context.

1. Who determines the proper conduct of the test/sample collection in the dental clinic?
2. Who would be responsible for governing proper use of tests and maintenance of quality assurance in dental clinics?
3. Would dentists be held responsible for both specimen collection and testing in the clinic or would it be only specimen collection and then referral of testing to an outside laboratory.
4. In case of disputes, what would be the moral and legal standing and involvement of the dentist offering TSDs?

Dentists need to be able to recognize patients appropriate for TSD, especially for genetic testing. For example, it is difficult to know when to use a particular genetic test and how to interpret results. For many genetic tests, gold standards are not available and interpretation of test results may not be clear.⁵³ Saliva as a noninvasive diagnostic tool diminishes discomfort associated with blood collection and privacy issues associated with urine collection.⁷⁰ However, before salivary diagnostic tests can replace conventional tests, the diagnostic value of a new salivary test has to be compared with accepted diagnostic methods.

Another important issue that needs to be considered is, Who will be tested? Are dentists going to offer TSD to all patients who come to the clinic? If so, then false-positive and false-negative results will carry much more importance to keep costs in check. At the same time, positive and negative predictive values and likelihood ratios of tests also will need to be considered. If dentists prioritize/target their patients based on clinical signs and symptoms, then would not costs be lower, efficiency higher, and time involved lesser if those patients simply were referred for appropriate medical diagnosis based on their clinical status but without a test?

E. How Does Testing/Reporting of TSDs Relate to Dentists' Professional Standing?

Dentists believe that the results of the TSDs they would offer in dental clinics would be preliminary and in-office testing should not be intended to diagnose medical conditions.⁴² Whether preliminary or not, would dentists be free/required/not required to interpret results? Would all interpretation and communication be referred to other health care specialties? Would individuals be allowed personal property rights to their DNA, cells, or tissues collected at dentists' offices? With genetic and other systemic testing laboratories marketing their tests directly to consumers, is there any additional value in charging for TSDs that may be obtained and conducted at home? This would make a dentist's role similar to a trader, where an individual tested by a dentist goes to a physician for interpretation, diagnosis, and treatment. In this situation a dentist's office truly becomes a one-stop shop in letter and spirit! In the name of service provision, would the dental profession become a trade instead? Ethical considerations demand assigning specific roles to the health care provider. It is assumed that dentists' offices would accept the responsibility of the referrals made based on TSD results (which implies that dentists receive, read, and interpret the results)? Would dentists be required to follow-up on their referral or would further patient care be under the physician's domain? Alternately, are dentists interested in providing testing and counseling, in which case specialized training and licensing may be needed? If such an advance does occur, then that would be a true advance, with some value added to dentists' services and expansion of the health care delivery system, potentially leading to improved health outcomes, and dentists would be able to use counseling training to counsel their other patients on other professional issues as well.

F. What Is the Value of Testing Without Counseling?

Counseling is crucial to elucidate the significance of test results irrespective of the outcome. The impact of the diagnosis on the person is difficult to estimate, especially if nobody is there to help the user assimilate the knowledge produced by diagnostic testing device/service. Dentists need to be aware that there is a definite and tangible risk of incorrect test results, beyond factors associated with sensitivity and specificity.⁷¹ Wrong decisions based on test results have important implications. For example, misclassification of disease status could be associated with high health care costs as well as stress and impact on quality of life.⁷² If the test result is negative, problems may be minimal. If the result is positive,

however, support structures ought to be in place to help deal with the new diagnosis and its significance for those who may be affected directly. Reporting results to spouses of patients may have negative consequences; for example, in a trial assessing the efficacy of voluntary counseling and testing, women infected with HIV suffered physical beatings and break-up of relationships, especially when the spouse was HIV negative.⁷³ Lack of counseling potentially could leave the patient in fear and stress, which may lead to clinical depression. Dentists are minimally trained in risk communication and counseling, especially about communication of genetic test results involving significant understanding of uncertainty and probabilities. What would be the implications of no counseling if testing of one disease association also results in other disease associations?⁵³ What would be the dentist's role in explaining this information to the patient? Who would determine the need for referral to the respective health care stakeholders to facilitate follow-up confirmatory testing, psychological and prevention counseling, and medical care?

