



**DELTA REGION
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Diagnosis, prevention and treatment of perinatal HIV have undergone dramatic changes

Hannah Gay, MD, and April Palmer, MD

The first diagnosis of pediatric HIV infection in the state of Mississippi where we practice was made in 1987. In the years since that time, our understanding of the virus, the natural history of HIV disease, and the prevention and treatment of HIV infections has expanded at a dizzying pace. The past five years especially have presented dramatic changes in the areas of prevention of perinatally acquired infection and the treatment of infected children. *In the view of many experts, HIV disease, under proper therapy, is now considered a chronic illness rather than a fatal one.*

Current testing procedures

- *Antibody testing*

The antibody test remains the standard method of detection of HIV infection in patients over the age of 18 months. Because of the very serious consequences of an error of diagnosis, it is always

prudent to repeat diagnostic testing as confirmation for any patient with a positive test at one point in time.

Currently the “gold standard” for antibody testing consists of a two-step test. An initial assay for antibody by ELISA is extremely sensitive but lacks the specificity that is required for diagnosis. Therefore, a repeatedly positive ELISA is followed by confirmatory testing with Western Blot or IFA. The overall sensitivity and specificity of this combination of tests is reported to be greater than 99.9%. Although false negatives can occur under certain circumstances (i.e., very recent infection, agammaglobulinemia, loss of antibody during late stage disease, or infection with unusual strains of the virus), these cases are very rare.

During recent years, several rapid antibody tests and tests for detection of antibody in saliva and urine have been developed. Although the use of a rapid test may be clinically useful under

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Research

Where patient enters care impacts survival

Kathleen Welch, PhD

A number of studies have demonstrated differences in healthcare utilization patterns by race, gender, drug use and AIDS diagnosis.¹⁻⁴ Few studies, however, have investigated the effect of healthcare use on survival. The purpose of this study

was to determine if HIV+ persons who first obtained healthcare in New Orleans through public hospital inpatient services had a higher risk of death or disease progression than patients who first entered care through public outpatient services.

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Perinatal

50-80% of perinatal transmissions occur near or during delivery

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certain circumstances, each of these tests has limitations that render it unreliable as the sole method for making the diagnosis of HIV infection.

• HIV DNA PCR (Qualitative HIV PCR)

Because maternal antibodies to HIV readily cross the placenta and may be expected to remain detectable in the infant's blood for up to 18 months, antibody testing cannot be used to make the diagnosis of HIV infection in a perinatally exposed infant. Viral culture was at first used as the standard method for early neonatal diagnosis. Although the culture is highly specific and quite sensitive under optimal circumstances, it proved to be too expensive and logistically cumbersome to be used as screening for every exposed baby. Another early method, detection of viral protein p24 in plasma, was useful in some cases but lacked the sensitivity needed for reliable diagnosis.

The detection by polymerase chain reaction (PCR) of proviral DNA within infected mononuclear cells became available to clinical practice in the early 1990s and has revolutionized the diagnosis and treatment of perinatally exposed infants. Both the sensitivity and specificity of this test are very high and results can routinely be obtained in less than one week from the time of submission of the sample. *HIV DNA by PCR has now become the standard tool for making the diagnosis of HIV infection in*

babies less than 18 months of age.

Because of the extreme sensitivity of this method, greater than 90% of infections can be detected within the first two weeks following exposure and at least 98% of infected patients will test positive within the first month. *This makes it a very useful test not only in exposed neonates, but also in cases of older children and adults with suspected recent exposure and a need for rapid diagnosis, as in pregnancy.*

Prevention of perinatal transmission

Greater than 95% of cases of HIV infection in children under 13 years of age are perinatally acquired. Thus, breaking the cycle of mother-to-child transmission of HIV has been a major goal of researchers world-wide.

Information concerning factors that influence the risk of transmission of the virus from a mother to her infant has been gathered through various observational and treatment trials over the past decade. It has been established that transmission of the virus can occur in utero, during labor and delivery, or post-partum via breast milk. In the United States, it is estimated that 50-80% of transmissions occur near or during delivery.

Factors that are now known to increase the risk of transmission include:

1. high viral burden in the mother
2. advanced maternal disease (low CD4)

3. recent maternal infection, probably related to the high viral load observed at this stage of disease
4. prolonged rupture of membranes (>4 hours) prior to delivery
5. presence of other sexually transmitted diseases which may increase inflammation and compromise the integrity of the placental barrier
6. preterm delivery
7. procedures which increase fetal exposure to maternal blood and vaginal fluids (i.e., fetal scalp electrodes, fetal blood sampling, forceps delivery, etc.)

