NEW JERSEY AIDS Line

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Antiretroviral Agents Rise as the Primary Means of HIV Prevention

On November 8, 2011, Secretary of State Hillary Rodham Clinton called on the United States and other countries to use new scientific discoveries to create an "AIDS-free generation" in the world. In her speech, Clinton noted that it was essential to combine treatment and prevention rather than seeing them as competing for effort and funding. She stated that the United States must scale up the most effective, evidence-based prevention methods, and announced that the federal government will commit $60 million to clinical trials to document the efficacy of immediate treatment upon diagnosis of HIV infection, or "test and treat."

The prevention strategies Clinton outlined for achieving an "AIDS-free generation" were:

1) Reduce mother-to-child transmission to ZERO by 2015, internationally, through antiretroviral treatment (ART).
2) Voluntary medical male circumcision.
3) "Test and Treat" with ART to reduce viral load as soon as HIV status is known.

In two of three prioritized HIV prevention strategies, strategic use of antiretroviral treatment is the tool that can reduce viral loads, thus both improving the health of the person with HIV/AIDS and reducing the likelihood that he or she will transmit HIV to an uninfected person. This medical approach is in stark contrast to the prevention education and counseling campaigns targeted to uninfected individuals, from the mid 1980s until recently. HIV prevention messages were crystallized in the international slogan of "A,B,C" or "abstain, be faithful, and/or use condoms." The goal of public health campaigns and educational programs was to persuade everyone who was not infected that they must change their individual sexual and drug-use behavior to protect themselves from HIV infection.

HIV treatment rose to public awareness as a means to reduce future infection, and to contain the growth of the epidemic, following the development of the President's Emergency Plan for AIDS Relief (Pepfar) in 2003, when President George W. Bush committed the United States to international medical aid targeted to countries most devastated by AIDS. An HIV/AIDS vaccine was eagerly anticipated, which would provide protection to those at highest risk of HIV infection. This hope has not resulted in an effective vaccine, leading to intensified efforts to find other biomedical prevention interventions.

Education, counseling, and medical approaches have become more integrated in recent years as HIV antibody testing has been incorporated in medical care and substance abuse treatment. There have been reductions in intravenous drug use, and condom use has become more common, but there are still many thousands of new cases of HIV infection every year attributed to unprotected sexual encounters and shared needles/drug works.

(Continued on page 38)

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Continuing Education

CME/CE Article #1

CME/CE Article #2

News

Resources

CONTINUING EDUCATION

HIV and Oral Healthcare

Release date: December 1, 2011 • Expiration date: November 30, 2013 • Code: 14HC02-DE01 • Nursing credit for this activity will be provided through November 30, 2013.

SPONSOR:

Sponsored by UMDNJ-Center for Continuing and Outreach Education, Division of AIDS Education.

GRANTOR ACKNOWLEDGEMENT:

This activity is supported by an educational grant from the New Jersey Department of Health and Senior Services (NJDHSS) - Division of HIV, STD and TB Services, through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS." The New York/New Jersey AETC (AIDS Education and Training Center (NY/NJAETC) provided in-kind support through the work of its Dental Co-Director, Cheryl R. Stolarski, DMD.

STATEMENT OF NEED:

Oral diseases associated with HIV infection include oral candidiasis and Kaposi's sarcoma, which are indicators included in the diagnostic definition of AIDS, and oral cancer. These conditions have become less common since the advent of HAART in 1996. However, HIV/AIDS patients with uncontrolled viral loads, indicating immunocompromise, continue to present to both dentists and other healthcare professionals with ulceration of the oral cavity and other, often-painful, symptoms. These patients may not be in routine dental care, and all healthcare providers seeing HIV patients should be able to identify oral manifestations and provide emergency care as well as facilitating access to dental providers for necessary treatment. Oral disease is indicative of systemic inflammatory processes which may exacerbate chronic infections including HIV and hepatitis.

The USDHSS-HRSA-HIV/AIDS Bureau has added routine oral screening to the quality benchmarks of HIV care that should be provided to all individuals with HIV/AIDS. They note that "when the oral cavity is compromised by the presence of pain or discomfort, maintaining adherence to complicated antiretroviral therapy regimens becomes more difficult."

TARGET AUDIENCE:

This free knowledge-based activity is designed for physicians, nurses, pharmacists, social workers, dentists, dental hygienists and other health care professionals in New Jersey who are involved in the care of persons with HIV/AIDS and/or hepatitis.

METHOD OF PARTICIPATION:

Participants should read the learning objectives, review the activity in its entirety, and then complete the self-assessment test which consists of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test; participants will receive a letter of credit and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials; or may complete the activity online at www.umdnj.edu/ccoe. Estimated time to complete this activity as designed is 1.32 hours for nurses, and 1.0 hours for physicians, pharmacists, dentists and dental hygienists.

LEARNING OBJECTIVES:

Following completion of this activity, participants should be able to:

1. Identify the impact of oral disease on systemic health of HIV/AIDS patients, and symptoms of disease including oral lesions.
2. Implement oral health screening, as part of the overall healthcare plan.
3. Distinguish and differentiate the need for emergency dental care due to acute infection, pathology or pain. Prescribe analgesics and antibiotics when appropriate and facilitate access to a dental provider for follow up treatment.

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ACCREDITATION STATEMENTS:

CME

UMDNJ-Center for Continuing and Outreach Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

UMDNJ-Center for Continuing and Outreach Education designates this Enduring material for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

Pharmacists: UMDNJ-Center for Continuing and Outreach Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This course (ACPE #0374-0000-11-015-H02-P) qualifies for 1.0 contact hour (0.10 CEU) of continuing pharmacy education credit.

Pharmacists should claim only those contact hours actually spent participating in the activity.

CNE

UMDNJ-Center for Continuing and Outreach Education is an approved provider of continuing nursing education by NJSNA, an accredited approver by the American Nurses Credentialing Center's COA. Provider Number P173-11/09-12. Provider Approval is valid through November 30, 2012.

Nurses should claim only those contact hours actually spent participating in the activity.

Provider approved by the California Board of Registered Nursing, Provider Number CEP 13780.

This course is awarded 1.32 contact hours (60 minute CH).

Approved provider status refers only to continuing education activities and does not imply ANCC COA or NJSNA endorsement of any commercial products.

CDE

Dentists: The New York State Dental Foundation is approved by NYSDA and the New York State Education Department as an approved provider for dental continuing education in conjunction with the New York State Department of Health-AIDS Institute.

CDE

Dental Hygienists: The Dental Hygienists' Association of the State of New York, Inc., an accredited approver by the New York State Department of Education, has approved the NY/NJ AETC's continuing education learning activities for dental hygienists.

CEU

UMDNJ-CCOE certifies that this continuing education offering meets the criteria for up to 0.10 Continuing Education Units (CEUs), provided the activity is completed as designed. One CEU equals 10 contact hours of participation in an organized continuing education experience under responsible sponsorship, capable direction and qualified instruction. Participants should only claim those contact hours actually spent participating in the activity.

PEER REVIEW:

In order to help ensure content objectivity, independence, and fair balance, and to ensure that the content is aligned with the interest of the public, UMDNJ-CCOE has resolved all potential and real conflicts of interest through content review by a non-conflicted, qualified reviewer. This activity was peer-reviewed for relevance, accuracy of content and balance of presentation by Patricia Kloser, MD, MPH; Debbie Mohammed, MS, MPH, APRN-BC, AACRN; Humberto Jimenez, BCPS, PharmD, AAHIVE, Brenda Christian, MEd, PA-C; Director of AIDS Education, UMDNJ-CCOE.

Field test: This activity was pilot-tested for time required for participation by Kinshasa Morton, MD; Shobha Swaminathan, MD; Jojy Cheriyan, MD; Mary C. Krug, MSN, APN; Renee Powell, BS, RN; Kara Winslow, BSN, RN; Polly Jen, PharmD; John Faragon, PharmD, AAHIVE; and George Rusuloj, PharmD.

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Disclosure Declarations: There were no relevant financial relationships to disclose reported by the activity director, faculty, planning committee members, peer reviewers or field testers.

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NEW JERSEY AIDSLine December 2011

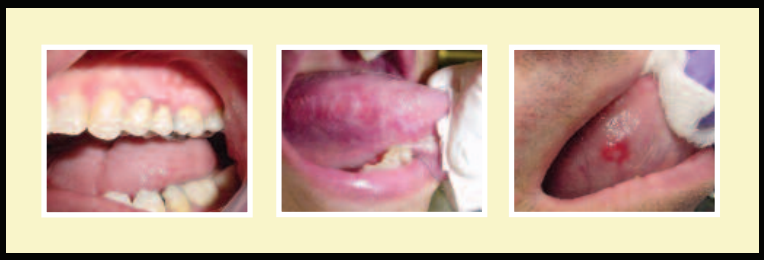
HIV and Oral Healthcare

Cheryl R. Stolarski, DMD

Learning Objectives:

Following completion of this activity, participants should be able to:

1. **IDENTIFY** the impact of oral disease on systemic health of HIV/AIDS patients, and symptoms of disease including oral lesions.
2. **IMPLEMENT** oral health screening, as a part of the overall healthcare plan.
3. **DISTINGUISH AND DIFFERENTIATE** the need for emergency dental care due to acute infection, pathology or pain. Prescribe analgesics and antibiotics when appropriate and facilitate access to a dental provider for follow up treatment.



Patients with HIV disease have unique oral conditions associated with HIV disease and the associated decline in the immune system which effects systemic health.

Current strategies to engage primary care providers in oral care include: oral health education, risk assessment and appropriate referrals to dental providers. In most cases, it is the primary care provider who has the first medical contact with a patient after receiving the initial diagnosis of HIV.

Release Date: December 1, 2011 • Expiration Date: November 30, 2013 • Course Code: 14HC01 • Nursing Credit for this activity will be provided through November 30, 2013.

Cheryl R. Stolarski, DMD is Dental Co-Director, NY/NJ AIDS Education & Training Centers; AIDS Institute – Office of the Medical Director.
Cases provided by Mahnaz Fatahzadeh, BSc, DMD, MSD, Dip ABOM, Associate Professor, NJ Dental School, UMDNJ.

Sponsor: UMDNJ-Center for Continuing & Outreach Education-Division of AIDS Education.

Funding: This activity is supported by an educational grant from NJDHSS Division of HIV/AIDS, STD and TB Services through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS.

The New York/ New Jersey AETC (AIDS Education and Training Center (NY/NJAETC) provided in-kind support through the work of its Dental Co-Director, Cheryl R. Stolarski, DMD, and accreditation through collaboration with the New York State Dental Foundation.

To obtain continuing education credit, complete the quiz, registration, and evaluation on the following pages, or go to: www.umdnj.edu/ccoe/aids

HIV and Oral Healthcare

Primary Care Provider Strategies Include: Education + Risk Assessment + Referrals to Dental Providers

Introduction

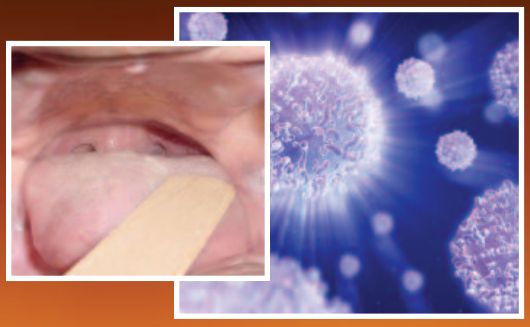
Oral Disease can be found in most populations and through all stages of life. Many times oral disease is a result of lack of care and basic prevention. It has been well documented that oral health and systemic health can affect one another in both oral and systemic presentations.

In 2000, then Surgeon General David Satcher issued the first Surgeon General's Report on Oral Health. It focused on the relationship between oral health and general health. "A poorly functioning dentition can adversely effect the quality of life, complicate the management of medical conditions, and create or exacerbate nutritional and psychosocial problems."[1] The World Health Organization, since 1948, has used an expanded definition of health to mean "a complete state of physical, mental, and social well-being, and not just the absence of infirmity."[2] It follows that oral health is essential to that well-being.

Oral health is a vital component of comprehensive patient care.[3,4] Access to oral health care for all people living with HIV/AIDS (PLWHA) is often cited as one of the greatest areas of unmet need.[5,6,7] Patients with HIV disease have unique oral conditions associated with HIV disease and the associated decline in the immune system which effects systemic health. Recently HRSA has prioritized a plan to engage primary care providers in HIV oral health care. Examples of HRSA's plan include the development of the Community Based Dental Partnership program (CBDPP), which supports the linkage of dental schools and their communities. This has resulted in the formation of twelve dental partnerships in eleven states, in which dental students and residents visit and provide care in community-based medical clinics.[4] This type of interdisciplinary approach allows for the integration of oral health care into overall health care service.[5] AIDS Education and Training Centers (AETC's) also play an important educational role by providing oral health training to primary care providers. Quality indicators for these programs include site visits, data reports, and client feedback.[8,9]

Current strategies to engage primary care providers in oral care include: oral health education, risk assessment and appropriate referrals to dental providers. In most cases, it is the primary care provider who has the first medical contact with a patient after receiving the initial diagnosis of HIV. The medical provider will be the one to complete a thorough examination and refer patients for further treatment. The recognition and management of oral manifestations, and timely referral to the dentist, should begin with the initial history and physical. Systemic health and oral health should not be thought of independently. A medical provider examining the oral cavity must also focus on teeth and other hard/soft tissues of the mouth. This approach emphasizes the importance of good oral health and facilitates access to oral care. The medical provider should also determine if further dental treatment is urgent or routine. In many cases the medical provider will be able to identify oral health emergencies, make appropriate referrals, and offer pain relief when necessary.

Access to oral health care for all people living with HIV/AIDS is often cited as one of the greatest areas of unmet need.[5,6,7]



The recognition and management of oral manifestations, and timely referral to the dentist, should begin with the intitial history and physical. Systemic health and oral health should not be thought of independently.

Many patients living with HIV disease are taking HAART medications. With the use of these medications, there has been a decrease in the occurrence of many oral lesions. HAART therapy has enabled patients living with HIV to live more productive and healthy lives. It has also reduced the prevalence of oral lesions associated with HIV disease. Although the incidence of many oral lesions has been dramatically reduced due to ARV treatment, their presence can be a marker of disease progression and even be the initial sign of HIV infection.

Living longer also means that HIV+ patients are developing medical conditions associated with aging. A weakened immune system may also play a role in the vulnerability of developing systemic disease. One example of this is cancer. The American Cancer Society reports that "the likelihood of developing oral cancer increases with age, especially after age 35."[10] Case 1 describes a 45-year-old HIV+ patient diagnosed with Stage III Squamous Cell Carcinoma. This patient had not visited his dentist in five years. If this case was not referred to a dentist for biopsy, the patient's prognosis would have been very different.

Other diseases associated with living longer include periodontal disease, medication-induced xerostomia (dry mouth) and increased caries.

This article will focus on some of the factors that link oral health and systemic health. It describes the role of a medical provider in supporting oral health care for their patients. This includes performing an oral exam to screen for periodontal disease, oral dryness, caries, oral cancer, and the need for urgent care and referral.

While there is no substitution for a patient being seen by a dentist, the medical provider should provide oral health education, including an intraoral and extraoral screening as part of the overall exam.

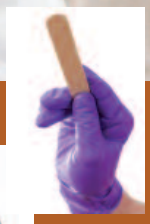
Living longer also means that HIV+ patients are developing medical conditions associated with aging.

Recently HRSA has prioritized a plan to engage primary care providers in HIV oral health care. Examples of HRSA's plan include the development of the Community Based Dental Partnership program (CBDPP), which supports the linkage of dental schools and their communities.

The medical provider should perform an oral exam to screen for periodontal disease, oral cancer… urgent care/referral needs.

HIV and Oral Healthcare

Performing the Intra/Extra Oral Exam



For performing the oral exam, the medical provider will need gloves, a tongue blade or disposable mouth mirror, a light source for the intra-oral exam and a piece of 2x2 gauze.

This exam is similar to an oral cancer screening and should take 2 to 5 minutes to complete. The medical provider will need gloves, a tongue blade or disposable mouth mirror, a light source for the intra-oral exam and a piece of 2X2 gauze. This exam should be preceded by subjective questions regarding oral health. Some examples are included on page 7. All findings should be documented and appropriate (urgent or routine) referrals made.