Existing evidence about counseling in dental clinics is sparse. In a study assessing oral health care providers' readiness to provide health behavior counseling and OC examinations, 82% of dentists and 72% of dental hygienists indicated that OC examinations were a routine part of their practice, however, there were substantially low rates of tobacco use and alcohol abuse counseling. Systematic barriers to the adoption of these services by dentists were lack of proper reimbursement, lack of appropriate office systems, and lack of incentives to offer these services.⁴⁶ Response rates ranged from 55% to 66%; thus, results may be biased if dental providers with strong feelings (pro or con) were more likely to respond to the survey. Absence of counseling associated with TSDs may result in a situation similar to the current state of OC screening. If dentists who are already trained in OC preventive counseling are unable to provide counseling before and after OC examinations, how would this situation translate to TSD, where lack of training is a barrier, especially for diseases that fall outside the purview of dentists' professional boundary?

G. How Would Data from Dental Clinic–Based TSDs be Used in Clinical Practice and “Research”?

Practice-based research networks consists of practitioner--investigators, staff, and patients in outpatient dental practices, which constitute a wide variety of practice types, treatment philosophies, and patient populations.⁷⁴ Could a practice that offers TSDs and is a participant in a practice-based research network use TSD data for research? When appropriately adhered to, research from TSDs could provide useful scientific information about disease, treatments, outcomes, and trends; aid in obtaining estimates of the prevalence of diseases; and contribute to monitoring mechanisms over time.

The availability of enormous amounts of data from TSDs potentially could be used to expand the scope for further establishing systemic disease databases as well as linkages between systemic diseases and oral health. Such data could be used for business and research purposes, which raises more concerns about the informed consent process, scope, and validity. Research with such data would need to be carried out in conformity with protocols established by review boards and research governing bodies. Data may be collected by clinicians; however, studies would require close collaboration with academic researchers to refine them into researchable questions.⁷⁴ Common reasons for practitioner motivation to participate in research include increased stature of the practice as well as remuneration provided for time. Factors determining patient participation such as remuneration and cultural sensitivities should be taken into account when collecting TSD data. Testing-related informed consent needs and processes have ranged from requiring no informed consent to verbal informed consent to detailed, multipage signed consent forms. However, for research purposes, interacting with an institutional review board is a must even

if the research is expected to be exempt from institutional review board review. Dentists typically do not have formal research training and would need to be educated and trained in standard procedures of data collection.⁷⁴

H. Do the ADA and American Association for Dental Research Codes of Ethics Need to Incorporate Guidance for Practicing Dentists Offering TSD Services?

In a Statement on Oral Fluid Diagnostics in 2008, the ADA Council on Scientific Affairs welcomed the development of rapid POCT, strongly advocated interdisciplinary collaborations, and expanded funding for research programs to permit evaluation of diagnostic and predictive value of tests and translation into clinical applications for screening patients.⁷⁵ The ADA believes that, “dentists and oral health professionals may be positioned to expand the reach and impact of preventive medicine through the application of cost-effective and noninvasive oral fluid screening tests and referring patients for necessary medical care.” The American Association for Dental Research acknowledges that, “there exist a number of diseases that are currently difficult to diagnose, involving blood and urine tests that are labor intensive, expensive, and invasive. With saliva showing promise to become a noninvasive diagnostic fluid for a number of oral and systemic conditions, oral researchers are working to simultaneously catalogue the proteins in saliva while building a point-of-care platform to detect and monitor these valuable biomarkers.”⁷⁶ With the support and collaboration of the ADA, American Association for Dental Research, and other agencies, there is a need to establish guidelines for practicing dentists.

