



Diamond Age Systems
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Defining the Future of Oral Healthcare

Heart Disease and Diabetes Risk Testing in the Dental Office Changing the Dental/Medical Paradigm

The Oral / Systemic connection is probably the most important movement in dentistry, and possibly all of medicine, in this decade. It is the recognition that many systemic diseases originate in, or are accelerated by, diseases of the oral cavity.

The recent research shows:

- Periodontal disease is a persistent inflammation which increases C - reactive protein, now considered to be more predictive of heart attack than High Cholesterol and implicated in colon cancer and Alzheimer's. (2),(3),(4) (5)
- Periodontal disease allows the release of the anaerobe *P. Gingivalis* into the bloodstream which increases HbA1C- the factor which determines how well a diabetic can control his blood sugar and if individuals are at risk for diabetes. (6)

Just as importantly, successful treatment of periodontal disease has been shown to:

- Significantly decrease C. Reactive protein often from the high risk to the safe level. (8)
- Significantly reduce HbA1c, aiding diabetics. (9)
- Actually reduce the cost of medical care due to Cardiovascular disease, stroke and diabetes. (31)

These results have changed attitudes to the extent that for 2006 CIGNA Health care is rolling out the "Dental Oral Health Maternity Program" as well as a Cardiovascular and Diabetes which will provide many pregnant women with 100% coverage for periodontal treatment. This is now being extended to diabetes and cardiac patients(12))

<http://www.Cigna.com/dental>. http://www.healthdecisions.org/Dental/News/default.aspx?doc_id=67594

The Centers for Dental Medicine™

The Centers for Dental Medicine is a growing nationwide network of dental practices that has been created to facilitate the oral systemic connection:

"The mission of the Center for Dental Medicine™ is to improve the health of our patients by being the bridge between dentistry and medicine through communication and collaboration with associated members of the medical profession.

Part research resource and part treatment center, we seek to understand how oral disease can affect patient total health, collaborate with practitioners in the area at risk



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and treat in such a way as to minimize the strain on the patient immune system, and maximize overall health”.

Diagnostic Protocol

In developing their diagnostic protocol it became evident that lab tests to assess risk factors for heart disease and diabetes, before and after treatment. The diagnostic Protocol used by CDM follows:

1. All patients are tested for periodontal disease with the Florida Computer Probe which measures probing depth, bleeding and exudate.
2. Those testing positive, with probe scores of 4mm or greater are advised as follows:

“You have developed periodontal disease”. Research has shown that periodontal disease can increase risk for heart disease, stroke and diabetes which can be measured with blood tests. Therefore we need to see if the periodontal disease has “gone systemic” yet just to make sure you are OK.

If current tests are available we will request them from your physician, otherwise we will test you for C-Reactive Protein for heart disease and HbA1c- Glycated Hemoglobin for diabetes.

3. The physician is contacted making him aware of the patient’s periodontal disease, how that can impact risk for systemic disease and requesting recent Hs-CRP and HbA1c tests if available.
4. If the tests are not available, the patient is sent to a local lab for Hs-CRP and HbA1c.
5. The results are discussed with the patient and interpreted according to the most valid recent findings (this changes).
6. The results are also sent to the MD, letting them know that periodontal treatment might make a significant impact on the scores and that you will keep them involved. If the scores are very high, greater than 10mg/L it would be strongly suggested that the patient be investigated for other inflammatory conditions as well.
7. After completion of treatment, the patient is retested . It would be expected that a patient with high CRP (3 mg/L or above) would decrease 25%-75%, hba1C would be expected to decrease 10%.
8. The after treatment results are discussed with the patient and MD. If CRP remains high, it is strongly recommended that other sources of inflammation be investigated.



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Results.

There have been many benefits of incorporating blood testing into the periodontal protocol

- It has always been difficult to get the patient to grasp the concept that perio is a systemic disease and does not just involve teeth. Blood testing takes the conversation into “real medicine” and really brings home the perio/systemic connection and the serious nature of their problem.
- As described above it provides an opening to the relationship with the MD.
- It documents the effects of your treatment, which could vary significantly with methodology.
- The dentist may become the leading edge of preventative medicine and save lives.
 - The medical profession does not use Hs-CRP as a screening since it is non specific and they don't have a pill for it. However a high value which does not decrease to normal with perio treatment should be investigated and may turn up serious disease that would otherwise go undetected. It should be noted that one of our offices helped discover cancer in a patient from these tests, and she credits her dentist with saving her life.
 - Offices report finding undiagnosed diabetics weekly. If untreated, diabetes can reduce life expectancy by 15 years, especially when combined with periodontal disease.

Limitations

- Compliance (send a patient to an outside laboratory) varies from practice to practice but often is no better than 50%. This is especially a problem for after treatment monitoring.
- It cost money. Each test will cost from \$35-\$100 and the question is who will, pay for it. Health insurance maybe, dental not likely.
- Sending out for testing can create a delay in the treatment process.

The Solution – In Office Testing

What if you could do blood testing in the dental office

- As part of the periodontal exam
- With a simple finger stick
- With no prior preparation or fasting
- At a cost of less than \$25.00 per test.

This would clearly provide all the benefits and remove the limitations.

Centers for Dental Medicine offers two methods of in-office testing avoiding the problem of compliance and cost for the patient.