Extra-oral Exam

Bilateral palpation and Inspection of the following structures should be included:

- Palpate and visually inspect the head and neck region for any asymmetries, tenderness or swelling.
- Palpate the patient's tempromandibular joint and facial musculature.
- Palpate the patient's lymph nodes starting from the submandibular area extending down the cervical chain along the sternocleidomastoid muscle into the clavicular area for any swellings, tenderness or abnormalities.

Intra-oral Exam

Use a light source (ex.penlight) to look inside the oral cavity. Be sure to wrap a piece of gauze around the tongue when examining the tongue. Gloves, a tongue blade or disposable mouth mirror should also be used. **Note: If the patient wears a removable denture, it must be removed so that the oral tissue can be examined.

- Examine the lips including the commissures (corners of the mouth) by sliding a finger over the inner and outer surface.
- Check the palate, buccal mucosa, (inside of the cheek) gingival and sublingual area (under the tongue) for discolorations and/or ulceration.
- Examine the tongue by gently wrapping gauze around it and have the patient extend their tongue forward. Check the dorsal, ventral, lateral borders including the posterior border of the tongue.
- Examine the soft palate.
- Examine the teeth and periodontal structures for obvious signs of swelling, decay and/or infection.

***** For more detailed instruction and step-by-step tutorials, please visit the following websites:**

- **Head, Neck and Oral Cancer Examination.** Association of American Medical Colleges. 40 minute video. Requires free registration with AAMC, at www.aamc.org. video is at: http://services.aamc.org/30/mededportal/servlet/s/segment/mededportal/find_resources/browse/?subid=7768
- **Oral Health Training for Nursing Professionals.** AIDS Education and Training Centers National Resource Center. 12 minute video presentation of external and intraoral exam. http://www.aidsetc.org/mpeg/archive/oral_health_03.mpg

The oral exam should be preceded by a Subjective Risk Assessment.

Subjective Risk Assessment

A medical provider can include oral health questions in a subjective risk assessment, such as the following:

- Do you visit a dentist regularly? If so, when was the last time?
- Do you have any pain or swelling in your mouth, head or neck?
- Have you noticed any changes like lumps or bumps in your mouth, head or neck?
- Do you have any pain or difficulty in chewing or swallowing your food?
- Does your mouth feel dry?
- Do you have any irritation under your dentures?

Integrating oral health assessment into routine medical assessment greatly enhances the identification of oral health problems, and patient education regarding oral health and access to care.

All findings should be documented and appropriate referrals made.

URGENT or ROUTINE

Urgent versus Routine Care and Referral to a Dentist

Dental emergencies are extremely painful. In some cases a medical provider can provide relief by prescribing pain medication and/or antibiotics. Analgesics that can be prescribed vary from ibuprofen or naproxen to narcotics such as hydrocodone, codeine or in extreme cases oxycodone. Patients who are on protease inhibitors that inhibit CYP2D6 may not achieve adequate analgesia on these agents and may need morphine or hydromorphone. Antibiotics that are prescribed are usually penicillin or clindamycin (if the patient is allergic). However, this kind of palliative care needs to be followed up by a dentist.

If the patient has pain, abscess, broken teeth, or sustained pain to hot or cold then the patient should be seen by a dentist within 24 hours. This would be considered **Urgent Care.** If the patient cannot be seen at a dental office within 24 hours, then they should be referred to a hospital with a dentist on staff.

All patients should be questioned about the last time they visited their dentist. If there is no sign of infection or pain, the patient should be instructed to visit their dentist for **Routine Care,** which includes an oral exam, and cleaning the teeth. Routine Care is generally recommended every 6 months. If the patient does not have a dentist, then the medical provider or their staff can help to facilitate an appointment with a dentist.

In either case the importance of maintaining one's oral health should be emphasized by the medical provider.

All patients should be questioned about the last time they visited their dentist.

HIV and Oral Healthcare
Xerostomia

The most common adverse effect of many medications is Xerostomia (dry mouth).

Xerostomia is defined as a subjective complaint or feeling of dry mouth. Dry mouth occurs when there is a change in the amount of saliva felt in the mouth. This change can be a side effect of prescription or over-the-counter medications, smoking, alcohol consumption, radiation to the head and neck, and dehydration. HIV medications that can cause xerostomia include protease inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs).

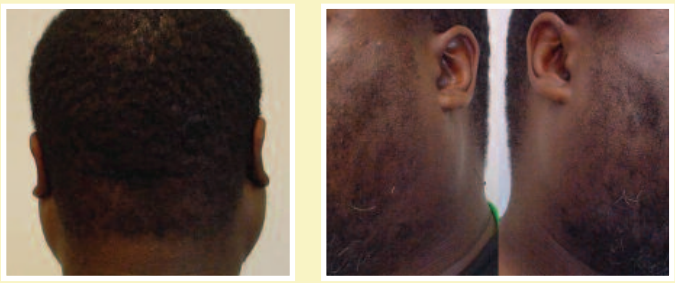


Image of HIV-associated salivary gland enlargement.

In 2% to 10% of HIV-positive patients, salivary glands are affected (see case study 2). This is characterized by two clinical presentations, major salivary gland enlargement and xerostomia. Salivary gland disease typically presents as bilateral enlargement of the parotid glands, due to either the development of lymphoepithelial cysts or a lymphocytic infiltrate within the parenchyma of the gland.[12,13,14] Examination of the oral cavity and careful review of the patient's history can be useful in diagnosing xerostomia. Sialometry can be used to measure saliva flow. The average salivary flow rate for unstimulated saliva is 0.3 to 0.4 milliliters per minute. Values less than 0.1 mL/minute are considered xerostomic.

HIV medications that can cause xerostomia include protease inhibitors and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs).[11,12]

Signs and Symptoms of Xerostomia

Symptoms of xerostomia may be experienced without a decrease in salivary gland output. Oral soreness or a "burning mouth" is frequently associated with xerostomia. Patients will complain of a constant sore throat, burning sensation, difficulty speaking and swallowing, hoarseness and/or dry nasal passages. Patients often complain of a change of taste (dysgeusia), a painful tongue (glossodynia) and increased need to drink especially at night.

Complications associated with Xerostomia

Sometimes patients may not be aware that their mouth is dry until some of the complications associated with dry mouth arise. The condition is certainly not life threatening but its effects can negatively impact a patient's quality of life. Swallowing and digestion can be difficult without adequate saliva. Removable dentures are uncomfortable to wear due to the lack of saliva which helps to create better adhesion. Halitosis, gum disease, candidiasis, chapped lips and tooth loss are also associated.

Function of Saliva

Saliva contains water, proteins and electrolytes which lubricate the mouth and protect mucous membranes. It also functions as an antimicrobial and pH buffer in the mouth. Xerostomia decreases the pH of the mouth and leads to the development of plaque and dental caries.

Management/Treatment of Xerostomia

Palliative treatment is the general rule for the relief of symptoms. If the xerostomia is caused by medication the medical provider can sometimes prescribe alternate therapy. Taking the medication at a different time of day may also be helpful. There are many over-the-counter products and prescription saliva substitutes that can be used to alleviate symptoms. These include, (non-alcohol containing) mouth rinses, lubricants, aerosols, chewing gum and toothpastes.

Xerostomia (Dry Mouth)[15]

Why knowledge of Xerostomia is important:

- Xerostomia is a common finding in adults and can be a side effect of over the counter and prescription medication, smoking, alcohol consumption, caffeine and dehydration.
- Salivary glands are affected in 2% to 10% of HIV seropositive patients.
- Xerostomia increases the incidence of bacterial plaque, gingival bleeding and candidal organisms.
- Xerostomia related oral pathologies can be prevented and/or treated.

How can a medical provider recognize Xerostomia (Dry Mouth)?

- Xerostomia is the subjective feeling or perception of oral dryness.
- Xerostomia occurs either because of hypo salivation, a reduction in the quantity of saliva produced (objective), or as a qualitative change (subjective).
- Measurement of the salivary flow rate may help to distinguish between subjective xerostomia and objective hypo salivation.
- The average unstimulated whole salivary flow rate is 0.3 to 0.4 milliliters per minute.
- An unstimulated rate of 0.1 mL/minute or less indicates hyposalivation.

Clinical signs and symptoms of Xerostomia:

- Mucosal burning, soreness and ulceration.
- Glossodynia (painful or burning feeling of the tongue).
- Atrophic (erythematous) Candidiasis.
- Smooth bald red tongue.
- Halitosis (bad breath).
- Gingivitis.
- Ropey Saliva.
- Visible dryness, cracked lips, angular chelitis.

Quality of life concerns of a patient with Xerostomia:

- Difficulty eating
- Saliva aids in the chewing, swallowing, and digesting of food that may result in a compromised nutritional status.
- Changes in food and fluid selection.
- Dysgeusia (bitter or metallic taste) and halitosis.
- Rampant tooth decay (cavities) at the gingival margin (gumline) and/or the occlusal plane (biting surface).
- Poorly fitting dentures.
- Saliva creates the vacuum seal that is critical for the retention, adhesion, and comfort of removable dentures.
- Denture associated discomfort, ulceration, stomatitis.

What are the treatments Primary Care Providers can recommend to the patient with Xerostomia?

- If there is a decrease in the salivary flow rate sialagogues (drugs that stimulate saliva flow) may be indicated.
- If the glands exhibit adequate salivary flow, and the patient exhibits oral dryness then palliative care is indicated.
- Recommend lubricating agents in the form of OTC gels or mouthwashes or RX salivary substitutes, that may relieve the symptoms of xerostomia. Sugarless gum and lozenges also help increase salivary output.
- Prescribe antifungal medication if candidiasis is present.
- Prescribe mouth rinses and toothpastes with increased percentage of fluoride to prevent tooth decay.

What is the level of urgency to get this patient to a dentist?

Patients must be referred to a dentist if they present with:

- Severe tooth related pain.
- Abscess, pus, acute infection.
- Sustained pain to cold, hot or sweet in a tooth with visible decay.
- Broken teeth.

Adapted from NY/NJ AETC

HIV and Oral Healthcare
Periodontal Disease

For the last several years researchers have focused on the link between periodontal disease and chronic inflammatory conditions such as diabetes, respiratory disease cardiovascular disease and Alzheimer's disease.

A recent study by Sharma and Shamsuddin published in the January 2011 Journal of Periodontology suggests a possible link between periodontal disease and upper respiratory diseases.[16] Periodontal bacteria have often been thought to play a role in many of the possible connections between oral health and overall health. This study emphasizes that chronic inflammation caused by periodontal pathogens in the mouth may also play a role in the progression of systemic disease. Effective treatment of periodontal inflammation may have systemic effects in management of other chronic inflammatory conditions. While the presence of bacteria is essential to inflammation and disease it is also important to remember that other factors are also involved. Other risk factors for periodontal disease include smoking, pregnancy or other hormonal changes in women, genetics, diabetes, medications and HIV.

Periodontal disease is also related to age and generally begins when people are in their 30's or 40's. Teenagers can develop gingivitis which is a milder form of gum disease. When gingivitis occurs in adults and it is left untreated it can progress to periodontal disease which is a more severe form of gum disease affecting the supporting structures of the teeth leading to tooth loss. Both gingivitis and periodontal disease are caused by "plaque" or bacteria that accumulate at the gum line of the teeth causing chronic inflammation. The milder form of gingivitis is usually reversible by increased oral hygiene efforts (brushing and flossing) and professional cleaning by a dentist or dental hygienist. In both cases early treatment can help prevent tooth loss.

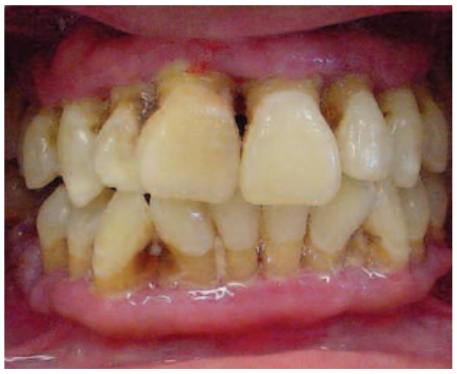
Periodontal diseases unique to the immunocompromised patient are Necrotizing Ulcerative Periodontitis (NUP) (Figure1) and Linear Gingival Erythema (LGE) (Figure 2).

NUP is characterized by the rapid destruction of bone that can lead to tooth loss in a matter of months. Patients will complain of severe pain, often referred to as "deep jaw pain." Extensive soft tissue necrosis, bleeding, loosening of the teeth and fetid mouth odor are also associated symptoms. The presence of NUP is indicative of severe immunosuppression.

LGE is a form of gingivitis characterized by a distinct red band (2-3 mm in width) along the gingival margin. In some cases it presents as small petechial-like patches on the gingiva. It presents most frequently in anterior teeth but it can extend to the posterior teeth, in some case bleeding and discomfort occur.[3] If left untreated, LGE can progress to NUP over time. The American Academy of Periodontology classifies LGE as fungal in origin, although antifungals are typically not used to treat LGE. Plaque is minimal in patients presenting with LGE.

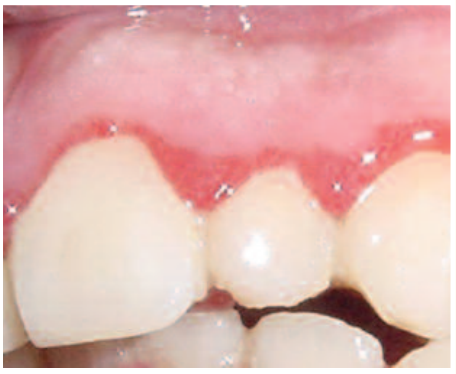
Periodontal disease is a chronic inflammation process involving specific bacteria affecting the tissue and bone supporting the teeth. There are several forms of periodontal disease that are unique to the immunocompromised patient.

FIGURE 1



Necrotizing Ulcerative Periodontis (NUP)

FIGURE 2



Linear Gingival Erythema (LGE)

Periodontal Disease

Treating inflammation may not only help manage periodontal diseases but may also help with the management of other chronic inflammatory conditions.

Complications Associated with NUP and LGE

Pain management and nutrition are crucial for patients with NUP. Since this patient is severely immunosuppressed, other systemic opportunistic infections need to be ruled out.[3] This patient might also require nutritional supplements as the pain can interfere with proper diet. Referral to a dentist for both LGE and NUP is urgent.

Management/Treatment of NUP and LGE

Managing NUP includes pain control. The medical provider can prescribe analgesics for pain and Chlorhexidine gluconate 0.12% as a mouth rinse before referral to a dentist. Dental treatment or both LGE and NUP are similar. Both stress the importance of meticulous oral hygiene. Treatment for NUP includes extraction of infected teeth. Local debridement of infected areas and scaling and root planning of the teeth are included. Infected areas are irrigated with providine iodine 10% or chorhexidine gluconate 0.12%. Daily rinses with antimicrobials and systemic antibiotics (Metronidazole) are also recommended. Periodontal maintenance is also indicated generally every three months once the infection is controlled.

This section is adapted from Steve Abel, DDS, NY/NJ AETC, with permission.
For further information on periodontal disease:

American Academy of Periodontics. www.perio.org • www.dentalcare.com/en-AU/products/promotion_sa.jspx

Signs and Symptoms of NUP and LGE

NUP (Figure1)	*LGE (Figure 2)*
• Rapid bone loss.	• No bone loss.
• Severe deep seated jaw pain.	• May have some bleeding and discomfort.
• Fetid mouth odor.	• May not have halitosis.
• Indicative of severe immunosuppression.	• Indicative of advanced immunosuppression.
• Soft tissue necrosis (loss of interdental papilla).	• Red banding occurs at the gingival margin.

HIV and Oral Healthcare

SUMMARY

Engaging the medical provider in HIV oral care promotes the importance of good oral health as a part of overall health. With proper training medical providers could screen for oral disease, distinguish between routine and urgent care, be familiar with the relationship of oral and systemic health, and provide temporary relief from oral infection and pain.

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Acknowledgment:
The New York/ New Jersey AIDS Education and Training Center (NY/ NJ AETC) Oral Health Regional Resource Center, based at the New York State Department of Health AIDS Institute contributed to this article as a collaboration with the UMDNJ-CCOE Division of AIDS Education and NJDHSS-DHSTS. NY/NJ AETC training slide sets used by permission. Urgent versus Routine Care Section, by A. Ross Kerr, DDS; and Periodontal Disease, by Steve Abel, DDS.