I. What Assurances Need to be in Place to Ensure Voluntary Testing in Practice Settings?

The principle of autonomy recognizes the rights of individuals to make informed decisions about personal matters. A distinction between voluntary counseling and testing and routine testing needs to be made for TSDs in dental clinics. The voluntary model is based on the right to decide whether or not to undergo testing. Routine testing is initiated by health care providers, though the individual maintains the right to refuse testing. Routine testing does not inhibit an individual's rights, but voluntary testing allows for greater control, respect, and autonomy. Volunteering to be tested may indicate greater motivation to take control of one's health.⁷⁷ Patients should be reassured that refusing to undergo testing will not interfere with their routine dental treatment, and the benefits of testing, the procedure, and the risks involved should be explained in clear language. The information provided should be direct and comprehensible and should eliminate coercion in any form. Signed informed consent procedures would be required of the dental clinic staff. Inducements that ordinarily would be acceptable may become undue influences, especially if the person is considered a vulnerable subject. Would this be a feasible option considering the routine, fast-paced dental practice? In addition, when dentists as persons in positions of authority urge testing for a patient, it may be difficult to draw a boundary between reasonable persuasion and undue influence. Any form of manipulation of patients' choices through convincing a close relative or threatening to withdraw health services to which an individual would otherwise be entitled would violate ethical principles. Care should be taken to follow appropriate procedures of informed consent for patients lacking mental capacity.

Recommendations for incorporation of TSDs in dental practice settings are not without bioethical issues. The questions we pose initiate a debate to seek a solution. Answers to the above 9 questions would aid in establishing guidelines and help build an “ethical framework toward testing of systemic diseases in a dental clinic.” Emerging trends in the types of

services provided by dental clinics can alter the image of dentistry and inspire and promote innovations beyond the scope of current routine dental practice.

IV. CONCLUSIONS

There is a lot of interest in instituting testing for systemic diseases in dental clinics. However, a variety of questions arise related to this interest. (1) What should be the level of training that dentists must acquire to deal with TSDs? (2) How well are dental practices HIPAA compliant? (3) What is the state of evidence regarding acceptability and the effectiveness of TSDs in dental settings? (4) What should be the acceptable standard of practice for conduct of invasive and noninvasive TSDs in dental settings? (5) What is the boundary delineating “testing” and “reporting” vis-à-vis counseling? (6) What is the value of testing without counseling? (7) How would data from TSDs be used in “research”? (8) Do professional organizations’ codes of ethics need to incorporate guidance for practicing dentists for such testing? (9) What assurances need to be in place to ensure voluntary testing in practice settings? Rethinking dental training toward an “oral physician” model to serve the needs of the future dental practice, keeping pace with scientific growth, and developing solutions to the 9 questions will help to resolve the question of whether and how dentists may offer TSDs with knowledge, understanding, preparedness, and authority to improve access to preventive and diagnostic opportunities in a useful, cost-effective, professional manner without increasing overall health care costs.

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Table 1

Systemic disease testing scenarios being considered for use in dental settings

Test	Description
Diabetes Risk Assessment Plus	Combines an immediate result blood glucose test with a self-collected, laboratory- tested hemoglobin A1c test; kit contains testing supplies (lancets, gauze, bandage), glucose test card, consent form, lab requisition and transport materials, and detailed instructions
Framingham Risk Score	Estimates absolute 10-year risk of developing CHD, where risk categories are defined as low (<10%), intermediate (10–20%), and high (>20%)
CRP test (high sensitivity)	A self-contained collection kit approved for patient self-collection or professional use for a quantitative hs-CRP determination
The Cholestech LDX System	Measures complete lipid profile and glucose, ALT, AST, and hs-CRP
The Perio-Metabolic Profile blood screening test	Examines effects of glucose and lipid metabolism on periodontal inflammation and checks for effects of periodontal disease on body metabolism
The DNA chip	Provides quick analysis of the entire genome of a particular individual; photolithographic techniques are used to generate miniaturized arrays of densely packed oligonucleotide probes; these probe arrays can be applied to parallel DNA hybridization analysis to directly yield sequence information; the chip is scanned by a laser and read by a computer

ALT, alanine aminotransferase; AST, aspartate aminotransferase; CHD, coronary heart disease; CRP, C-reactive protein; hs-CRP, high-sensitivity C-reactive protein.

