Health Screenings in the Dental Office

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Why Screen in a Dental Clinic?

- 64% of the general population see a dental health care professional in the course of a year compared to 39% who went to a medical office—25% more access dental care.

  *Dr. Michael Glick, 2010 OSAP Symposium – Tampa, Florida – 06/2010*
Discordance in National Estimates of Hypertension Among Young Adults

5.23.11 – Epidemiology – Nguyen QC et al

- **Background**
  - Coronary heart disease (CHD) is the leading cause of mortality in the U.S.
  - CHD risk assessment is a priority and accurate blood pressure (BP) measurement is essential.

- **Methods**
  - Hypertension estimates in the National Longitudinal Study of Adolescent Health (Add Health), Wave IV (2008)-a nationally representative field study of 15,701 participants aged 24-32-was referenced against NHANES (2007-2008) participants of the same age.
Discordance in National Estimates of Hypertension Among Young Adults
5.23.11 – Epidemiology – Nguyen QC et al

○ Results
  ● Hypertension rates (BP: \( \geq 140/90 \) mm Hg) were higher in Add Health compared with NHANES (19% vs. 4%)

○ Conclusions
  ● The prevalence of hypertension among Add Health Wave IV participants suggests an unexpectedly high risk of cardiovascular disease among US young adults.
Diabetes affects 25.8 million people, 8.3% of the U.S. population
- DIAGNOSED - 18.8 million people
- UNDIAGNOSED – 7.0 million people

Among U.S. residents aged 65 years and older, 10.9 million, or 26.9%, had diabetes in 2010.

Approximately 1.9 million people aged 20 years or older were newly diagnosed with diabetes in 2010 in the U.S.
In 2005–2008, based on fasting glucose or hemoglobin A1c levels, 35% of U.S. adults aged 20 years or older had prediabetes (50% of adults aged 65 years or older).

Applying this percentage to the entire U.S. population in 2010 yields an estimated 79 million American adults aged 20 years or older with prediabetes.

Diabetes is the leading cause of kidney failure, nontraumatic lower-limb amputations, and new cases of blindness among adults in the United States.

Diabetes is a major cause of heart disease and stroke.

Diabetes is the 7th leading cause of death in the U.S.

Age-adjusted percentage of adults aged ≥20 years with diagnosed diabetes, 2007

MMWR 58:1259-1263, 2009
Age-adjusted percentage of adults aged ≥20 years who are obese, 2007

MMWR 58:1259-1263, 2009
Counties in the top and bottom two quintiles of both diabetes and obesity, 2007

MMWR 58:1259-1263, 2009
Number and Percentage of U.S. Population with Diagnosed Diabetes, 1958-2009

Bayer A1CNow
1981-CDC-first reports of what later would be known as AIDS – 30 years

Pneumocystis Pneumonia — Los Angeles

In the period October 1980–May 1981, 5 young men, all active homosexuals, treated for biopsy-confirmed Pneumocystis carinii pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had lab confirmed previous or current cytomegalovirus (CMV) infection and candidal infection. Case reports of these patients follow.

Patient 1: A previously healthy 33-year-old man developed P. carinii pneumonitis in March 1981 after a 2-month history of fever associated with oral mucosal candidiasis. The serum complement was elevated, liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria. The serum complement was elevated liver enzymes, leukopenia, and CMV viruria.
Emory Launches AIDSVu
Persons Living with an HIV Diagnosis, by County, 2008
Approximately 50,000 Americans become infected with HIV annually.

16,000 people with AIDS died in 2008.

The number of people living with HIV in the United States, now at nearly 1.2 million, continues to grow by tens of thousands each year, creating more opportunities for HIV transmission.

- e-HAP FYI updates for Centers for Disease Control and Prevention 10.20.11
CDC HIV Counseling and Testing Recommendations

- The CDC estimate that 1 in 5 persons living with HIV infection in the United States is unaware of his or her diagnosis, accounting for more than 232,000 undiagnosed cases of HIV infection.
- To facilitate timely detection, the CDC revised their HIV testing guidelines in 2006 to recommend routine HIV testing in all health care settings for patients aged 13–64 years.
In 2006, CDC updated recommendations for HIV testing in part due to the following reasons:

- decreasing effectiveness of risk-based screening in identifying HIV-infected persons;
- the failure to identify new HIV infections even when patients access medical care;
- the low percentage of people tested for HIV in conventional settings who return for their test results;
- a failure to increase the number of people tested for HIV per year.

These recommendations also emphasize the importance of using outpatient health care settings to increase rates of detecting new HIV infections.
2006 CDC Recommendations

Make HIV Screening a ROUTINE part of healthcare!