Case 1: Oral Cancer

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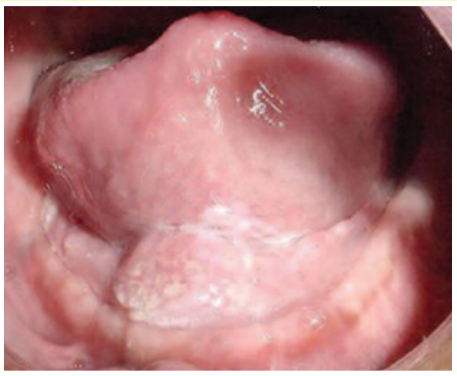
New Jersey Dental School, UMDNJ

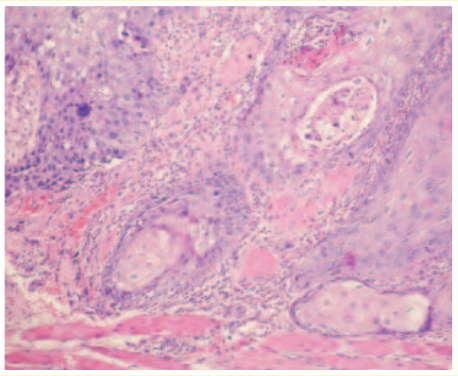
A 45-year-old African-American male was referred for evaluation of an asymptomatic mass on the floor of the mouth (FOM) noted during oral screening by his internist.

FIGURE 3



Oral Squamous cell carcinoma in the floor of the mouth.

FIGURE 4



Histology photomicrograph of squamous cell carcinoma in the biopsy specimen.

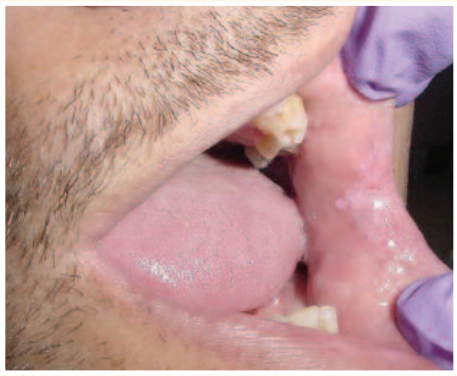
He reported the mass was interfering with full-sitting of his denture, causing difficulty with mastication and poor nutritional intake over the past few months. The patient's last dental visit was five years ago when he had received his complete upper and lower dentures. He had failed to present for oral health examination and denture maintenance thereafter. The patient's past medical history was significant for HIV infection, hepatitis C and infective endocarditis. He was not taking any medications, and was monitored by a hepatologist for hepatitis C and by his internist for HIV, which was stable as documented by a recent CD4 count of 590. He had a 30-pack-year history of tobacco smoking and a 3-year history of IVDU. He denied current drug use.

On extraoral examination, there was cervical lymphadenopathy, but no salivary gland enlargement or facial lesions. Intraorally, mucosa was pink and moist. There was mild pooling of saliva on the floor of mouth and no tongue coating. Close examination revealed a spherical mass of about 2 cm in diameter with pink and white texture on the floor of his mouth (Figure 3). It was indurated but not tender on palpation. The patient reported it developed gradually, and did not recall obvious oral trauma. It was not clear if the poor fit of the patient's oral prosthesis was the result rather than the etiology of oral growth. Differential diagnosis included a reactive lesion such as traumatic fibroma as well as oral malignancy. The latter was certainly a concern as the patient was a chronic and heavy smoker.

In view of prior history of infective endocarditis, patient was premedicated with 2g amoxicillin prior to the invasive oral procedure and an incisional biopsy was performed under local anesthesia to determine the nature of the oral mass. Histopathological evaluation revealed a segment of oral mucosa which is replaced by nests and islands of neoplastic stratified squamous epithelium in a fibrous stroma containing infiltrates of chronic inflammatory cells. The tumor islands invaded skeletal muscle and showed nuclear enlargement, hyperchromatism and keratin production. (Figure 4). These features were consistent with invasive, moderately differentiated squamous cell carcinoma (SCC). The patient was informed of the diagnosis, and referred to a head and neck surgeon for management.
Diagnostic work up revealed FOM stage III SCC with cervical node involvement and no distant metastasis. Patient underwent surgical resection of tumor, radical neck dissection of the metastatic lymph nodes and adjuvant radiotherapy. Although free of malignant disease following completion of therapy, he had difficulty performing normal oral functions and received nutritional intake through a gastric tube for months while healing. He was also educated about the risk factors for oral cancer and the potential for development of second primaries, and recurrence of treated oral malignancy with continued use of tobacco. He was referred to tobacco cessation service. Two years later, oral tissues were healed enough to tolerate a modified oral prosthesis; however, the altered oral anatomy due to surgery seriously impacted the stability and support of the oral prosthesis, and the patient's overall quality of life.

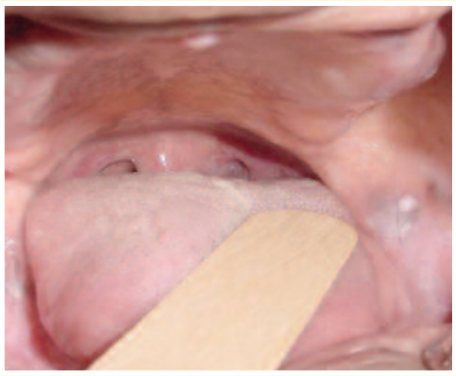
Case 1: Oral Cancer

FIGURE 5



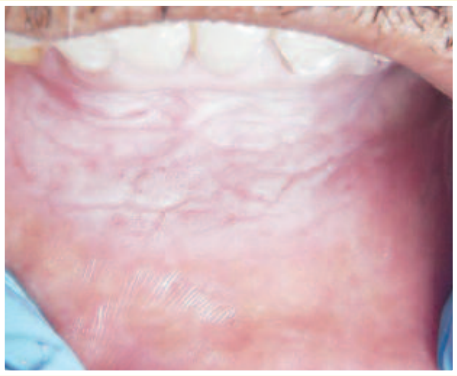
Leukoplakia affecting left anterior buccal mucosa.

FIGURE 6



Leukoplakia on left retromolar pad area.

FIGURE 7



Leukoplakia with focal areas of erythema on lower anterior vestibular mucosa.

Learning Issue:

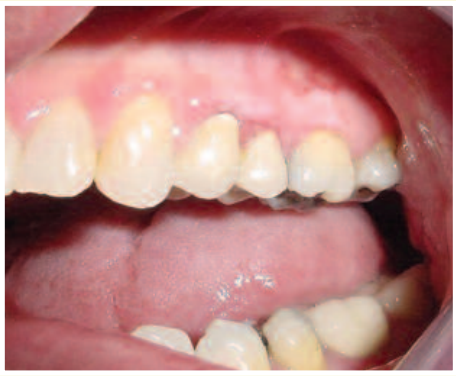
Examination of the oral cavity is an integral component of primary care. It provides a valuable opportunity to assess dental and oral health, to identify symptomatic lesions which may interfere with oral function, to detect asymptomatic lesions with malignant potential, to identify detrimental effects of substance abuse on oral tissues, and to detect oral manifestations of systemic disease and medical therapy. The American Cancer Society estimates that nearly 39,400 individuals will be diagnosed with oropharyngeal cancer in 2011, for 7,900 of whom the disease will prove fatal. High risk sites for oral cancer include the floor of the mouth, the posterolateral and ventral tongue as well as soft palatal complex. Significant racial disparities among adults with oral cancer have been noted, with black males having a higher incidence, more advanced stage of disease at diagnosis and worse survival rates compared to whites.

Although multifactorial in etiology, the main risk factors are abuse of tobacco and alcohol. Oral cancer also affects men more than women. Substance abusers from low socioeconomic groups with poor access to oral health suffer particularly poor prognosis, as disease is often discovered late, leading to mortality or greater morbidity due to aggressive therapy. Nevertheless, oral cancer also affects individuals who do not smoke or drink. In fact, a rise in the incidence of oral cancer among younger adults without the typical risk factors has been noted in recent years. A role for oral human papillomavirus (HPV) infection as a risk factor for a subset of these patients has been suggested. Therefore, all patients, irrespective of their social history, should undergo periodic screening for oral cancer. Primary care providers have the potential to positively impact the morbidity and survival outcome associated with oral cancer through patient education, regular oral surveillance as well as early detection of pre-malignant and cancerous lesions.

A thorough examination of the oral cavity involves both visual inspection and palpation, and can be accomplished in about five minutes. To perform the procedure properly, the clinician requires adequate lighting, a disposable mouth mirror or tongue blade and a 2x2 gauze. The patient should remove any oral prosthesis to allow examination of the oral tissues underneath. Also, it is advisable to develop a routine for the examination to avoid leaving any anatomical area unexamined. The anatomical regions to be examined include lip vermillion, upper and lower labial mucosa, right and left buccal mucosa, the floor of the mouth, ventral and dorsal tongue surfaces, right and left lateral borders of the tongue, hard and soft palatal mucosa, facial and lingual gingivae. In addition, the posterior oral cavity should be visually inspected and the floor of the mouth bimanually palpated. Any alteration in the color (leukoplakia, erythroplakia, erythro-leukoplakia, abnormal pigmentations) or texture (thickening, mucosal overgrowth, submucosal lumps, induration) of oral mucosa noted during the examination should be documented, followed to ensure resolution and if the abnormality persists, referred for further evaluation including biopsy (Figures 5-10).

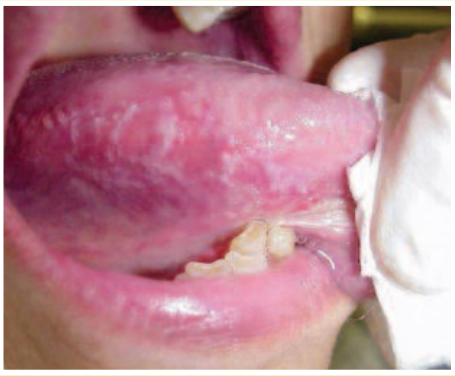
Case 1: Oral Cancer

FIGURE 8



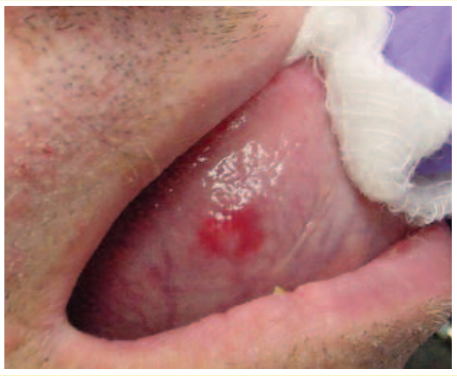
Erythro-leukoplakia affecting maxillary left posterior attached gingiva.

FIGURE 9



Erythro-leukoplakia affecting right ventro-lateral border of tongue.

FIGURE 10



Erythroplakia affecting right ventral tongue.

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Case 2: HIV-associated salivary gland disease & Xerostomia

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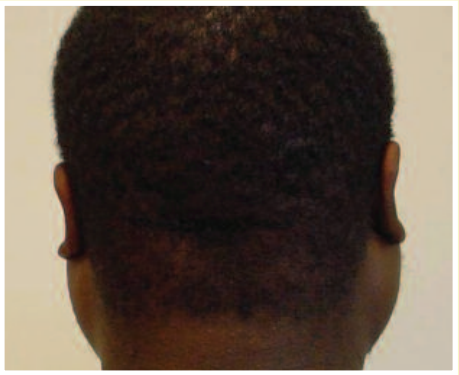
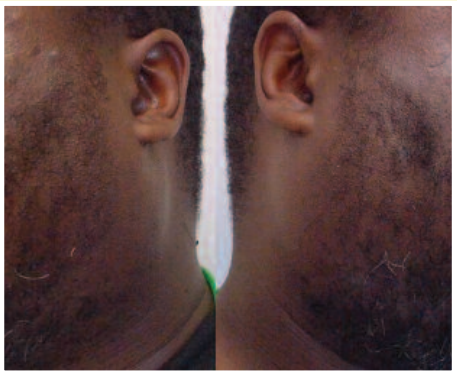
A 45-year-old African-American male was referred for evaluation of xerostomia and oral burning to patient's internist during his oral screening.

FIGURE 11



Parotitis - Rear of Head

FIGURE 12



Parotitis - Side of Head

The patient stated that his oral dryness had progressively worsened and interfered with eating, mastication and swallowing. He admitted to drinking several cans of soda throughout the day to alleviate oral dryness and to help with oral lubrication at mealtimes. His teeth were also extremely temperature-sensitive on intake of foods and fluids. His last dental visit was over five years ago when he had several unrestorable teeth extracted. He admitted not brushing on a regular basis and complained of halitosis causing him embarrassment in social situations.

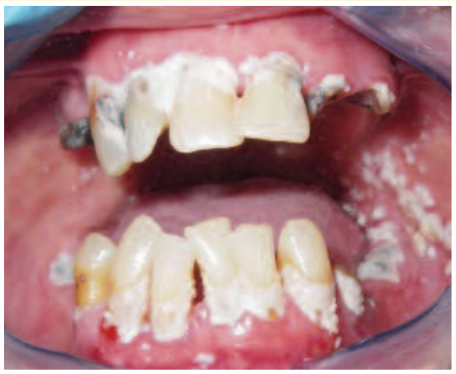
His past medical history was significant for HIV infection, Hepatitis C and type 2 diabetes. His medications included efavirenz/emtricitabine/tenofovir disoproxil fumarate and glyburide. He was not receiving treatment for Hepatitis C. He had a 20 pack-year history of tobacco smoking and was a former alcoholic but had stopped drinking 5 years ago. His risk factor for HIV and Hepatitis C was IVDU which he had stopped years ago. On review of systems, he denied skin or ocular dryness and rheumatologic disorders. Review of blood work within the past three months revealed CD4 cell count = 300 cell/mm^3, viral load = 500 copies/mm^3, ANC = 5,000 cells/mm^3, plt = 130,000 cells/mm^3, HBA1C = 8.2%.

On extraoral examination, there was bilateral facial swelling affecting the parotid region (Figures 11 & 12). Swelling was palpable and non-tender. There were no lymphadenopathy or facial lesions. Intraorally, the patient's oral hygiene was very poor and an offensive odor emanated from his mouth. Removable white plaques resembling food debris, tissue slough or fungal infection were also present throughout the oral cavity (Figure 13). Oral mucosa was dry and a tongue depressor applied to the soft tissue adhered upon attempts to lift it away. There was minimal salivary pooling on the floor of the mouth. Digital palpation of parotids and submandibular glands yielded minimal discharge from Stenson's and Wharton's ductal orifices. Expressed saliva was clear, viscous and free of pus or blood. Sialometry revealed resting secretion of less than 0.1 ml/min and stimulated secretion = 0.6 ml/min, both of which were consistent with hyposalivation. Examination of dentition revealed generalized plaque and gingival inflammation, tobacco staining, cervical decalcification and multiple broken, carious teeth. There were no periodontal pockets but there was generalized bleeding on probing.

Differential diagnosis of bilateral parotid swellings included parotitis secondary to HIV or hepatitis C, diabetic sialadenosis, sarcoidosis, Sjögren's syndrome and Warthin's tumors, for all of which except the latter xerostomia could be a common complaint. The patient's HIV medications could also have contributed to oral dryness although a temporal relation between the start of his medications and onset xerostomia was absent. He was referred to an otolaryngologist for diagnostic evaluation of his salivary gland enlargement. A tongue blade was used to sample removable white plaques and prepare a smear on a glass slide. Microscopic examination of the specimen revealed presence of numerous fungal hyphae in the cytologic smear (Figure 14) and confirmed diagnosis of oral candidiasis possibly caused by a combination of systemic and local factors such as HIV-parotitis, diabetes and oral dryness.