Table 2

Current diagnostic applications of saliva

Category	Analytes/Diseases
Steroid hormones	Cortisol, dehydroepiandrosterone, testosterone, estradiol, estriol, progesterone
Drugs of abuse/chronic dependence	Barbiturates, benzodiazepines, caffeine, carbamazepine, cisplatin, cyclosporin, diazepam, digoxin, lithium, methadone, methotrexate, metoprolol, paracetamol, phenytoin, primidone, procainamide, quinine, sulfanilamide, lysergic acid diethylamide, marijuana, opioids, phencyclidine, and tobacco
Viral infections	Human immunodeficiency virus, hepatitis, human herpes virus, cytomegalovirus, Epstein-Barr virus, measles, mumps, rubella, rotavirus
Bacterial infections	<i>Helicobacter pylori</i> , <i>Shigella</i> , <i>Borrelia burgdorferi</i>
Cancers	Oral squamous cell carcinoma, breast cancer, epithelial ovarian cancer
Hereditary diseases	Cystic fibrosis, coeliac disease, 21-hydroxylase deficiency
Autoimmune diseases	Sjögren's syndrome

Adapted from Refs. 17–18.

Table 3

Summary of selected recent studies examining dentists' training in TSD areas

Authors	Issue Examined	Result
Patton et al, 2006 ⁴⁶	Educational preparedness and adequacy of training of medical and dental professionals in oral cancer prevention and screening	<ul style="list-style-type: none"> •Dental providers were significantly less likely than medical providers to feel adequately trained in tobacco and alcohol cessation and to palpate neck nodes •Dental providers were significantly more likely to feel adequately trained to perform oral cancer examinations • Dental providers who felt they had adequate training in tobacco and alcohol cessation were significantly more likely to assess these risk factors on patient medical histories
Patton et al, 2002 ⁴⁵	Teaching and practice of HIV risk screening, the opinions of dental educators regarding HIV counseling and testing and a possible role for oral fluid-based HIV antibody testing in dental offices	<ul style="list-style-type: none"> • All responding dental schools had curriculum and clinical education training in HIV behavioral risks, medical history, and use of oral manifestations as indicators of HIV •One-third of respondents indicated they might include HIV counseling and testing using a rapid oral fluid-based HIV antibody test in their clinics. • Respondents lacked confidence that graduating dentists have the skills and willingness to conduct HIV counseling and testing in dental practice • Lack of training in prevention counseling was seen as a primary barrier
Applebaum et al, 2009 ⁴⁴	Dentists' and primary care physicians' oral cancer knowledge, attitudes, and practices in the Commonwealth of Massachusetts	<ul style="list-style-type: none"> • 85% of dentists agreed or strongly agreed that they were adequately trained to examine patients for oral cancer • Approximately 50% of dentists agreed or strongly agreed that their knowledge about oral cancer was current • Only 24% and 12% of dentists believed that they were adequately trained to provide tobacco-use cessation and alcohol-use cessation education, respectively, to their patients
Radmer et al, 2009 ⁴⁰	Teaching casual random blood glucose screening to second-year dental students	<ul style="list-style-type: none"> • Predoctoral students were willing to incorporate glucose "screening" into practice • Frequent barriers identified toward testing were lack of adequate training and knowledge • Six US dental schools responded that casual random glucose screening was being taught in the predoctoral dental curriculum, 14 schools responded that it was not taught, and 32 schools did not respond to the survey

Table 4

Dental curricula changes suggested to effectively conduct testing for systemic diseases (TSD) in dental clinics

Dentists Will be Required to Have:

- An in-depth understanding of systemic conditions such as cardiovascular, cerebrovascular, and respiratory diseases; diabetes mellitus; and infections; this would require modifications in the syllabus involving substantive areas such as physiology, anatomy, biochemistry, genetics, molecular biology, pharmacology, pathology, medicine, surgery, research methods, and evidence-based literature interpretation
 - A thorough knowledge of diagnostic tests and an understanding of the role they play in patient evaluation; this will also require incorporation of clinical epidemiology course work and “lab”/project experiences
 - Comprehensive training in the conduct of TSD in dental clinic settings; this will require training and certification (when needed) in counseling, health education, health communication
 - A readiness to keep up with the rapidly changing science and technology that influences the development and practice of new tests; this will require a re-think on the type of continuing education program that dentists should attend
 - A willingness to adopt TSD and adjust to its incorporation into practice
 - An appreciation of one's professional position as part of the larger health care team and accept the training and related responsibilities that come with upgrading skills and expanded professional roles
-

Adapted from Refs. 48–50.