- All patients ages 13 to 64 years.
- Repeated annually for high risk groups.
- Eliminate pre-test counseling.
- *Elimination of separate consent process* [longer term goal, state by state regs]

Rationale for Current Prevention Efforts

- Persons who know their status significantly reduce high-risk sexual behavior
  - (Marks et al. JAIDS 2005)
- Linkage to care after screening improves the course of HIV/AIDS.
- Early diagnosis of HIV not only prolongs healthy, productive lives, it also increases the effectiveness of antiretroviral medication and is cost effective over time.

  - Saag M, et al. CD4 Count at HAART Initiation, 8th Conference on Retroviruses and Opportunistic Infections, February 2001 Chicago, IL USA
HAART Within 6 Months of Infection Preserves Immunity

- The immune system is better able to recover when ART is initiated early in the course of HIV infection as opposed to during the chronic phase of HIV disease.

HIV Prevention Trials Network (HPTN) Study 052

- HPTN 052 was designed to evaluate whether immediate versus delayed use of ART by HIV-infected individuals would reduce transmission of HIV to their HIV-uninfected partners and potentially benefit the HIV-infected individual as well.
- The study concluded that initiation of ART by HIV-infected individuals substantially protected their HIV-uninfected sexual partners from acquiring HIV infection, with a 96 percent reduction in risk of HIV transmission.
- This is the first randomized clinical trial to show that treating an HIV-infected individual with ART can reduce the risk of sexual transmission of HIV to an uninfected partner.
Dental Examinations as an Untapped Opportunity to Provide HIV Testing for High-Risk Individuals

- Data from the 2005 National Health Interview Survey to examine the potential role of dental care in reaching untested individuals at self-reported risk for HIV.

- **An estimated 3.6 million Americans report that they are at significant HIV risk yet have never been tested.**

- Three quarters of these people have seen a dental health care worker within the past 2 years.


- **These dental visits represent missed opportunities for HIV screening!**
The Rapid Screening Solution

- March 2004- FDA approves Rapid HIV screening Test and grants it a CLIA waiver.
- Can be preformed by non-laboratory staff.
- Oral Fluid, Serum or Whole Blood.
Resources

- **Quality Assurance guidelines:**

- **HIV Screening Model for Dental Care – National Association of Community Health Centers**
  - [http://www.nachc.org/Dental%20Tools.cfm](http://www.nachc.org/Dental%20Tools.cfm)

- **Compendium of State Testing Laws – National HIV/AIDS Clinicians Consultation Centers**
  - [http://www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws/](http://www.nccc.ucsf.edu/consultation_library/state_hiv_testing_laws/)
  - Clinicians with questions about HIV testing are encouraged to call the National HIV Telephone Consultation Service (Warmline) at (800) 933-3413
What is the prevalence of chronic HCV infection in the United States?

- Approximately 3.2 million persons in the United States have chronic HCV infection. Infection is most prevalent among those born during 1945–1965, the majority of whom were likely infected during the 1970s and 1980s when rates were highest.
What is the incidence of HCV infection in the United States?

- Although only 849 cases of confirmed acute Hepatitis C were reported in the United States in 2007, CDC estimates that approximately 17,000 new HCV infections occurred that year, after adjusting for asymptomatic infection and underreporting.

- Persons newly infected with HCV are usually asymptomatic, so acute Hepatitis C is rarely identified or reported.
How HCV is Transmitted?

- HCV is transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood, such as Injection drug use (currently the most common means of HCV transmission in the United States)
- Receipt of donated blood, blood products, and organs (once a common means of transmission but now rare in the United States since blood screening became available in 1992)
- **Needlestick injuries in health care settings**
- Birth to an HCV-infected mother
- HCV can also be spread infrequently through
  - Sex with an HCV-infected person (an inefficient means of transmission)
  - Sharing personal items contaminated with infectious blood, such as razors or toothbrushes (also inefficient vectors of transmission)
  - Other health care procedures that involve invasive procedures, such as injections (usually recognized in the context of outbreaks)
Who is at risk for HCV infection?

- Current or former injection drug users, including those who injected only once many years ago
- Recipients of clotting factor concentrates made before 1987, when more advanced methods for manufacturing those products were developed
- Recipients of blood transfusions or solid organ transplants before July 1992, when better testing of blood donors became available
- Chronic hemodialysis patients
- **Persons with known exposures to HCV, such as health care workers after needlesticks involving HCV-positive blood**
- Recipients of blood or organs from a donor who tested HCV-positive
- **Persons with HIV infection**
HCV

○ How likely is HCV infection to become chronic?
  ● HCV infection becomes chronic in approximately 75%–85% of cases.

○ Is Hepatitis C a common cause for liver transplantation?
  ● Yes. Chronic HCV infection is the leading indication for liver transplants in the United States.