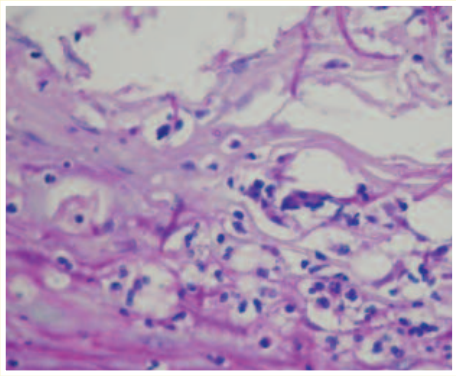
Case 2: HIV-associated salivary gland disease & Xerostomia

FIGURE 13



Intraoral white plaques

FIGURE 14



Fungal hyphae

The patient was prescribed a two week course of nystatin oral solution 100,000 units/ml to swish in the mouth for two minutes and then swallow three times daily to address oral candidiasis. He was also advised to sip water throughout the day and particularly during mealtimes, and use over the counter moisturizing gel or artificial saliva spray to palliate oral dryness and help with mastication and swallowing. In addition, the patient was advised to reduce intake of tea, coffee and alcohol to avoid dehydration of oral mucosa, and to use a humidifier in his bedroom to alleviate his symptoms while sleeping. Dental treatment plan included debridement and dental prophylaxis, extraction of non-restorable teeth, application of desensitizing agents and multiple restorations to be executed over the upcoming dental visits. He was educated about the increased risk of dental caries with hyposalivation and significance of preventive measures to maintain his remaining teeth caries free. An alcohol-free antimicrobial mouthrinse was prescribed for daily use to reduce bacterial load and assist with oral hygiene. Custom made oral trays were fabricated and patient was instructed on regular use of topical fluoride gel within these oral trays at bed time.

During the follow-up visit, the patient reported alleviation of oral burning within the first week of using the antifungal oral solution. He had found the recommended oral moisturizing agents beneficial in lubricating his mouth and facilitating oral functions. On examination, oral mucosa was still dry but oral hygiene, gingival inflammation and halitosis had improved and fungal infection had resolved. The result of work up by the patient's otolaryngologist confirmed HIV-associated salivary gland disease as the etiology of his parotid swelling and ultimately his oral dryness. The patient reported his symptoms were manageable with recommended measures. He declined a trial course of a pharmacologic sialogouge, such as pilocarpine, bethanechol, or cevimeline, which would stimulate salivary output and provide further palliation.

Case 2: HIV-associated salivary gland disease & Xerostomia

Learning Issue:

Xerostomia refers to the subjective complaint of dry mouth which may reflect a true decrease in salivary output or distorted oral perception. Clinical evaluation of xerostomia should include:

- **A review of the patient's medications/treatments** and inquiring about the start of therapies known to cause dry mouth and onset of xerostomia, (i.e., antidepressants, diuretics, antihistamines, radiotherapy, chemotherapy, protease inhibitors, NNRTIs, etc.). If xerostomia appears related to a specific medication, it may be warranted to ask the physician to consider a substitute with less oral xerostomic side effect or altering the dose or frequency of the offending medication, if possible.

- **A focused review of systems** inquiring about cutaneous, ocular, nasal and vaginal dryness to determine if the problem is of local or systemic nature followed by a referral to a physician for evaluation when indicated.

- **A review of past medical history** is also necessary to exclude systemic conditions with oral manifestation of xerostomia, (i.e., Sjögren's syndrome, diabetes, or sarcoidosis). If dryness appears related to an underlying systemic disease, primary management should be directed at the etiology.

- **Evaluation of major salivary glands** for enlargement, pain and tenderness on palpation, expression of saliva from ductal orifices upon digital palpation and noting the clarity and viscosity of secretions. Salivary output (sialometry) should also be measured objectively to confirm or exclude hyposalivation as the etiology of xerostomia. In clinical practice, whole unstimulated saliva (WUS) representing total discharge from all salivary glands is measured by asking the patient to spit or drool into a collecting cup for 10-15 minutes. Whole stimulated saliva (WSS) is measured in the same manner following a gustatory or masticatory stimulation such as application of lemon juice on the patient's tongue or chewing on paraffin gum for about one minute. Although there is large variability in the normal values reported for UWS or SWS in the literature, WUS <0.1 ml/min and WSS<0.7 ml/min are considered abnormal and consistent with hyposalivation.

Case 2: HIV-associated salivary gland disease & Xerostomia

Management Strategies:

In addition to the clinical evaluation outlined on page 18, the dentist has a role in palliation of xerostomia and prevention of oral disease (soft and hard tissue) secondary to xerostomia.

The management strategies for xerostomia are numerous and should be tailored to the patient's needs. Examples include:

- Frequent sips of water throughout the day.
- Oral moisturizing gels and rinses as needed.
- Using humidifiers in the sleeping area to help with oral dryness at night.
- Gustatory or masticatory sialogouges (chewing sugar-free gum or candy).
- Avoiding alcohol containing mouthrinses which dehydrate oral mucosa.
- Avoiding strong flavorings which may irritate dry, sensitive oral mucosa.
- Watching for and treating oral fungal infections, if any.
- Meticulous oral hygiene.
- Frequent preventative recalls.
- Low cariogenic diet (relatively high amounts of protein, calcium and phosphorus, minimal fat and carbohydrate and high concentration of foods with pH greater than 6).
- Fabrication of custom oral trays for topical application of fluoride at home.
- Prescribing systemic sialogouges, such as pilocarpine (Salagen®), cevimeline (Evoxac®) [if no contraindication].

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CONTINUING EDUCATION

HIV and Oral Health

POST TEST – Page 1 of 2

Questions refer to the content of the article and the notes that follow. To receive CME/CE/CEU credit: complete exam, registration, and evaluation forms on-line at www.umdnj.edu/ccoe/aids or fill in the forms on the following pages, and mail or fax to UMDNJ-CCOE (see Registration Form).

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1. **What kind of treatment can a medical provider offer the patient described in case 2 (Xerostomia) to help relieve the feeling of his mouth being dry?**
   - A. Recommend strongly flavored foods to stimulate salivation.
   - B. Recommend that the patient take frequent sips of water, especially during mealtime.
   - C. Tell the patient to drink a lot of caffeinated drinks.
   - D. Recommend that the patient rinse with a mouthwash that contains alcohol.

2. **Case 1 describes a patient who was referred by a medical provider to a dentist for evaluation of an asymptomatic mass on the floor of the mouth. What are some of the key learning points of this case?**
   - A. Only dentists can recognize abnormal lesions in the mouth.
   - B. The medical provider has the potential to positively impact the survival outcome of a case by performing an oral exam.
   - C. Most oral cancers present on the lips.
   - D. Dentists prefer to remove the whole lesion when they perform a biopsy.

3. **Which is a high risk site for oral cancer?**
   - A. The floor of the mouth.
   - B. Posterolateral border of the tongue.
   - C. Soft palate.
   - D. All of the above.

4. **Routine, as opposed to urgent, dental care refers to:**
   - A. All dental emergencies.
   - B. Fillings.
   - C. Brushing and flossing teeth.
   - D. Visiting the dentist at least every 6 months for an exam and cleaning.

5. **Periodontal disease has been associated with several systemic diseases. What may be one of the reasons for this association?**
   - A. Chronic inflammation of the gums may promote other inflammatory conditions.
   - B. Patients who do not visit their dentists frequently enough are in poorer health.
   - C. Systemic diseases originate in the mouth.
   - D. Periodontal disease cannot be cured.

6. **A new patient presents to your medical clinic complaining of a toothache that started 2 days ago. You look inside the mouth and see a broken tooth surrounded by swelling in the area that the patient points to. Would this patient require routine or urgent dental care?**
   - A. Routine care, because the source of the swelling is probably the broken tooth.
   - B. Urgent care, so you refer the patient to be seen by a dentist within 24 hours.
   - C. Urgent care, so you refer the patient to be seen by a dentist by the end of the week.
   - D. Routine care, because the patient can eat on the other side of their mouth.

CE Activity Code: 14HC02-DE01

CONTINUING EDUCATION

HIV and Oral Health

POST TEST – Page 2 of 2

Questions refer to the content of the article and the notes that follow. To receive CME/CE/CEU credit: complete exam, registration, and evaluation forms on-line at www.umdnj.edu/ccoe/aids or fill in the forms on the following pages, and mail or fax to UMDNJ-CCOE (see Registration Form).

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7. Which one of the following will help make the intra-oral exam more thorough for a patient wearing dentures?

A. Have the patient sit in a chair.

B. Tell the patient to leave their dentures in their mouth so that the provider can see how they fit.

C. Ask the patient to remove the dentures so that the oral tissues are visible.

D. Ask the patient to rinse with water before doing the exam.

8. A patient known to your HIV clinic presents for her annual exam. She tells you that she hasn't seen a dentist in 3 years because her teeth are not hurting. What can you do to stress the importance of oral health to this patient?

A. Let the patient know that HIV patients should have a dentist perform routine exams at least twice a year.

B. Tell her that she should go every 5 years at a minimum.

C. Do an oral exam yourself since she does not want to go to the dentist.

D. Give the patient a prescription for a mouthwash.

9. A patient known to your HIV clinic presents and says "I have pain in my whole mouth and I am beginning to feel that my teeth are getting loose." Upon examination you notice red band-like lines around the teeth and bleeding when you touch the gums with a tongue blade. What can you recommend for the patient until they can be seen by a dentist?

A. A prescription for chlorhexidene gluconate mouthrinse.

B. Don't eat anything salty or spicy.

C. Rinse your mouth with water before you eat.

D. Brush your teeth at least 3 times a day.

10. A patient known to your HIV clinic presents with halitosis, difficulty in chewing and swallowing their food and many trips to the dentist due to an increase in cavities, a "burning" in the tongue and a constant bad taste in their mouth. What kind of concerns might this patient most likely be describing?

A. Periodontitis.

B. Toothache.

C. Quality of life concerns associated with xerostomia.

D. Ordinary minor issues related to poor diet, nothing to be concerned about.

CONTINUING EDUCATION

HIV and Oral Health
REGISTRATION FORM

In order to obtain continuing education credit, participants are required to:

(1) Read the learning objectives, and review the activity, and complete the post-test.

(2) Complete this registration form and the activity evaluation form on the next page, and record your test answers below.

CCOE
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(3) Send the registration and evaluation forms to: UMDNJ-Center for Continuing and Outreach Education
• VIA MAIL: PO Box 1709, Newark, NJ 07101-1709 • VIA FAX: (973) 972-7128
Dentists: please mail or fax your completed registration form with self assessment test answers, and program evaluation form (2 pages) to: Howard E. Lavigne • NYSDOH • 217 S. Salina St. • Syracuse, NY 13202 • Fax: 315-477-8581

(4) Retain a copy of your test answers. Your answer sheet will be graded and if you achieve a passing score of 70% or more, a credit letter and the test answer key will be mailed to you within four (4) weeks. Individuals who fail to attain a passing score will be notified and offered the opportunity to complete the activity again.

Online option: This activity will be posted at www.umdnj.edu/ccoe/aids where you may obtain a credit letter upon successful completion of the online post-test and evaluation.

Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

SELF-ASSESSMENT TEST *Circle the best answer for each question.*					
	1. A B C D	**3.** A B C D	**5.** A B C D	**7.** A B C D	**9.** A B C D
	2. A B C D	**4.** A B C D	**6.** A B C D	**8.** A B C D	**10.** A B C D

– PLEASE PRINT –

First Name _____ M.I. _____ Last Name _____ Degree _____

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Indicate the type of continuing education credit you wish to obtain as a result of your participation in this activity.

☐ **Nurses:** 1.32 CNE Contact Hour(s). Contact Hours Claimed: _____
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☐ **Pharmacists:** 1.0 CPE Contact Hour(s). Contact Hours Claimed: _____
☐ **Dentists:** 1.0 CDE credit. Credit Hours Claimed: _____
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One credit/contact hour for each hour of participation. Continuing Education Units: one unit per ten hours of participation.
I attest that I have completed this activity as designed. I will report the number of credits/contact hours claimed during my filing of continuing education credit with professional organizations, licensing boards, or other agencies.

Signature _____ Date _____

Release date: December 1, 2011 • Expiration date: Credit for this activity will be provided through November 30, 2013.
Nursing credit for this activity will be provided through November 30, 2013.
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CE Activity Code: 14HC02 This form may be photocopied.

CONTINUING EDUCATION

HIV and Oral Health
ACTIVITY EVALUATION FORM

The planning and execution of useful and educationally sound continuing education activities are guided in large part by input from participants. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please take a few moments to complete this evaluation form. Your response will help ensure that future programs are informative and meet the educational needs of all participants.

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Please note: CE credit letters and long-term credit retention information will only be issued upon receipt of completed evaluation form.

PROGRAM OBJECTIVES: *Having completed this activity, are you better able to:*

		Strongly Agree				Strongly Disagree
Objective 1:	Identify the impact of oral disease on systemic health of HIV/AIDS patients, and symptoms of disease including oral lesions.	5	4	3	2	1
Objective 2:	Implement oral health screening, as part of the overall healthcare plan.	5	4	3	2	1
Objective 3:	Distinguish and differentiate the need for emergency dental care due to acute infection, pathology or pain. Prescribe analgesics and antibiotics when appropriate and facilitate access to a dental provider for follow up treatment.	5	4	3	2	1

OVERALL EVALUATION:	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The faculty demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
The teaching and learning methods were effective.	5	4	3	2	1
The self-assessment was appropriate and helpful.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

Based on the content of the activity, what will you do differently in the care of your patients? *(check one)*

- ☐ Implement a change in my practice.
- ☐ Seek additional information on this topic.
- ☐ Do nothing differently. Current practice reflects activity recommendations.
- ☐ Do nothing differently as the content was not convincing.
- ☐ Do nothing differently. System barriers prevent change.
- ☐ Not applicable. I do not see patients in my current position.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

_____

May we contact you in two months to see how you are progressing on the changes indicated above?

☐ Yes. Please provide your email address. _____ ☐ No. I do not wish to participate in the follow-up assessment.

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

_____

Please list any topics that you would like addressed in future educational activities.

_____

CONTINUING EDUCATION

Chronic Hepatitis and HIV

Release date: December 1, 2011 • Expiration date: November 30, 2013 • Code: 14HC01-DE01 • Nursing credit for this activity will be provided through November 30, 2013.

SPONSOR:

Sponsored by UMDNJ-Center for Continuing and Outreach Education, Division of AIDS Education.

GRANTOR ACKNOWLEDGEMENT:

This activity is supported by an educational grant from the New Jersey Department of Health and Senior Services (NJDHSS) - Division of HIV, STD and TB Services, through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS."

STATEMENT OF NEED:

Chronic hepatitis B (HBV) and C (HCV) infection, added to HIV infection, make both diseases more complex to treat effectively, and significantly increase the risk of liver damage including end stage liver disease (ESLD). In the Multicenter AIDS Cohort Study, men co-infected with HBV were 8 times more likely to die from liver disease than those infected with HIV alone and almost 19 times more likely to die from liver disease than those infected with HBV alone.[2]

HBV is both preventable and treatable. HBV treatment can readily be combined with HIV therapy, and should lead to complete viral suppression. All HIV medical care programs should incorporate HBV screening and vaccination of all HBV-negative individuals.[3]

HCV treatment includes few FDA-approved treatment options for HIV co-infected individuals. Clinicians should discuss the prognosis and treatment options with these patients, provide ongoing monitoring and risk reduction counseling addressing alcohol consumption, and provide hepatitis A and B vaccination to non-immune patients.

Co-treatment of HBV or HCV with HIV is associated with risks of adverse physical and psychological effects, requiring ongoing close monitoring. These risks are balanced by the opportunity to minimize and even reverse liver damage, and improve quality and length of life for many co-infected individuals.

TARGET AUDIENCE:

This free knowledge-based activity is designed for physicians, nurses, pharmacists, social workers, and other health care professionals in New Jersey who are involved in the care of persons with HIV/AIDS and/or hepatitis.

METHOD OF PARTICIPATION:

Participants should read the learning objectives, review the activity in its entirety, and then complete the self-assessment test which consists of a series of multiple-choice questions. Upon completing this activity as designed and achieving a passing score of 70% or more on the self-assessment test; participants will receive a letter of credit and the test answer key four (4) weeks after receipt of the self-assessment test, registration, and evaluation materials; or may complete the activity online at www.umdnj.edu/ccoe. Estimated time to complete this activity as designed is 1.0 hour for physicians, 1.08 hours for nurses, and 1.0 hours for pharmacists.

LEARNING OBJECTIVES:

Following completion of this activity, participants should be able to:

1. Screen and monitor HIV patients for hepatitis B and C infection.
2. Make decisions about treatment initiation and regimens that incorporate recent revisions in treatment recommendations for hepatitis B and C.
3. Identify challenges of co-management of HIV and Hepatitis B and/or Hepatitis C, including timing of sequential or simultaneous treatment and potential adverse effects and drug interactions.