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- ***Cholestech***– *where using special analyzers and cassettes the entire process is done in house in five minutes, and*
- ***Biosafe Laboratories***- *where the blood is drawn in the office using a finger stick and sent to the lab for analysis with a 1-2 week turnaround.*

Pros and Cons Diabetes- HbA1c

Cholestech- GDX starter kit is \$1295.00 including the analyzer and 48 cassettes

- Each subsequent test is only \$7.95
- You have the result immediately

Biosafe- each test is \$14.99- you wait 1-2 weeks for the result.

The bottom line is it takes about 129 tests for you to break even dollar wise.

The question is the convenience with Cholestech vs no-risk, no investment with Biosafe.

C-Reactive Protein

Cholestech- At the present time the Cholestech LDX CRP testing is only available to moderately complex labs or for research. It is not fully FDA approved for use in the dental office.

When it is available the analyzer will be \$2115 and the cassettes \$13.00 each.

Biosafe- Available now at \$24.99 per test.

The bottom line is right now there is no choice – so start with Biosafe.

Cholesterol- For offices doing health coaching.

Cholestech- The same LDX analyzer that has yet to be approved for CRP has been approved for Cholesterol.. The cost is \$1225 for the analyzer and \$10.00 per cassette.

Biosafe- Cholesterol panel is \$20.99 per test.

The bottom line is that it takes a couple hundred tests to break even on the LDX, but you have the immediate response. Also you will eventually be able to use the LDX for CRP.

We would be happy to discuss these choices with you. But either one is a tremendous break through for the CDM practice compared to getting people to go to a lab unless the lab is right next door and has a no waiting policy.

Concept of the “CLIA waived” device.



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CLIA is government alphabet soup for “Clinical Laboratory Improvement Act”. 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. A laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

The categorization of commercially marketed in vitro diagnostic tests under CLIA are now the responsibility of the FDA. FDA has assumed primary responsibility for performing the CLIA complexity categorization functions that include the process of assigning commercially marketed in vitro diagnostic test systems to one of three CLIA regulatory categories based on their potential risk to public health:

- waived tests
- tests of moderate complexity
- tests of high complexity.

On February 28, 1992, regulations were published to implement CLIA. In the regulations, waived tests were defined as simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Cholestech

In 1996 Cholestech Corporation a company that had been involved with cholesterol medication received a waiver for their “LDX” Analyzer to do Cholesterol lipid profiles. This has recently been extended to Hs CRP and Liver enzymes. From their website <http://www.cholesteck.com>

LDX Analyzer



The Cholestech LDX[®] System, using patented, innovative technology, measures a complete lipid profile plus glucose, ALT•AST, and hs-CRP in only 5 minutes (6 minutes for hs-CRP) from a simple fingerstick. With our ALT•AST test, you can get immediate liver enzyme results.

The scope of its measurement capabilities is not the only advantage to healthcare providers. The physician, nurse or technician can now share the results of testing with the patient **on the spot**, which means that **action** can be taken and treatment can begin **immediately**.

Images





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Key Features

- A small, portable footprint (21cm x 12cm or 8¼" x 4¾") for easy tabletop usage and storage
- System includes an easy-to-use printer that provides duplicate copies of test-results – one for you, one for the patient
- Lightweight design ideal for office and other point-of-care applications
- Factory calibrated, with easy and inexpensive software upgrades
- Fast, 3-step procedure saves time, enhances productivity
- Requires only a single drop of blood from a simple fingerstick and eliminates the anxiety of venipuncture.
- Provides virtually immediate feedback for on-the-spot adjustment of therapy and improved patient compliance
- It's the only CLIA-waived system of its kind and meets all relevant National Cholesterol Education Program (NCEP) guidelines for precision and accuracy
- CRMLN certified 426 13188 Rev. A
Cholesterol Reference Method Laboratory Network

Cholestech LDX System

Includes:

- Analyzer
- Printer
- Power Supply
- Starter Pack (U.S. only)
- Optics Check Cassette
- Printer Cable
- User Manual
- Procedure Manual (U.S. only)
- Training Video

Cat. No 10-959

In 2002 they received a CLIA waiver for the "GDX" analyzer for HbA1c analysis:

GDX Analyzer

- >Single drop of blood
- >CLIA-waived*
- >NGSP-certified†
- >Lab-accurate

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>Reimbursable

The American Diabetes Association recommends that people with diabetes have their average glucose levels checked by A1C testing up to 4 times a year to help them avoid complications of the disease.

Now, with the CLIA-waived Cholestech GDX™ System, you can do the A1C testing right in your own office. In just 5 minutes. It will maximize the power of face-to-face counseling during the same office visit.

*510(k) cleared for prescription home use and, accordingly, is CLIA-waived.

[†]National Glycohemoglobin Standardization Program certified as traceable to the Diabetes Control and Complications Trial.

Awaiting CLIA waiver for Hs CRP testing

Cholestech added Hs-CRP capability to their LDX analyzer by a change in software and cassette. However they have not yet received a full CLIA waiver for that function. There are certain special conditions where a dental office can qualify as a “moderately complex lab” or use it for research. In any case one could get going with cholesterol testing now and add the Hs-CRP when the LDX has cleared waivers.

Summary

Adding in office blood testing to the dental office involved in periodontal treatment promises to provide a revolution in diagnosis, patient communication, physician relationships and treatment evaluation.