The first major breakthrough in prevention of mother to child transmission of the virus occurred in 1994 with the analysis of data from the Pediatric AIDS Clinical Trials Group (PACTG) protocol number 076. Results of this double-blind, placebo controlled trial showed that perinatal transmission of HIV can be reduced by a factor of 66% when using a regimen of prenatal, intrapartum, and neonatal zidovudine (AZT) therapy.¹ Since the implementation of "the 076 regimen" in the state of Mississippi in 1994, the perinatal transmission rate has fallen from almost 30% to about 5%.²

Offering zidovudine therapy to prevent perinatal HIV transmission has now become the minimum standard of care in the United States. The standard regimen involves two diagnostic and three therapeutic steps as summarized in Table 1. Steps include:



1. *Accurate detection of HIV infection in pregnant women*

Standard antibody testing should be offered to every woman during early pregnancy accompanied by appropriate pretest counseling. A clearly positive Western Blot should lead to further testing, either by a repeat antibody test or a DNA PCR, on a second sample to eliminate the possibility of error in diagnosis. In cases where the initial test is negative but risk-taking behavior has been identified by history, repeat testing later during the pregnancy may also be indicated.

Positive ELISA tests in uninfected women, occasionally accompanied by indeterminate Western Blot, are not infrequent during pregnancy, presumably due to the presence of cross reactive allo-antibodies. One cannot distinguish between this type of false positive and the similar test results that would be expected in early HIV infection. Because these cross reactive antibodies would be expected to remain in circulation until after delivery, it is essential that HIV infection be ruled out using DNA PCR testing in cases where Western Blot results are unclear.

This step of detection of maternal infection is quite troublesome in cases of delivery where prenatal testing has not been accomplished. The rapid antibody tests may be clinically useful in these cases, especially if high-risk behavior can be identified by history. If the rapid test is positive, intense counseling with the mother is essential to obtain informed consent since there will not be adequate time for confirmation of the diagnosis before initiating therapy for the baby. If neonatal therapy is begun on the

basis of a rapid antibody test result, confirmation of the mother's infection status by the most rapid method available (usually DNA PCR) should be done and the baby's therapy halted if the mother's PCR is negative.

2. *Prenatal therapy*

In the PACTG 076 study which concluded in 1994, the prenatal therapy which was shown to be effective at reducing perinatal transmission was 100 mg

HIV disease, under proper therapy can be a chronic illness rather than a fatal one.

zidovudine po five times a day beginning as soon as possible after 14 weeks gestation and continuing until onset of labor. Since that time, further pharmacokinetic studies have shown that less frequent dosing of ZDV provides adequate intracellular levels of the drug. Thus it is now recommended that ZDV administered for the prevention of perinatal transmission be given as 200 mg TID or 300 mg BID in order to increase ease of administration for the patient.

In addition to the change in dosing regimen, clinical experience over the past five years has led to the general consensus that combinations of antiretroviral drugs during pregnancy may be indicated to maximally treat the mother's disease and should be offered after discussion with the

mother of the known and unknown benefits and risks to the fetus. The Public Health Service has developed guidelines for antiretroviral therapy during pregnancy, the latest published in the MMWR on May 4, 2001.³ These guidelines discuss issues related to both the treatment for the mother's disease and the reduction of risk to the baby, and should be considered for each individual case.

Some foreign studies have shown benefit in using shorter term courses of ZDV during pregnancy. The reduction in risk in these trials has, however, not matched that of the 076 regimen and the short course treatment is recommended only when standard therapy has not been possible.

3. *Intrapartur therapy.*

The PACTG protocol used intravenous zidovudine from the onset of active labor until delivery of the infant. Although it is not known which portion of the therapy is most important (prenatal, intrapartur, or neonatal therapy), this intrapartur therapy is thought to be an important part of the efficacy and remains in the recommendations for the standard of care. A clinical trial conducted in Africa recently showed that even in the absence of long-term ZDV therapy, a single intrapartur dose of nevirapine followed by a single oral dose for the baby at age 48 hours resulted in a 50% decrease in the rate of viral transmission.⁴ Currently it is unknown whether the use of nevirapine in labor may add to the efficacy of the standard ZDV therapy.

Elective cesarean section as the mode of delivery has also been

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It is considered prudent to continue testing until age 6 months

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studied as a method of reducing perinatal transmission of HIV. Studies have shown reduction in the rates of transmission when elective cesarean is used over both vaginal delivery and emergency cesarean section. These findings have prompted the American College of Obstetrics and Gynecology to recommend offering elective cesarean section at 38 weeks gestation to HIV-infected women unless the woman has a known viral load <1000 near the time of delivery.