FACULTY:

Activity Director(s)/CME Academic Advisor(s)

Patricia Kloser, MD, MPH, Professor of Medicine, UMDNJ-NJ Medical School and UMDNJ-School of Public Health.

Planning Committee

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Faculty

Jihad Slim, MD, is an Attending Physician in the Department of Infectious Diseases at St. Michael's Medical Center in Newark, NJ; Assistant Professor of Medicine, Seton Hall University Graduate School of Medical Education, South Orange, NJ; and Assistant Professor of Medicine, St. George's University, West Indies.

ACCREDITATION STATEMENTS:

CME

UMDNJ-Center for Continuing and Outreach Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

UMDNJ-Center for Continuing and Outreach Education designates this Enduring material for a maximum of 1 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

Pharmacists: UMDNJ-Center for Continuing and Outreach Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

This course (ACPE #0374-0000-11-014-H02-P) qualifies for 1.0 contact hour (0.1 CEU) of continuing pharmacy education credit.

Pharmacists should claim only those contact hours actually spent participating in the activity.

CNE

UMDNJ-Center for Continuing and Outreach Education is an approved provider of continuing nursing education by NJSNA, an accredited approver by the American Nurses Credentialing Center's COA. Provider Number P173-11/09-12. Provider Approval is valid through November 30, 2012.

Nurses should claim only those contact hours actually spent participating in the activity.

Provider approved by the California Board of Registered Nursing, Provider Number CEP 13780.

This course is awarded 1.08 contact hours (60 minute CH).

Approved provider status refers only to continuing education activities and does not imply ANCC COA or NJSNA endorsement of any commercial products.

CEU

UMDNJ-CCOE certifies that this continuing education offering meets the criteria for up to 0.10 Continuing Education Units (CEUs), provided the activity is completed as designed. One CEU equals 10 contact hours of participation in an organized continuing education experience under responsible sponsorship, capable direction and qualified instruction. Participants should only claim those contact hours actually spent participating in the activity.

PEER REVIEW:

In order to help ensure content objectivity, independence, and fair balance, and to ensure that the content is aligned with the interest of the public, UMDNJ-CCOE has resolved all potential and real conflicts of interest through content review by a non-conflicted, qualified reviewer. This activity was peer-reviewed for relevance, accuracy of content and balance of presentation by Patricia Kloser, MD, MPH; Debbie Mohammed, MS, MPH, APRN-BC, AACRN; Humberto Jimenez, BCPS, PharmD, AAHIVE, Brenda Christian, MEd, PA-C; Director of AIDS Education, UMDNJ-CCOE.

Field test: This activity was pilot-tested for time required for participation by Kinshasa Morton, MD; Shobha Swaminathan, MD; Jojy Cheriyan, MD; Mary C. Krug, MSN, APN; Renee Powell, BS, RN; Kara Winslow, BSN, RN; Polly Jen, PharmD; John Faragon, PharmD, AAHIVE; and George Rusuloj, PharmD.

DISCLOSURE DISCLAIMER:

In accordance with the disclosure policies of UMDNJ and to conform with ACCME and FDA guidelines, individuals in a position to control the content of this educational activity are required to disclose to the activity participants: 1) the existence of any relevant financial relationship with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, with the exemption of non-profit or government organizations and non-health care related companies, within the past 12 months; and 2) the identification of a commercial product/device that is unlabeled for use or an investigational use of a product/device not yet approved.

Disclosure Declarations: There were no relevant financial relationships to disclose reported by the activity director, planning committee members, peer reviewers or field testers. Jihad Slim, MD has disclosed the following relevant financial relationships: Speaker's Bureau: Genentech, Merck, Vertex.

OFF-LABEL/INVESTIGATIONAL USE DISCLOSURE:

This activity contains information of commercial products/devices that are unlabeled for use or investigational uses of products not yet approved.

Dr. Slim discusses use of the combination of tenofovir + emtricitabine for HBV+HIV co-infected patients, based on clinical trial reports and DHHS guidelines, pending FDA approval.[3]

CONTENT DISCLAIMER:

The views expressed in this activity are those of the faculty. It should not be inferred or assumed that they are expressing the views of NJDHSS) – Division of HIV, STD and TB Services, any manufacturer of pharmaceuticals or devices, or UMDNJ. It should be noted that the recommendations made herein with regard to the use of therapeutic agents, varying disease states, and assessments of risk, are based upon a combination of clinical trials, current guidelines, and the clinical practice experience of the participating presenters. The drug selection and dosage information presented in this activity are believed to be accurate. However, participants are urged to consult all available data on products and procedures before using them in clinical practice.

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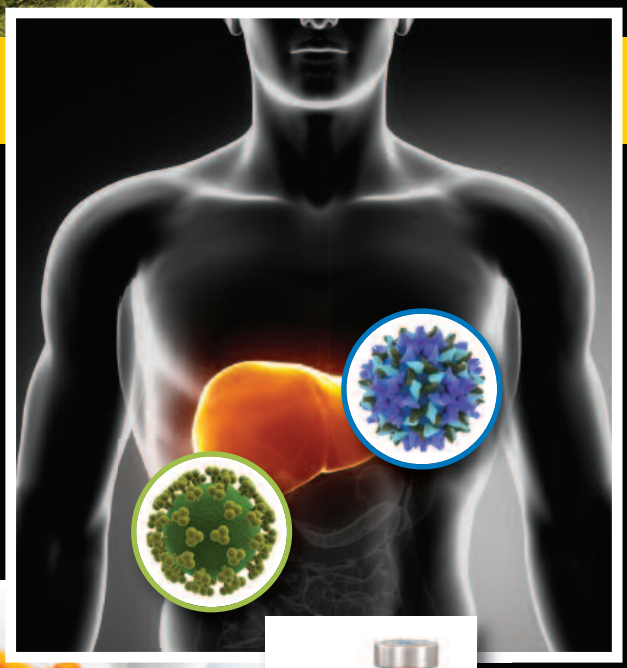
CE
CONTINUING EDUCATION

NEW JERSEY AIDSLine December 2011

Chronic Hepatitis and HIV

Jihad Slim, MD



Learning Objectives:

Upon completion of this activity, participants should be able to:

1) Screen and monitor HIV patients for hepatitis B and C infection.

2) Make decisions about treatment initiation and regimens that incorporate recent revisions in treatment recommendations for hepatitis B and C.

3) Identify challenges of co-management of HIV and Hepatitis B and/or Hepatitis C, including timing of sequential or simultaneous treatment and potential adverse effects and drug interactions.

Once human immunodeficiency virus (HIV) infection is diagnosed and managed appropriately in an individual, the long-term prognosis depends on multiple factors, of which the most important appears to be the presence of chronic hepatitis C or hepatitis B infection.

Release Date: December 1, 2011 • Expiration Date: November 30, 2013 • Course Code: 14HC01 • Nursing Credit for this activity will be provided through November 30, 2013.

Jihad Slim, MD, is an Attending Physician in the Department of Infectious Diseases at St. Michael's Medical Center in Newark, NJ; Assistant Professor of Medicine, Seton Hall University Graduate School of Medical Education, South Orange, NJ; and Assistant Professor of Medicine, St. George's University, West Indies.

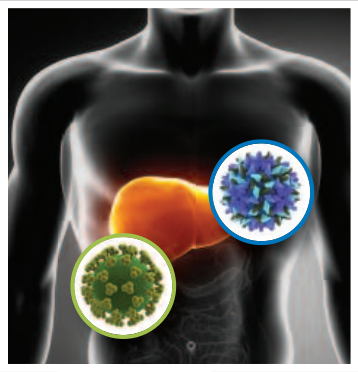
Sponsor: UMDNJ-Center for Continuing & Outreach Education-Division of AIDS Education.

Funding: This activity is supported by an educational grant from NJDHSS Division of HIV/AIDS, STD and TB Services through an MOA titled "Education and Training for Physicians and other Healthcare Professionals in the Diagnosis and Treatment of HIV/AIDS.

The New York/New Jersey AETC (AIDS Education and Training Center (NY/NJAETC) provided in-kind support through consultation with its Pharmacy Director, John Faragon, PharmD, AAHIV.

To obtain continuing education credit, complete the quiz, registration, and evaluation on the following pages, or go to: www.umdnj.edu/ccoe/aids

Chronic Hepatitis and HIV



Introduction

Once human immunodeficiency virus (HIV) infection is diagnosed and managed appropriately in an individual, the long-term prognosis depends on multiple factors, of which the most important appears to be the presence of chronic hepatitis C or hepatitis B infection. To understand how these infections impact HIV prognosis, we will review the data on epidemiology, clinical aspects, and management of hepatitis B virus (HBV) and hepatitis C virus (HCV) in patients co-infected with HIV.

HIV and HBV

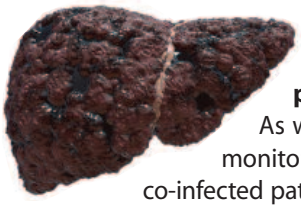
Both HIV and HBV are transmitted sexually, vertically, and through blood contact, but their epidemiology differs by geographic location. Co-infection with those two viruses reaches a peak of 40% in some areas of South Africa, but is relatively uncommon in the US at 3-5%; worldwide it is estimated that 10% of patients with HIV are co-infected with HBV.[1]

In the Multicenter AIDS Cohort Study (MACS), men co-infected with HBV were **8 times more likely to die** from liver disease than those infected with HIV alone and almost **19 times more likely to die** from liver disease than those infected with HBV alone.[2]

Treatment of HBV

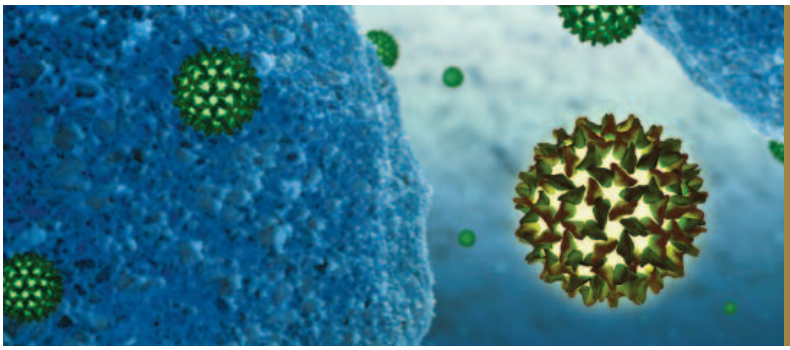
MACS and other studies led to the recommendation from the Department of Health and Human Services (DHHS) to start antiretroviral therapy (ART) in co-infected patients who require HBV treatment.[3] This recommendation stems from the fact that most FDA approved drugs for HBV have anti-HIV activity (except telbivudine). If used without full HIV suppression, their use could lead to development of HIV resistant strains (with the exception of pegylated interferon).

Indications for treatment of HBV are based mainly on the combination of three criteria: serum HBV DNA level, serum aminotransferase, and histological grade and stage. Patients should be considered for treatment when HBV DNA levels are above 2,000 IU/ml, and/or the serum ALT levels are above the upper limit of normal, and/or liver biopsy shows moderate to severe active necroinflammation and/or fibrosis. It is recommended to use 2 active drugs against HBV in the setting of HIV disease, mainly to avoid selection of HBV resistant mutants; the most studied regimen in this setting is tenofovir + emtricitabine (co-formulated as Truvada©). The goal of therapy is to attain an undetectable HBV DNA PCR (below 10-15 IU/ml) by week 24 of therapy.



Control of HBV replication will result in less liver damage, and subsequently a reduced risk of developing decompensated liver cirrhosis and hepatocellular carcinoma (HCC). As with HIV monoinfected patients, the use of tenofovir warrants monitoring for renal dysfunction and decreased bone density. In HBV co-infected patients, acute hepatitis flares can occur as a result of an immune reconstitution inflammatory syndrome soon after initiating therapy or later secondary to poor treatment adherence.

Hepatitis infection impacts HIV prognosis



Control of HBV replication will result in less liver damage, and subsequently a reduced risk of developing decompensated liver cirrhosis and hepatocellular carcinoma (HCC).

Table 1. Interpretation of Hepatitis B (HBV) Testing

Test	Acute HBV	Prior HBV	Chronic Active HBV	Prior Vaccination
HBsAg	+	-	+	-
Anti-HBs	-	+	-	+
Anti-HBcIgM	+	-	-	-
Anti-HBc	+	+	+	-
HBV DNA PCR	+	Undetectable	+	Undetectable
AST/ALT	Very High	Normal	Elevated/Normal	Normal

HBsAg: Hepatitis B surface antigen, Anti-HBs: Hepatitis B surface antibody, Anti-HBcIgM: Hepatitis B core antibody IgM, Anti-HBc: Hepatitis B core antibody, HBD DNA PCR: Hepatitis B virus load,

In HBV co-infected patients, acute hepatitis flares can occur as a result of an immune reconstitution inflammatory syndrome soon after initiating therapy or later secondary to poor treatment adherence.

Table 2. Anti-HBV Drugs Available in 2011

Drug	Class	FDA-approved for HBV	Anti-HIV Activity	HIV Primary Mutation
Interferon-α	Immunomodulator	Yes	Yes	None
Lamivudine	Nucleoside analog	Yes	Yes	M184V
Emtricitabine	Nucleoside analog	No	Yes	M184V
Telbivudine	Nucleoside analog	Yes	No	
Entecavir	Nucleoside analog	Yes	Yes	M184V
Adefovir	Nucleotide analog	Yes	Weak	
Tenofovir	Nucleotide analog	Yes	Yes	K65R

Case Study 1: Hepatitis B

A 28-year-old Peruvian male presents to the HIV clinic for evaluation. He was recently diagnosed HIV-positive, when he was tested following a positive syphilis test. He is currently asymptomatic, has no other past medical or surgical history, denies any allergy to medication, and has recently received IM benzathine penicillin weekly for 3 weeks after undergoing a CSF examination that was negative for neurosyphilis.

He was born and raised in Peru, immigrated to the US at a young age, reports no recent travel, no contact with pets. He works as a salesman in a clothing store, has no steady sexual partner, and denies alcohol, tobacco, and injection drug use. His family history is significant for liver cancer in a maternal uncle who died in Peru at the age of 60, probably related to excessive alcohol consumption. Review of systems is unrevealing, and physical examination is within normal limits.

Relevant laboratory work: CD4 550 cells/mm^3, VL 65,000 copies/ml, RPR titer 1:16 (down from 1:128 two months earlier), albumin 3.8 gm/dl, Bilirubin 1.0mg/dl, Alk Phos 165 u/l, AST 45u/l, ALT 65 u/l, Protime 11.2 sec., Hep A IgG positive, HCV ELISA negative, Hep BsAg positive, Hep BsAb negative, Hep BcAb IgG positive.

The patient was counseled about avoiding alcohol, and practicing safe sex. At this time his HIV genotypic resistance was pending, and HBV DNA PCR was drawn to evaluate for chronic active hepatitis B. He returns 2 weeks later for his results: he is still asymptomatic, had no resistance mutation for HIV, and his HBV virus load was 6,345,721 IU/ml, alpha-fetoprotein 4.1ng/ml. He was recommended to have a liver biopsy to decide on the staging for his disease, but he declined and asked to be started on therapy for HIV.

Discussion:

This patient's HIV laboratory numbers do not meet the criteria for immediate therapy, based on current DHHS guidelines. However, the guidelines recommend HIV treatment based on his clinical condition of hepatitis B infection that requires treatment. If his liver pathology had very little fibrosis (stage 0, or 1) he could be followed clinically without any treatment at this time, with the assumption that he could have had HBV transmitted vertically. However, his family history of HCC, increased liver function tests (LFTs), high HBV virus load, lack of information on liver staging, and preparedness for a lifelong treatment for HIV, this patient is a candidate for initiation of therapy.

One option could be treating his HBV without treating his HIV. Although it is not a DHHS recommendation, one could attempt a course of pegylated interferon therapy with a pre-defined time on therapy. This approach has been studied in HBV mono-infected patients, offering them the best chance of "cure" before embarking on what is usually a lifelong therapy with nucleoside analogs; this approach has not been studied in co-infected patients. Treating him with telbivudine alone, which is the only nucleoside analog approved for HBV without any anti-HIV activity, would be wrong for two reasons. First, this drug has not been studied in co-infected patients; and second is the need to always use two drugs against HBV in HIV patients in order to minimize the chance of HBV resistance.