○ Is it possible for someone to become infected with HCV and then spontaneously clear the infection?
  ● Yes. Approximately 15%–25% of persons clear the virus from their bodies without treatment and do not develop chronic infection; the reasons for this are not well known.
As long as Standard Precautions and other infection control practices are used consistently, medical and dental procedures performed in the United States generally do not pose a risk for the spread of HCV. However, HCV has been spread in health care settings when injection equipment, such as syringes, was shared between patients or when injectable medications or intravenous solutions were mishandled and became contaminated with blood. Health care personnel should understand and adhere to Standard Precautions, which includes safe injection practices and other guidance aimed at reducing bloodborne pathogen risks for patients and health care personnel. If health care-associated HCV infection is suspected, this should be reported to state and local public health authorities.
Boceprevir, Telaprevir to Usher in New Era of HCV Therapy

"We need to do a better job of educating the public, as well as physicians, (dental healthcare workers) about hepatitis C, developing targeted screening programs, and then getting these patients into an evaluation process. Having more effective treatments, in many ways, creates a greater public health mandate to be more aggressive in identifying patients."

- Mark S. Sulkowski, MD, from Johns Hopkins University School of Medicine, Baltimore, Maryland, noted in an interview with Medscape Medical News 4.16.11
Rationale for the Utility of a Rapid, Point-of-Care (POC) Test to Aid in Identification of HCV Infection

- Despite significant evolution in the quality of laboratory based tests for HCV, the majority of HCV infection remains undiagnosed.
- Availability of a rapid, non-instrumented POC test will increase opportunities for diagnosis through increased testing outside of laboratory settings.
- Expected improvements in efficacy and reduced treatment durations is expected to increase the number of patients initiating therapy.
- Availability of improved therapies will mean increased diagnoses will be an important factor in reducing future morbidity and mortality associated with HCV.
A Simple Test Procedure Utilizing All Sample Types

<table>
<thead>
<tr>
<th>COLLECT</th>
<th>TEST</th>
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<tbody>
<tr>
<td>Oral Fluid</td>
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<tr>
<td>Venipuncture</td>
<td>MIX</td>
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<tr>
<td>Whole Blood</td>
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<td>Serum / Plasma</td>
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<tr>
<td>Fingerstick</td>
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<td>Whole Blood</td>
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Prototype OraQuick® HCV Test- Interpretation

- **Non-reactive:** Single line appears at the C (control) triangle
  - A negative result indicates the absence of HCV antibodies in the sample

- **Reactive for anti-HCV:**
  - Two lines appear
    - One at the C (control) triangle and the other at the T (test) triangle
    - Indicates the presence of HCV antibodies in the sample.
OraQuick® HCV seroconversion results compared to FDA-approved EIA were as follows:

<table>
<thead>
<tr>
<th></th>
<th>Days to Evidence of HCV Infection</th>
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<tbody>
<tr>
<td></td>
<td>OraQuick® HCV Rapid Antibody Test</td>
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<tr>
<td></td>
<td>Time to Detection</td>
</tr>
<tr>
<td>Average</td>
<td>59.2</td>
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- OraQuick® HCV was able to detect antibodies earlier than the approved EIA in 9 of 18 seroconversion panels and by an overall average of 3.6 days (CIs = 1.2 to 5.9 days earlier).
- OraQuick® HCV at least as sensitive as EIA
OraQuick® HCV Test- Status

- Product now registered and available for sale in most European countries
- Product launched worldwide with 18 months dating
- Approved for use with venous blood and fingerstick blood by US FDA
- Low prevalence study in VB and F/S completed and submitted for FDA review
- CLIA waiver application for VB and F/S submitted to FDA
- Oral fluid performance study completed – preliminary data analysis completed
  - Additional testing of clinical specimens in process
  - Expect to submit data in support of FDA oral fluid approval in 2011
Clinical Laboratory Improvement Amendments (CLIA)

- The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the CDC and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.
What is a laboratory?

- Under CLIA, a laboratory is defined as a facility that performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings.
Example – Physician’s office

- I AM A PHYSICIAN PERFORMING URINE DIP STICKS AND FINGER STICKS FOR BLOOD GLUCOSE IN MY OFFICE AS PART OF THE PATIENT’S VISIT. AM I CONSIDERED TO HAVE A LABORATORY AND DO I NEED A CLIA CERTIFICATE?
  - A. No
  - B. Yes
  - C. Haven’t a clue
Answer

- Yes, the testing you perform qualifies as waived laboratory testing and you need a CLIA Certificate of Waiver. This testing requires a CLIA certificate regardless of how many tests you perform and even if you do not charge the patient or bill Medicare or other insurances.
Dental Office

- I AM A DENTIST PERFORMING FINGER STICKS FOR BLOOD GLUCOSE IN MY OFFICE AS PART OF THE PATIENT’S VISIT. AM I CONSIDERED TO HAVE A LABORATORY AND DO I NEED A CLIA CERTIFICATE?
  - A. No
  - B. Yes
  - C. Haven’t a clue
Answer

- Yes, the testing you perform qualifies as waived laboratory testing and you need a CLIA Certificate of Waiver. This testing requires a CLIA certificate regardless of how many tests you perform and even if you do not charge the patient or bill Medicare or other insurances.
WHAT IS A WAIVED TEST?