The most appropriate choice at this point would be to treat him with a combination of tenofovir + emtricitabine. Even though the latter has not been FDA approved for HBV treatment, it has shown efficacy in a randomized controlled study,[3] and is often used in practice.

Since a patient with HIV should never be treated with 2 NRTIs alone, adding a third agent against HIV is required in this situation. A non-nucleoside reverse transcriptase inhibitor (NNRTI), a ritonavir-boosted protease inhibitor (PI), an integrase inhibitor, or a CCR5-receptor antagonist (if a Trofile® assay reveals an R5 virus) are all acceptable options when there are no pre-existing mutations detected.

Does entecavir have any role in treatment of HBV in HIV patients?

Entecavir has not been studied in this population, but conceivably a co-infected patient failing the combination of tenofovir and emtricitabine, with an HBV virus having resistance to epivir (evidenced by the YMDD mutation in HBV), would be a good candidate to exchange emtricitabine for high dose entecavir, while continuing tenofovir. The HIV virus in this situation would usually be resistant to epivir, emtricitabine and entecavir (M184V mutation), and keeping HIV undetectable in this setting by using appropriate HAART is crucial.

HIV and HCV

According to the US Centers for Disease Control, approximately one-quarter of HIV-infected persons in the United States are also infected with hepatitis C virus; this incidence is 50% to 90% among IDUs with HIV.[4]

To minimize liver damage, patients are given the recommendation to avoid alcohol intake altogether.

HCV-associated liver fibrosis is accelerated in HIV-infected individuals, especially in those with low CD4 (<200 cells/mm^3), coexisting HBV infection, continuous alcohol consumption, and/or older age.[4] In the US, it is recommended that all patients with HIV be screened for HCV; if the ELISA is positive then an HCV virus load is measured. If HCV is detected, the genotype should also be determined. To minimize further damage to the liver, the patient is given the recommendation to avoid alcohol intake, and vaccination for Hepatitis A and B virus (if not already immune due to hepatitis B infection).

With the improvement of HIV therapy, end stage liver disease (ESLD) is becoming the most common cause of non-AIDS related death in co-infected patients.[6] HCV in patients infected with HIV has many consequences, of which the best known are an increased incidence of drug induced liver injury, HCV-related glomerulonephritis, and porphyria cutanea tarda. Many other co-morbidities have been linked to HCV infection, such as diabetes mellitus and lymphoma.

Treatment of HCV

Treatment of HCV is becoming increasingly important in this population, although it is challenging given generally lower rates of Sustained Viral Response (SVR) compared to HCV monoinfected patients. On average, patients infected with HCV genotype 2 & 3 receiving standardized treatment of pegylated interferon with ribavirin (usually weight based) use of for 48 weeks have SVR rates of approximately 65%. Those patients with genotype 1 HCV reach SVR rates approximately 30% of the time.[7]

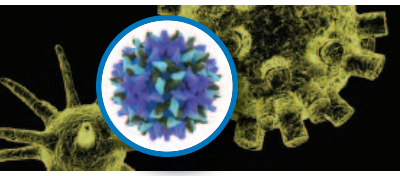
Very few commonly used antiretroviral agents adversely interact with interferon and ribavirin. The two best studied interactions are ribavirin: didanosine, and ribavirin: zidovudine. When co-administered with ribavirin, didanosine concentrations increase, which can lead to an increased risk of mitochondrial toxicity. This interaction may increase the risk of pancreatitis, and lactic acidosis with liver failure, especially in patients with advanced liver fibrosis. Ribavirin can also potentiate anemia in those receiving zidovudine. Other toxicities reported more frequently in co-infected patients are weight loss and anemia. Although the absolute number of CD4 cells will decrease on therapy, the CD4 percentage (a better marker in this setting) and the HIV virus load are not adversely affected.

(Continued on page 30)

Table 3. Interpretation of Hepatitis C Testing

Entity	HCV Enzyme Immunoassay (EIA)	HCV RNA Quantitative PCR (or Virus load)	AST/ALT
Acute HCV	Usually negative	Very High	Elevated
Prior HCV (or False positive serology)	Positive	Undetectable	Normal
Chronic Active Hepatitis C	Positive[1]	Detectable twice, ≥6 months apart.	Elevated/Normal

[1] Can be negative if CD4 count very low.



Chronic Hepatitis and HIV

Treatment of HCV (continued from page 29)

The same predictors of response have been described in co-infected patients as in HCV mono-infected patients, namely: non-African American race, IL-28 CC polymorphism genotype, HCV genotype 2 or 3, non-cirrhotic, non-insulin resistant, and low HCV virus load (<400,000 IU/ml). Recent studies have also confirmed an association between severe vitamin D deficiency and significantly lower rates of SVR for patients with genotypes 1, 2, or 3.[8]

The best predictor of SVR still seems to be the on-treatment response to therapy; indeed a rapid virologic response defined as an undetectable virus load at week 4 of interferon+ribavirin treatment will predict a very good sustained virologic response (SVR) in the range of 85% regardless of the patient's other characteristics. Unfortunately, this situation is not commonly encountered in co-infected individuals. Nonetheless, the faster their HCV becomes undetectable, the better their chances for an SVR.

The two new direct-acting antiviral agents (DAA) recently approved for HCV genotype 1 in mono-infected patients, telepravir and boceprevir, have been studied in HIV/HCV co-infected patients, and both show a favorable virologic response.[9] However, neither DAA has been FDA approved in HIV/HCV co-infection to date.

Both the HCV DAA and the HIV protease and NNRT inhibitors are metabolized by CYP3A4, making interactions likely. As a result there is a list of contraindicated medications when these HIV medications are combined with either boceprevir or telaprevir. See Table 7. These drug-drug interactions will need to be carefully studied before their use in this population. What is known so far regarding telepravir is the following: it is associated with a significant decrease in boosted darunavir and fosamprenavir levels, when used with telepravir 750mg q 8 hrs. On the other hand, boosted lopinavir and efavirenz will decrease telepravir levels significantly.[10]

Current Phase III studies of telaprevir, in HIV-positive individuals limit antiretroviral agents to two HIV regimens: ritonavir boosted atazanavir in combination with tenofovir/emtricitabine (with standard dose telaprevir), and efavirenz plus tenofovir/emtricitabine (with increased telaprevir dose to 1125 mg every eight hours). Also, at least 20g of fat is recommended to be used with telaprevir.

Drug interactions with the DAA will be challenging. Those familiar with HIV protease inhibitor interactions with other CYP3A4 substrates will be well versed in this area. However, some interactions are slightly different with the DAA when compared with the HIV protease inhibitors.

Providers need to also be cautious of other CYP3A4 inhibitors, inducers and substrates when using the HCV DAA. References for online use are available to assess risk of drug interactions including www.hep-druginteractions.org, www.clinicaloptions.com, and www.hiv-druginteractions.org. Providers are encouraged to assess interactions with current medications prior to initiating therapy with either HCV DAA, especially until the FDA approves their use for people with HIV infection.

Table 4. Definitions of Virological Responses During Anti-HCV Therapy, for Genotype 1 Virus.

Virological Response	Change of Viral Load (VL) from Baseline	# of Weeks Since Start of Therapy
Rapid Virological Response (RVR)	Undetectable	4
Null Responder (NR)	Failure to decrease VL by 2 logs	12
Early Virological Response (EVR)	Undetectable	12
Delayed Virological Response (DVR)	More than 2 logs drop in VL, but still detectable	12
Partial responder (PR)	≥2 logs drop at week 12, but still detectable	24
End of Treatment Response(ETR)	Undetectable	48
Relapser	Detectable, After achieving ETR	Between 48 and 72
Sustained Virological Response (SVR)	Undetectable	72

Table 5. Favorable Factors toward a Sustained Virological Response to HCV Therapy[1]

Host	Virus	Treatment Adherence
Genes (IL28 polymorphism CC)	Genotype (2-3)	At least 80% of Interferon dose
Younger age	Low baseline Virus Load	At least 80% of Ribavirin dose
Race (White)	Response to Therapy (RVR[2])	No treatment interruption
Minimal liver fibrosis		
No hepatic steatosis		
Lack of insulin resistance		
Normal to High 25-OH Vit D level		
High ALT ratio at Baseline		

[1] With Pgylated Interferon+Ribavirin [2] Rapid Virological Response

Table 6. Interactions: Anti-HIV and HCV Drugs affected by CYP450 3A4 Isoenzyme

INHIBITORS[1]	SUBSTRATES with minimal induction or inhibition	INDUCERS[1]
Ritonavir	Maraviroc	Efavirenz
Atazanavir	Rilpivirine	Nevirapine
Lopinavir		Etravirine
Fosamprenavir		
Darunavir		
Telepravir		
Bocepravir		
All protease inhibitors		

[1] All of those medications are substrates of CYP 3A4

Table 7. Contraindicated Medications with Direct Acting Antivirals Boceprevir or Telaprevir

Drug Class Contraindicated	Boceprevir	Telaprevir
Alpha 1-adrenoreceptor antagonist	Alfuzosin	Alfuzosin
Anticonvulsants	Carbamazepine, phenobarbital, phenytoin	None listed
Antimycobacterials	Rifampin	Rifampin
Ergot derivatives	Dihydroergotamine, ergonovine, ergotamine, methylergonovine	Dihydroergotamine, ergonovine, ergotamine, methylergonovine
GI motility agents	Cisapride	Cisapride
Herbal products	Hypericum perforatum (St John's wort)	Hypericum perforatum
HMG CoA reductase inhibitors	Lovastatin, simvastatin	Atorvastatin, lovastatin, simvastatin
Oral contraceptives	Drospirenone	N/A
Neuroleptic	Pimozide	Pimozide
PDE5 inhibitor	Sildenafil or tadalafil when used for tx of pulmonary arterial HTN	Sildenafil or tadalafil when used for tx of pulmonary arterial HTN
Sedatives/hypnotics	Triazolam; orally administered midazolam	Orally administered midazolam, triazolam

Table 7 prepared by John Faragon, PharmD, AAHIVE, NY/NJAETC.

Case Study 2: Hepatitis C

A 42-year-old African American male, with AIDS diagnosed two years ago after an episode of pneumocystic jiroveci pneumonia, presented for evaluation and therapy of his chronic active hepatitis C. He is currently asymptomatic, and on efavirenz/ emtricitabine/tenofovir disoproxil furmarate (Atripla®) as his only medication. He has had an undetectable viral load for more than a year, and his CD4 count increased from a nadir of 65 cells/mm^3 to 340 cells mm^3.

He has no other past medical or surgical history, and no known drug allergies. His social history: he does not smoke, is a social drinker, no known history of IV drug use, has a steady male sexual partner for the last 4 years, practices safe sex, and is employed as a social worker. His family history is significant for diabetes mellitus in both parents, and early coronary artery disease. His review of system is negative except for some periods of depression in the last year not requiring any medication, and 15 lbs. weight gain in the last 6 months.

His physical examination was all within normal limits, and his pertinent laboratory values are: FBS 114mg/dl, Albumin 3.8 gm/dl, total bilirubin 0.8 mg/dl, Alk Phos 90 u/l, AST 36 u/l, ALT 42 u/l, Protime 12.1 sec, BUN 11 mg/dl, creatinine 0.8 mg/dl, WBC 4,200/µl, hemoglobin 14.1 gm/dl, platelets 134,000/µl, HCV RNA PCR 956,000 IU/ml, genotype 1b, Hep A IgG positive, Hep B surface Ab positive, Hep BcAb positive, and his TSH was normal. He underwent a liver biopsy that revealed a Scheuer grade 1-2 necro-inflammatory score, and stage 3 fibrosis. He was advised to stop drinking alcohol, and started treatment with pegylated interferon subcutaneously weekly, along with weight-based ribavirin therapy.

At week 4 of therapy he was tired, mildly depressed, his hemoglobin had dropped down to 9.2 gm/dl, his platelets decreased to 65,000/µl, CD4 decreased to 210 cells/mm3, his HIV VL was still undetectable, and his HCV RNA PCR was 1,000IU/ml. Ribavirin dose was decreased, erythrocyte stimulating factor was given until his hemoglobin increased over 10 gm/dl, and a serotonin reuptake inhibitor was started to address his depression. His HCV RNA PCR was undetectable at week 8, and he was stable enough to continue a 48 week course of therapy. At 12 weeks after the end of treatment, his HCV RNA PCR was detectable again. How should the clinician proceed?

Discussion:

The first question is: why did he relapse? He had a several poor predictors of response: HCV Genotype 1, African American race, high HCV virus load, advanced fibrosis, insulin resistance, HIV co-infection; on the other hand his response on therapy was very favorable with a rapid decline in VL. Some of the reasons for his poor outcome could be related to the decrease in ribavirin dosage early in therapy, poor compliance with treatment at some point related to his depression, or possibly a vitamin D deficiency.[11] The fact remains that the response he attained while on therapy was very encouraging, in spite of not achieving an SVR. Retreatment is reasonable, especially in view of his relatively advanced liver fibrosis. Theoretically a triple combination therapy consisting of pegylated interferon, ribavirin, and a protease inhibitor (notably teleprevir since the PK studies have been completed) will have a better chance in achieving an SVR; on this regimen we would expect a higher incidence of anemia, thus his hemoglobin will need to be monitored very closely. One would probably use erythropoietin stimulating factors early in the course of therapy in order to minimize the need for a ribavirin dose adjustment.

We would also pay attention to depressive symptoms and start therapy earlier if need be, with continuous counseling about adherence to therapy. If telepravir is chosen as the third agent, then the dose should be increased to 3 tablets of 375mg (1125mg) with food every 7 to 9 hours. Again, this dose adjustment is necessary due to the enzymatic induction of CYP 3A4 from efavirenz and subsequent reduction in telepravir exposure. The patient should also be educated about skin hygiene, and asked to report rashes as soon as possible. If bocepravir is chosen, a 4 week lead in phase with pegylated interferon plus ribavirin should be given before it is added. We have no guidance on drug dose adjustment with concurrent efavirenz, and it would be prudent at this point not to use this combination, and wait for further drug-drug interaction studies of bocepravir with antiretroviral agents, which will start being presented in the near future.

CONCLUSION

Chronic hepatitis B and C infection, added to HIV infection, make both diseases more complex to treat effectively, and significantly increase the risk of liver damage including the potential for ESLD.

Hepatitis B treatment can readily be combined with HIV therapy, and should lead to complete viral suppression, or rarely complete resolution of the hepatitis. Hepatitis B is preventable and prophylactic screening and vaccination of all HBV-negative individuals should be incorporated in all HIV medical care programs.

Hepatitis C treatment is more challenging due to the limits of current treatments that have been approved by the FDA for individuals co-infected with HIV. New Direct Acting Antivirals, boceprevir and telepravir, are promising options for patients mono-infected with hepatitis C, but the balance of outcomes with risks is still uncertain pending further clinical studies. However, clinicians should watch for these findings, and discuss the prognosis and current treatment options with all co-infected patients. They also provide ongoing monitoring and counseling on risk reduction through eliminating or reducing consumption of alcohol, and hepatitis A and B vaccination if the patient is not already immune. Co-management of HBV or HCV with HIV requires ongoing close monitoring for adverse effects of treatment, including both psychological and physical manifestations. The risks associated with co-management are balanced by the opportunity to minimize and even reverse liver damage, and improve the quality and length of life of many individuals living with HIV infection and hepatitis B and/or C.

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Resources:

American Association for the Study of Liver Diseases (AASLD) Practice Guidelines for Hepatitis C Virus: http://www.aasld.org/practiceguidelines/Documents/2011UpdateGenotype1HCVbyAASLD24641.pdf

USDHHS-HRSA. Integrating Hepatitis C Treatment In Ryan White Clinics Models & Steps [609kb] http://hab.hrsa.gov/resources/hepatitiscmodelstools.pdf.

A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV. January 14, 2011. [361 kb] http://hab.hrsa.gov/deliverhivaidscare/files/hepccoinfectguide2011.pdf.

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Chronic Hepatitis & HIV

POST TEST – Page 1 of 2

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1. Who is at the highest risk of being HIV/HBV co-infected, based on epidemiology?

A. A 45-year-old AAM IDU from Newark, NJ.

B. A 35-year-old WM hemophiliac from Washington, DC.

C. A 38-year-old AAM heterosexual from Cape Town, South Africa.

D. A 24-year-old WM MSM from San Francisco, California.

2. Which anti-HBV drug has no HIV activity?

A. Entecavir.

B. Pegylated interferon.

C. Telbivudine.

D. Emtricitabine.

3. A 35-year-old WM has HIV/HBV CD4 650 cells/mm^3, HIV VL 45,000 copies/ml and Sheuer stage 3 fibrosis on liver biopsy. What is the best therapeutic strategy?