- As defined by CLIA, waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result.”

- The Food and Drug Administration (FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer’s applications for test system waiver.
WHERE CAN I FIND A LIST OF WAIVED TESTS?

- For a list of waived tests sorted by the test categorization date and by the test system name, visit the FDA website at

HOW DO I ENROLL IN OR APPLY TO THE CLIA PROGRAM?

- You can enroll your laboratory in the CLIA program by completing an application (Form CMS-116) available online at www.cms.hhs.gov/clia or from your local State Agency. Forward your completed application to the address of the local State Agency for the State in which your laboratory is located.

- A list of State agencies is available at the web site listed above. If you cannot access the website listed above, you may contact the CLIA program at 410-786-3531
If I have more than one office and perform waived testing and more than one location, do I need additional certificates?

- You will need a CLIA certificate for each site where you perform testing unless you qualify for one of the exceptions listed below.
  - Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base using its address.
If I have more than one office and perform waived testing and more than one location, do I need additional certificates?

- Not-for-profit or Federal, State or local government laboratories that engage in limited public health testing may file a single application.

- Laboratories within a hospital that are located at adjoining buildings on the same campus and under common direction may file a single application for the laboratory sites within the same physical location or street address.
If I have more than one office and perform waived testing and more than one location, do I need additional certificates?

- Contact your State Agency if you have questions or you are filing a single application for more than one testing site.
WHEN CAN I START PERFORMING THE WAIVED TESTING?

- After you apply for your certificate, you will receive a fee coupon assessing a fee. Follow the instructions on the fee coupon for payment. After CMS receives your payment, your certificate will be mailed to you. You may begin testing once you have received your certificate.

- You also need to check with your State Agency since some states have additional requirements.
IF I ONLY PERFORM WAIVED TESTS, WHAT DOES CLIA REQUIRE THAT I DO?

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturers’ instructions for the waived tests you are performing;
- Notify your State Agency of any changes in ownership, name, address or director within 30 days, or if you wish to add tests that are more complex; and
- Permit inspections by a CMS agent, such as a surveyor from the State Agency. However, your laboratory is not subject to a routine survey or inspection.
HOW AND WHEN WILL I BE INSPECTED?

- Laboratories with a Certificate of Waiver are not subject to a routine inspection (survey) under the CLIA Program but may be surveyed in response to a complaint or if they are performing testing that is not waived.

- CMS is currently conducting a project whereby a small percentage of laboratories that perform waived testing may receive an educational visit at no charge. CMS representatives provide helpful information to the waived testing sites.
WHY IS IT IMPORTANT TO FOLLOW THE CURRENT MANUFACTURER’S INSTRUCTIONS?

- It is important to always follow the current test system’s instructions precisely to be sure your results are accurate.
- This includes performing any quality control procedures that the manufacturer recommends or requires.
WHERE CAN I FIND MORE INFORMATION ABOUT GOOD LABORATORY PRACTICES?

- The CDC has published recommendations for good laboratory practices for waived testing sites in Morbidity and Mortality Weekly Reports (MMWR) Recommendations and Reports. The MMWR publication provides comprehensive recommendations for facilities that are considering introducing waived testing or offering a new waived test, and good laboratory practices to be followed before, during, and after testing.

- You can find this article on the CDC website at http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf.
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

- **General information**
  - Initial application
  - Facility Name, Street address, Contact information, Federal Tax ID, Name of Director

- **Type of Certificate Requested**
  - Certificate of Waiver

- **Type of Laboratory** *(Check the one most descriptive of facility type)*
  - Practitioner other; FQHC; Community Clinic; Rural health clinic;

- **Hours of Testing**
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

- **Multiple Sites** – Are you applying for the multiple site exemption?
- **Waived Testing** - Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed
- **Type of Control**
  - VOLUNTARY NONPROFIT - religious, private, other
  - FOR PROFIT - proprietary
  - GOVERNMENT – city, county, state, federal, other government
DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

- CLIA number
- Name of laboratory
CLIA Recognized by States

Yes

CLIA state recognition

- Yes, but with limitations:
  - Arizona, California, Maine, Massachusetts, New Jersey, Tennessee, Florida (state additional fee of $100 every two years)

- No, CLIA is not recognized, but state may have its own regulations:
  - Alabama, Georgia, Maryland, Nevada, New York (has their own CLIA unit), North Dakota, Pennsylvania.
Questions?