A. Treat HBV first; once HBV DNA PCR is undetectable, start ART.

B. Treat HIV first; once HIV RNA PCR is undetectable start HBV therapy.

C. Treat both diseases simultaneously with Lopinavir/ritonavir + Zidovudine/Lamivudine.

D. Treat both diseases simultaneously with Emtricitabine/tenofovir/efavirenz.

4. A 46-year-old WM with HIV/HBV on Nevirapine and Emtricitabine/Tenofovir for the last 5 years with undetectable HIV and HBV for over 4 years, presents to the ED in fulminant liver failure. What is the most likely etiology?

A. Nevirapine induced hepatotoxicity.

B. Emtricitabine/Tenofovir-induced lactic acidosis.

C. Poor adherence to therapy.

D. Fulminant acute HCV.

5. Which HIV-positive person is at the highest risk of HCV-associated liver fibrosis?

A. A 42-year-old AAM receiving treatment as a prison inmate in NYC.

B. A 30-year-old WM on "crack" engaging in high risk unprotected sexual activity, in suburban Philadelphia.

C. A 21-year-old WF IV heroin user and sex worker in Seattle, WA.

D. A 55-year-old WM recovering heroin addict and alcoholic, drug free for 8 years, in Newark, NJ.

CE Activity Code: 14HC01

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Chronic Hepatitis & HIV

POST TEST – Page 2 of 2

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6. Who has the best chance of attaining SVR on pegylated interferon+Ribavirin?

A. A 24-year-old WF, genotype 1a, with undetectable HCV VL at week 4 of treatment.

B. A 52-year-old AAM, genotype 3, with cirrhosis.

C. A 45- year-old AAF, genotype 2, HIV positive.

D. A 35-year-old WM, genotype 1b, HIV positive.

7. Bocepravir and telaprevir are FDA approved for treatment of HCV in which one of the following categories:

A. Any patient with HCV who has failed prior treatment with pegylated interferon+ribavirin.

B. HCV-HIV co-infected patients whose HIV disease is well controlled.

C. Patient with HCV Genotype 4 mono-infection.

D. Patient with HCV Genotype 1a & 1b mono-infection.

8. Which of the following statements regarding telaprevir drug interaction is TRUE?

A. Telaprevir significantly increases the level of boosted darunavir.

B. Efavirenz increases telaprevir level.

C. Telaprevir significantly increases boosted atazanavir level.

D. Lopinavir/ritonavir significantly increases telaprevir level.

9. Of the following NRTIs which one is safest to use with interferon+ribavirin therapy?

A. Zidovudine.

B. Didanosine.

C. Tenofovir.

D. Stavudine.

10. Which statement is TRUE regarding the use of pegylated interferon+ribavirin in co-infected patients compared to HCV mono-infected patients?

A. The incidence of serious infections is higher.

B. The SVR rate is lower.

C. The incidence of anemia is lower.

D. The incidence of weight loss is lower.

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Chronic Hepatitis & HIV
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PROGRAM OBJECTIVES: *Having completed this activity, are you better able to:*

		Strongly Agree				Strongly Disagree
Objective 1:	Screen and monitor HIV patients for hepatitis B and C infection.	5	4	3	2	1
Objective 2:	Make decisions about treatment initiation and regimens that incorporate recent revisions in treatment recommendations for hepatitis B and C.	5	4	3	2	1
Objective 3:	Identify challenges of co-management of HIV and Hepatitis B and/or Hepatitis C, including timing of sequential or simultaneous treatment and potential adverse effects and drug interactions.	5	4	3	2	1

OVERALL EVALUATION:	Strongly Agree				Strongly Disagree
The information presented increased my awareness/understanding of the subject.	5	4	3	2	1
The information presented will influence how I practice.	5	4	3	2	1
The information presented will help me improve patient care.	5	4	3	2	1
The faculty demonstrated current knowledge of the subject.	5	4	3	2	1
The program was educationally sound and scientifically balanced.	5	4	3	2	1
The program avoided commercial bias or influence.	5	4	3	2	1
The teaching and learning methods were effective.	5	4	3	2	1
The self-assessment was appropriate and helpful.	5	4	3	2	1
Overall, the program met my expectations.	5	4	3	2	1
I would recommend this program to my colleagues.	5	4	3	2	1

Based on the content of the activity, what will you do differently in the care of your patients? *(check one)*

- ☐ Implement a change in my practice.
- ☐ Seek additional information on this topic.
- ☐ Do nothing differently. Current practice reflects activity recommendations.
- ☐ Do nothing differently as the content was not convincing.
- ☐ Do nothing differently. System barriers prevent change.
- ☐ Not applicable. I do not see patients in my current position.

If you anticipate changing one or more aspects of your practice as a result of your participation in this activity, please provide us with a brief description of how you plan to do so.

_____

May we contact you in two months to see how you are progressing on the changes indicated above?

☐ Yes. Please provide your email address. _____ ☐ No. I do not wish to participate in the follow-up assessment.

If you are not able to effectively implement what you learned at this activity, please tell us what the system barriers are (e.g., reimbursement issues, managed care rules, formulary decisions, countervailing practice guidelines, etc).

_____

Please list any topics that you would like addressed in future educational activities.

_____

Antiretroviral Agents Rise as the Primary Means of HIV Prevention (Cont'd from page 1)

MEDICAL APPROACHES TO HIV PREVENTION

PEP: Post-Exposure HIV Prophylaxis in occupational settings

The U.S. Public Health Service published its recommendations on the management of occupational HIV exposure in the *MMWR* in 1996, and updated the recommendations in 2005. This is an important aspect of workplace safety. Occupational exposures should be considered to be an urgent medical concern as it is preferable for post exposure prophylaxis (PEP) regimens to start within 72 hours of exposure. Timely post-exposure management and administration of HIV PEP regimens with an emphasis on adherence and monitoring for adverse events is important. Occupational transmission has become virtually nonexistent with the adoption of stringent infection control measures and PEP regimens based on current antiretroviral treatment standards.

PMCTP: Preventing Mother to Child Transmission

In 1994, the ACTG-076 clinical trial showed that the use of zidovudine (AZT, ZDV) during pregnancy, labor and delivery, and in the neonatal period significantly reduced mother-to-child HIV transmission, from 25% to 8%. Since then many antiretroviral agents have been approved by the Food and Drug Administration and combination antiretroviral treatment (ART) has become the standard of care. The combination of HIV testing of all pregnant women, obstetrical advances and use of ART in pregnancy and delivery has reduced perinatal HIV transmission nationwide by 95% and has decreased perinatal HIV transmission in New Jersey from 77 newborns (21% of those exposed) in 1993 to 2 (2%) in 2009. The Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission periodically issues updated recommendations, most recently on September 14, 2011. These new guidelines will be covered more fully in the June 2012 issue of *NJ AIDSLine*.

Prevention with Positives and "Test and Treat"

While an undetectable viral load cannot guarantee that an HIV-positive person will not transmit HIV, it dramatically reduces this risk. Undetectable viral loads are associated with slower rates of disease progression, fewer comorbidities, and improved overall health status. The reduction of transmission risk underscores the significance of this medical goal, as dramatically demonstrated in the success of perinatal treatment interventions in reducing and nearly eliminating perinatal HIV transmission. The CDC issued recommendations for a strategy that became known as "Prevention with Positives" in 2003, Incorporating HIV Prevention into the Medical Care of Persons Living with HIV. Clinicians were advised that they should conduct frequent behavioral risk screening, provide brief risk reduction interventions in medical care, and facilitate partner notification. More recently, the concept of "Test and Treat" is being implemented to immediately engage individuals newly diagnosed with HIV in medical care, and beginning ART regardless of CD4 and viral load counts, to reduce the "community viral load" and risks of HIV transmission.

nPEP: non-occupational Post-Exposure Prophylaxis

in 2005, the Centers for Disease Control and Prevention (CDC) released a ground breaking document, *Antiretroviral Postexposure Prophylaxis after Sexual, Injection-Drug Use, or Other Nonoccupational Exposure to HIV in the United States: Recommendations from the E.S. Department of Health and Human Services.* This opened up a national discussion of using medical treatment for HIV prevention, applying the concepts of post-exposure prophylaxis to the realm of sexual and drug-related HIV transmission, the most common routes of infection. The CDC nPEP recommendations included an algorithm to evaluate patient exposure status for possible nPEP treatment, although healthcare providers and administrators raised questions of inadequate funding and staff to provide treatment and follow-up.

PrEP: Pre-exposure Prophylaxis

Recently published studies document the efficacy of ART in lowering not only HIV viral load, but also reducing sexual transmission of HIV from people with HIV infection to their partners. Research studies have found that a daily regimen of Tenofovir DF plus lamivudine or emtricitabine was effective in reducing new HIV infections among men with male sexual partners, although it was less successful in protecting women with male sexual partners. The success of this pre-exposure treatment in at least one highly-impacted population adds urgency to further research to protect individuals who have continued exposure to HIV.

In New Jersey, the combined HIV education and treatment approaches of recent years appear to be having an effect, as demonstrated by reduced numbers of new HIV/AIDS cases despite a rise in chlamydia cases (see Table 1 on next page). The recent merger of HIV, STD and TB Division of the New Jersey Department of Health and Senior Services will bring together the experience and programs addressing HIV and STD prevention, diagnosis, and treatment.

Table 1.
Chlamydia cases continue to rise while HIV/AIDS cases are on a decline.

	CHLAMYDIA	HIV/AIDS
NJ CASES	2004: 17,448 2010: 23,974	2004: 2,028 2009: 1,342
Change in 6 Years	**49.9% increase** in new Chlamydia cases	**33.7% decrease** in new HIV/AIDS cases
Prevention Method	– Medical Model –Treatment to Prevent	– Behavioral Interventions – Community-level Interventions – Structural Interventions – Medical Model–Treatment to Prevent

The recent merger of HIV, STD and TB Division of the New Jersey Department of Health and Senior Services will bring together the experience and programs addressing HIV and STD prevention, diagnosis, and treatment.

REFERENCES & RESOURCES

USDHHS HIV Treatment Guidelines, FDA approved drug lists, and HIV vaccine research information are available at: http://aidsinfo.nih.gov

Post-exposure Prophylaxis (PEP, occupational)

- Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for Postexposure Prophylaxis. *MMWR* 2005;54 (No. RR-9):1-24. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm

Reducing Perinatal Transmission

- Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. September 14, 2011; pp 1-207. http://aidsinfo.nih.gov/Content Files/PerinatalGL.pdf.

Post-exposure Prophylaxis (non-occupational)

- Centers for Disease Control and Prevention. Antiretroviral post-exposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: Recommendations from the U.S. Department of Health and Human Services. *MMWR* 2005;54 (No. RR-2): 1-28. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm

Prevention with Positives

- Centers for Disease Control and Prevention. Incorporating HIV Prevention into the Medical Care of Persons Living with HIV. *MMWR* 2003. 52(RR12): 1-24. http://aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?GuidelineID=15&ClassID=4

Pre-exposure Prophylaxis (PrEP)

- Centers for Disease Control and Prevention. Interim Guidance: Pre-exposure Prophylaxis for the Prevention of HIV Infection in Men Who Have Sex with Men. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm. *MMWR*. 2011. 60(03):65-68.

Post-exposure Prophylaxis Clinical Trials

National Institutes of Health (NIH)
Truvada Plus Raltegravir for Nonoccupational Post-exposure Prophylaxis (nPEP). http://clinicaltrials.gov/ct2/show/NCT01214759

Hillary Clinton's "AIDS-Free Generation" speech may be seen at:
http://bcove.me/u4njl79t

Continuing Education on Antiretroviral Treatment as HIV Prevention:

UMDNJ-Center for Continuing and Outreach Education,
Division of AIDS Education, with funding from NJDHSS

HIV Medical Update Series:
Free onsite accredited in-service presentations for clinical providers. For more information, please contact Michelle Thompson at ccthomps@umdnj.edu or (973) 972-3690.

- Preventing Perinatal HIV Transmission in New Jersey
- Prevention and Prophylaxis for Occupational Exposure to HIV and Other Bloodborne Pathogens

Web-based Clinical Education: www.umdnj.edu/ccoe/aids

- The Role of Antiretroviral Agents in Pre- and Post-Exposure Prophylaxis

- New Jersey HIV/AIDS Report. December 31, 2010. http://www.state.nj.us/health/aids/documents/qtr1210.pdf

The Role of STD Screening In HIV Prevention with Positives

1.5 million STD cases were reported to the Centers for Disease Control and Prevention (CDC) in 2008. This number represents only a fraction of the estimated 19 million new STD infections occurring yearly. Chlamydia, gonorrhea and syphilis are the only reportable sexually transmitted diseases. The number of cases of syphilis in the United States has steadily increased in the past eight years with the numbers of reported cases doubling since 2003. According to the CDC, 1,244,180 cases of chlamydia were reported throughout the states in 2009. And even though the national gonorrhea rate was the lowest in recorded history, there were 301,174 cases reported that year. How many of those cases were HIV positive patients? But more importantly, how many HIV positive patients were infected with an STD that was not diagnosed?

Chlamydia trachomatis is the most frequently reported bacterial sexually transmitted disease. Although many men and women present for treatment because of discharge, and/or pain, 75% of infected women and 50% of infected men are asymptomatic. Similarly 50% of women experience no symptoms with gonorrhea, and the seemingly innocuous chancre of syphilis is most often overlooked.

The Health Resources and Services Administration HIV/AIDS Bureau (HRSA) included the screening for Chlamydia and gonorrhea as a Group Three Clinical Performance Measure recommending that every sexually active adolescent and adult over the age of 18 be screened annually.

In the FY 2010-2011 chart review conducted by the University of Medicine & Dentistry of New Jersey (UMDNJ) Quality Management Team for all Part A and Part B Ryan White funded clinics, a total of 1,111 charts were reviewed. 88% of the charts reviewed contained documentation of screening for syphilis; 46% contained screening for gonorrhea, and 47% contained a chlamydia screening. Several factors contribute to this disparity. The screening for syphilis is a blood test , the RPR (rapid plasma reagin), can easily be added to the routine laboratory panel, and has been routinely utilized by most facilities for many years. Testing for gonorrhea and chlamydia on the other hand, previously involved invasive testing which was a barrier for most asymptomatic males. The rates for testing for women have been slightly higher because the specimen may be obtained at the same time PAP screening is performed. However, the rate for routine pelvic examination and cervical cancer screening for women has been consistently low. The advent of urine screening for chlamydia and gonorrhea assays has improved adherence significantly, yet funding for this additional testing remains a barrier for many facilities.

Many care providers purport that achieving an undetectable viral load is a significant means of prevention. While maintaining an undetectable viral load decreases the likelihood of transmitting HIV, having unprotected sex, acquiring an STD or having sex with an individual with an STD can have serious consequences for the infected individual and increase the risk of transmission for the seronegative partner.

Improving adherence to STD screening should be a quality improvement focus for every clinician treating HIV infected patients. Screening should begin with a thorough sexual history aimed at identifying risks for acquiring an STD and setting the stage for education and risk behavior counseling. Although the cost of providing STD screening places an immediate burden on diminishing Ryan White budgets, the ultimate result will be improved patient outcomes, fewer new HIV diagnoses, and an overall reduction in heathcare dollars for the treatment of HIV patients.

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Sexually Transmitted Diseases (STDs) News

Antibiotic-Resistant Gonorrhea (ARG)

The development of antibiotic resistance in Neisseria gonorrhoeae is a growing public health concern, in particular because the United States gonorrhea control strategy relies on effective antibiotic therapy.

Since antibiotics were first used for treatment of gonorrhea, N. gonorrhoeae has progressively developed resistance to the antibiotic drugs prescribed to treat it: sulfonilamides, penicillin, tetracycline, and ciprofloxacin. Currently, CDC STD treatment guidelines recommend dual therapy with a cephalosporin antibiotic (ceftriaxone is preferred) and either azithromycin or doxycycline to treat all uncomplicated gonococcal infections among adults and adolescents in the United States. Dual therapy is recommended to address the potential emergence of gonococcal cephalosporin resistance. Given the ability of N. gonorrhoeae to develop antibiotic resistance, it is critical to continuously monitor gonococcal antibiotic resistance and encourage research and development of new treatment regimens for gonorrhea. **For additional information, please contact the New Jersey Department of Health & Senior Services, Sexually Transmitted Disease Program at (609) 826-4869.**

From the Centers for Disease Control and Prevention (CDC). Visit the CDC's webpage on of antibiotic-resistant gonorrhea for further information about tracking and treatment: http://www.cdc.gov/std/Gonorrhea/arg

Nucleic Acid Amplification (NAA) Testing Recommended for Rapid Confirmation of Tuberculosis Diagnosis

September 2011

The New Jersey Hospital Association and the New Jersey Department of Health and Senior Services, Tuberculosis Program strongly recommend that hospitals consider routine utilization of NAA testing in patients suspected to have pulmonary tuberculosis (TB) with smears positive for acid fast bacilli (AFB) and admitted to respiratory isolation. Such a routine clinical pathway would result in more efficient use of respiratory isolation rooms and earlier discharge for patients later determined not to have the disease confirmed by conventional culture. The cost savings realized would be proportional to the volume of patients with an initial diagnosis of pulmonary TB and admitted to your hospital. Read on to learn more about these tests which are offered by most, if not all, commercial reference laboratories currently used by New Jersey hospitals.

In 1995, the Food and Drug Administration (FDA) approved two rapid diagnostic tests based on NAA assays: the Gen-Probe AMPLIFIED™ Mycobacterium tuberculosis Direct (MTD) Test and the Roche AMPLICOR® *Mycobacterium tuberculosis* (MTB) Test. In 1998, the FDA approved a modified version of the MTD test that is even faster and more sensitive than the previous version. NAA tests identify the presence of genetic information unique to *M. tuberculosis* complex directly from clinical samples.

The NAA technique uses chemical, rather than biological, amplification to produce sufficient nucleic acid so that, within a few hours, these tests can distinguish between *M. tuberculosis* complex and non-tuberculosis mycobacterium in an AFB-positive specimen. The MTD and MTB tests are currently approved for use only with respiratory specimens. Specificity of NAA test results when compared to culture results for smear positive TB suspects is greater than 95%. In smear negative specimens, specificity drops to between 50% and 80% compared to culture results, so NAA testing is of limited positive predictive value in these patients.

While conventional culture remains the gold standard and should continue as a final confirmatory test, the growth and detection of *Mycobacterium tuberculosis* requires up to eight weeks for final results. Direct molecular methods do not require growth of the bacteria making it possible to detect *M. tuberculosis* complex within three to five hours after receipt of the specimen. The implications of rapid diagnostic tests for hospitals and public health clinics are significant, including improved patient care, reduced medical costs and more effective use of respiratory isolation rooms and personnel involved in contact investigation.

A 2008 study, demonstrated the use of NAA testing that could permit the vast majority of patients to be discharged from respiratory isolation (RI) within a single day of receipt of a specimen at the laboratory, reducing the demand for RI facilities by as much as 75%[1]. Other recent studies showed that further cost savings can be achieved in hospitals and public health clinics by using NAA test Results to prioritize contact investigations and reduce unnecessary TB treatment[2,3].

In its 2009 revised guidelines, for the use of NAA testing for the diagnosis of TB, the Centers for Disease Control and Prevention (CDC), National Advisory Council for the Elimination of Tuberculosis (ACET) and the Association of Public Health Laboratories (APHL) recommend that:

- *NAA testing can be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities.*

This document (resource 1 below) also provides a testing and interpretation algorithm which could be used in hospitals interested in supplementing smear, culture, and drug susceptibility testing for TB diagnosis and treatment with NAA testing.

The New Jersey Administrative Code (§8:57-5.7) allows for the discontinuation of [TB] infection control measures and discharge of a patient with smear(s) **positive** for AFB in the presence of a NAA test **negative** for *Mycobacterium tuberculosis.*

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3. CDC – Update: Nucleic Acid Amplification Tests for Tuberculosis. *MMWR* 2000: 9:593–4.
4. CDC – Nucleic Acid Amplification Tests for Tuberculosis. *MMWR* 1996; 45:950–1.
5. New Jersey Administrative Code §8:57-5.7.

Rethinking HIV Care Using the Joint Commission's Disease-Specific Certification Standards within a Medical Home Model

Kathleen M. Gekowski, MD
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Achieving and sustaining consistent excellence in safety and quality is the goal of high reliability organizations in health care. Providing timely evidence-based care in a safe and cost effective manner to all patients at every encounter is the mantra. Joint Commission Disease Specific Certification coupled with the NJ Cross Part Collaborative and the National Strategy for HIV/AIDS provide a roadmap to achieving these goals.

IN JULY, 2011, Capital Health's Mercer Area Early Intervention Services (MAEIS), a Part C Ryan White funded program, was first in the nation to achieve Joint Commission Disease-Specific Certification in HIV/AIDS. In the state of New Jersey, we have a unique opportunity to provide a coordinated approach to monitoring statewide progress in achieving the national goals via the New Jersey State-wide Collaborative and state/county statistics. For more than 20 years, HRSA funded Ryan White HIV/AIDS programs have been providing outpatient HIV early intervention and primary care services to the low income, medically underserved people living with HIV/AIDS (PLWHA). According to the Ryan White 2010 Biennial Report, Going the Distance, the goals for all Ryan White programs are to: 1) increase access to underserved populations; 2) reduce use of inpatient care; and 3) improve quality of life for people affected with HIV/AIDS. The approach utilized by Ryan White providers to achieve these goals has been one of the early examples of the medical home approach to healthcare focused on a specific disease. Ryan White programs have often provided multi-disciplinary, comprehensive, culturally and consumer oriented approaches to healthcare in a medical home setting.

The term "medical home" was first utilized in the 1960s by the American Academy of Pediatrics (Rosenthal, 2008) and has evolved to the present version which is described as the "patient centered medical home" (Casalino, Rittenhouse, Gilles, & Shortell, 2011) approach to health care delivery. This model combines the concept of personal physician-provided comprehensive care with responsibilities to improve the health of the client population utilizing data collection, information technology, and patient communication. These goals are achieved through four main functions: 1) patient relationship with a personal physician to provide continuous, comprehensive care; 2) provision of care for acute and chronic conditions, prevention, and end of life care; 3) coordinating care across the outpatient and inpatient health care continuum with the use of information technologies; and 4) providing enhanced care with examples including open scheduling, expanded hours, and new options for communication between patient and physician/staff (American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, & American Osteopathic Association, 2007). In the context of PLWHA, this model must be expanded to include case management and assessing for psychosocial barriers to care (e.g., housing, transportation, income, food availability, mental health disorders, etc.).

Capital Health's Ryan White Part C funded program, Mercer Area Early Intervention Services (MAEIS), has the unique ability to function as a medical home at its community office location while seamlessly coordinating HIV care and management with the support of Capital Health outpatient diagnostic services, subspecialty referral programs, and emergency departments/inpatient hospitalizations. MAEIS on-site services include: ambulatory HIV primary medical care; rapid HIV counseling, testing, and assistance with partner notification; treatment adherence and risk reduction counseling; medical case management; mental health, renal, gastrointestinal, and gynecologic care; psychosocial support and assistance with access to AIDS drug assistance; transportation, financial, legal, and other support services; substance use and nutrition screening; phlebotomy services; health education lecture series; and ongoing Community Advisory Board input regarding all aspects of MAEIS function.

In July 2010, President Obama released the National HIV/AIDS Strategy (Obama, 2010). This plan has three main goals with measurable targets to be achieved by 2015 (AIDS.gov): 1) reduce new HIV infections, 2) increase access to care and improve health outcomes for PLWHA, and 3) reduce HIV-related health disparities (improve access to prevention and care services for all Americans). It has been suggested that accomplishing these goals will require increased collaboration/coordination across all HIV programs in addition to developing mechanisms to monitor progress toward these goals. There are action steps provided to identify specific strategies to improve the success of achieving these goals. At Mercer Area Early Intervention Services, the following objectives are pursued in an attempt to contribute to the success of the national strategy by 2015. With regard to reducing new HIV infections, MAEIS proposes the following strategies: 1) Encourage universal HIV testing for the Capital Health emergency departments, medical and obstetrical clinics, and hospitalized patients; 2) Pursue the achievement of viral suppression (<200) as a performance improvement element (i.e. undetectable VL); and 3) Continue emphasis during each client visit on medication adherence, assessment for mental health and substance use problems, and mechanisms to prevent sexual transmission.

At Mercer Area Early Intervention Services, we are increasing access to care and improving the health outcomes of people living with HIV and AIDS by: 1) Establishing MAEIS contact with newly identified HIV infected clients within 24 hours and on-site medical evaluation within 10 days; 2) Tracking performance improvement criteria such as client no show (for office visit) rates, clients receiving an annual (at minimum) housing assessment, annual hepatitis C and other screenings, encouraging hepatitis B immunizations, and multiple elements of HIV care focused on health outcomes; 3) daily multidisciplinary team meetings focused on the medical and psychosocial barriers to health for each client scheduled to be seen that day; 4) utilizing MAEIS community advisory board input to improve office function and identify topics for our monthly health education lecture series; 5) developing an onsite physician medical resident educational elective.

Mercer Area Early Intervention Services attempts to reduce HIV related disparities and health inequities by providing primary medical care (with appropriate specialty referrals) to our clients. As people living with HIV and AIDS age, there must be continued focus on their non-HIV medical conditions including cardiovascular diagnoses, diabetes, hypertension, etc. This focus also includes prevention (e.g. immunizations) and screenings for cancer with examples including colonoscopy, PSA, cervical and anal PAPS. In addition, identification and management of the co-morbidities of chronic Hepatitis B and C must be a priority.

(Continued on next page)

The Mercer Area Early Intervention Services multidisciplinary team approach of physician, staff, and patient focused care results in the ability to assess, provide/refer, and educate each client regarding their unique medical and psychosocial needs. This process is initiated immediately when a client is referred (either inpatient or outpatient) by an MAEIS medical case manager and/or MAEIS physician and on-site initial medical evaluation. Coordination of medical visit compliance, diagnostic and specialty referrals, laboratory and inpatient data retrieval, and performance improvement data collection are esponsibilities shared among the MAEIS staff. The use of daily team meetings, which include the physician, nurse, and case manager to review the medical and psycho-social concerns for each client scheduled to be seen that day results in the ability to identify barriers to adherence, review medical and psycho-social evaluations (since the prior visit), and address missing data or performance improvement elements.

The Joint Commission, using a disease management model, provides a national certification process that establishes standards of care that can be applied to virtually any disease or condition. These standards, when applied to our HIV patient population, provided MAEIS with the unique opportunity to critically examine every process and practice used within the program. Major tenets of the program include:

1) A robust and consistent data-supported approach to patient care,
2) The use of current research and evidence-based care guidelines,
3) Client/Family involvement in care,
4) Client education that supports wellness, and
5) A healthcare team that is consistently and continuously educated (The Joint Commission, 2011).

These concepts provided the MAEIS interdisciplinary team with the opportunity to perform a comprehensive program analysis using established standards for disease management as our guide.

The Joint Commission's disease management model, the medical home model, and the National HIV/AIDS goals are uniquely aligned to drive a culture of excellence to serve the HIV patient. At Capital Health, the benefits of aligning these strategies has brought improvement in the quality of care by reducing variation in clinical processes, facilitating continued use of data-driven performance improvement, creating a cohesive team, and strengthening client confidence.

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- Free, confidential testing and treatment for STDs.

www.state.nj.us/health/std/locations.shtml

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- TB regulations, screening, treatment resources

www.state.nj.us/health/tb

Reorganization of the New Jersey Department of Health and Senior Services, Division of HIV, STD, and TB Services

The initial reorganization of the Division of HIV, STD, and TB Services was described in the June 2011 issue of AIDSLine. It included integration of the Sexually Transmitted Diseases (STD) Program and the Tuberculosis Program with the Division of HIV/AIDS Services to form the Division of HIV, STD, and TB Services (DHSTS). Since then, the Division has reorganized to create synergies among programs, improve services to the Division's clients, and foster greater efficiencies.

To enable greater focus on the medical needs of the Division's clients, the Medical Director, Sindy M. Paul, MD, MPH, FACPM, assumed leadership of the Care and Treatment Unit which is now within the Office of the Medical Director. The TB Program, under the direction of Thomas Privett, remains in the Office of the Medical Director. To focus on synergies between the STD and HIV programs, the STD Program, under the direction of Patricia Mason, is now in the Office of the Assistant Commissioner under the direction of Connie F. Meyers, JD, and fiscal consolidation has been completed with Grants Management Officers (GMOs) reporting to the New Jersey Department of Health and Senior Services Management and Administration Unit. The Project Management Officers (PMOs) have been united in a new unit under the supervision of Clara Gregory. The DHSTS staff continues to work together as a team to strengthen its services and continue its nationally recognized work. The HIV Prevention and Education unit remains under the direction of Steven Saunders, MS, Director. Barbara J. Bolden, PhD, CPM, remains the Acting Director of the HIV Surveillance unit.

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AIDSLine

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Management of Pediatric TB in New Jersey
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For more information, contact
Jennifer K. Campbell: (973) 972-1261
or campbejk@umdnj.edu
NJ Medical School Global Tuberculosis Institute
and NJDHSS-DHSTS

New Jersey STD Clinical Update
Friday, March 30, 2012
NJ Hospital Association, Princeton, NJ

HIV Clinical Update
HIV Clinical Update 2012
Thursday, June 7, 2012
Hyatt Regency, New Brunswick, NJ

HIV/AIDS Training & Information Resources

New Jersey Department of Health & Senior Services – Division of HIV, STD, and TB Services (NJDHSS-DHSTS)
(609) 984-6328 | Hotline: (800) 624-2377
www.state.nj.us/health/aids

- NJ HIV/AIDS statistical reports, regulations, forms, and links to HIV care, prevention programs, and training New Jersey rapid testing site: www.state.nj.us/health/aids/rapidtesting
- **New Jersey HIV (Testing) Helpline:** 1-866-HIV-CHEC
- **New Jersey AIDS/STD Hotline:** (800) 624-2377

University of Medicine & Dentistry of NJ-Center for Continuing & Outreach Education-Division of AIDS Education (UMDNJ-CCOE-AIDS) (973) 972-3690 • Fax: (973) 972-3371
www.umdnj.edu/ccoe/aids

- **HIV/AIDS Conferences, training.**
- Free online CME/CE for healthcare professionals.
- HIV/AIDS MEDICAL UPDATE SERIES: with funding from NJDHSS

Free on-site HIV medical education for healthcare sites: contact Michelle Thompson at (973) 972-1293 or ccthomps@umdnj.edu

US Dept. of Health & Human Services

- **HIV/AIDS treatment guidelines**: www.aidsinfo.nih.gov
  National Institutes of Health database: http://clinicaltrials.gov

Centers for Disease Control (CDC) – Division of HIV/AIDS Prevention
www.cdc.gov/hiv/hivinfo.htm#WWW

- Surveillance reports, funding announcements, epidemiology slides

HRSA: Health Resources and Services Administration of the US Department of Health and Human Services:
http://www.hrsa.gov

- **HAB:** HIV/AIDS Bureau of HRSA: http://hab.hrsa.gov
- **TARGET Center:** Ryan White Program Resources: www.careacttarget.org
- **National Quality Center:** (HRSA-HAB): www.nationalqualitycenter.org

FDA MedWatch: 1-800-FDA-1088; Subscribe to e-bulletin:
www.fda.gov/medwatch/elist.htm

AIDS Education and Training Centers (AETC)
Resources for clinicians and educators: www.aidsetc.org

- **National HIV/AIDS Clinicians' Consultation Center:** www.ucsf.edu/hivcntr
- **National Center for HIV Care in Minority Communities:** www.HealthHIV.org
- **National HIV/AIDS Clinicians' Consultation Center:** www.ucsf.edu/hivcntr
- **Warmline: (800) 933-3413**
- **Post-Exposure Prophylaxis Hotline/PEPline: (888) 448-4911**
- **Perinatal HIV Hotline: (888) 448-8765**
- **AIDS InfoNet: HIV treatment fact sheets:** www.aidsinfonet.org

Mailing List: current subscribers: please fax a copy of this page to (973) 972-3371 with your label and note changes or request to stop; new requests: send a message with complete mailing and e-mail contact information to: ccoe-aids@umdnj.edu