4. Neonatal therapy

The "076 regimen" includes as its third therapeutic element the treatment of the neonate with ZDV, beginning as soon as possible after delivery and continuing until age six weeks. The recommended dose of ZDV to be used in term infants was established in the 076 trial but later pharmacokinetic studies showed that lower doses and/or longer dosing intervals are indicated in infants born at less than 35 weeks gestation. Current dosing recommendations are summarized in Table 1.

In addition to the ZDV therapy, it is recommended that all exposed infants receive prophylaxis for *Pneumocystis carinii* pneumonia (PCP) beginning at age one month. Because HIV-infected infants between two and twelve months of age are susceptible to PCP and because the mortality rate is very high in this group, all potentially infected babies should receive prophylaxis until testing has conclusively shown the infant to be uninfected with HIV.

5. Determination of infant's infection status

Many perinatally infected infants will not have positive tests in the first few days of life even by the sensitive DNA PCR method. This is because the number of infected cells in a blood sample would be extremely low within the first few hours following the infecting event, and a majority of transmissions occur during the

labor and delivery process. However, an early PCR test is useful if a positive result is found. An early positive test may be indicative of intrauterine infection which carries a worse prognosis and demands early aggressive intervention. Therefore it is recommended that exposed babies have blood drawn for a DNA PCR prior to discharge from the nursery. In cases where the risk of transmission is higher

Table 1: Prevention of Perinatal Transmission of HIV

1. Accurate detection of HIV in pregnant women	<ul style="list-style-type: none"> A. Thorough history of risky behavior B. Testing offered to all women in early pregnancy C. Confirmation of all positive tests on a second sample D. Follow-up of indeterminate antibody tests (DNA PCR may be most appropriate for this) E. Rapid testing for women in labor with no previous testing results available
2. Prenatal therapy	<ul style="list-style-type: none"> A. ZDV 200 mg tid or 300 mg bid beginning at 14 week gestation B. Combination therapy if indicated for mother's disease, or viral load ≥ 1000, preferably containing ZDV as a component
3. Intrapart therapy	<ul style="list-style-type: none"> A. ZDV 2mg/kg IV over 1 hour followed by 1 mg/kg/hr IV until delivery B. Additional benefit of nevirapine during labor is under study C. Possible benefit of elective cesarean section
4. Neonatal therapy	<ul style="list-style-type: none"> A. ZDV to begin as soon as possible after birth and continue for 6 weeks: <ul style="list-style-type: none"> Term infants—2 mg/kg/dose po or 1.5 mg/kg/dose IV q 6 hours Preterm infants 30-34 weeks gestation—1.5 mg/kg/dose po or IV q 12 hours for 2 weeks followed by 2 mg/kg/dose q 8 hours Preterm infants <30 weeks gestation—1.5 mg/kg/dose po or IV q 12 hours with therapeutic drug monitoring B. PCP prophylaxis beginning at 1 month of age— <ul style="list-style-type: none"> TMP/SMX 5 mg/kg/dose q days until proven uninfected with HIV
5. Determination of infant's infection status	<ul style="list-style-type: none"> A. HIV DNA PCR at birth B. HIV DNA PCR at 1, 4, and 6 months of age C. Additional test at age 2 weeks if high risk for infection D. CBC at 1 and 4 months E. HIV antibody testing at 18 months of age



than normal because of failure to administer prenatal therapy or other causes of increased risk, a second PCR should be run at age two weeks. In routine exposure cases, the PCR should be done at one, four and six months of age in order to rule out HIV infection in the baby. The Centers for Disease Control guidelines stipulate that infection has been reasonably ruled out in an infant who has had at least one negative PCR past one month of age and a second negative past four months of age. Discontinuing PCP prophylaxis is indicated when these criteria have been met. However, a few cases of late conversion have been reported and it is now considered prudent to continue testing until age six months.

Most babies lose maternal anti-HIV antibodies at nine to fifteen months of age. An antibody test on the baby should be negative by age eighteen months and should be done on all HIV exposed HIV DNA PCR negative babies at that age so that perinatal infection can be ruled out.❖

REFERENCES

1. Conner EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med* 1994;331:1173-80.
2. Palmer AL, Gay H, Currier MM. The impact of zidovudine use in HIV-infected pregnant women on vertical transmission of HIV in Mississippi. *J Miss State Med Assoc* 2000;41:479-83.
3. Public health service task force recommendations for use of antiretroviral drugs in pregnant HIV-1 infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. *Living Document, publication pending.*
4. Quay LA, Musoke P, Fleming T, et al., Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* 1999;354:795-802.

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LaCARP is seeking special group of patients for study

Patients who have been exposed to all classes of antiretrovirals and are now resistant are being sought for a multidrug resistant (MDR) study at the Louisiana Community AIDS Research Program (LaCARP).

The main intent of the MDR study is to compare the long-term (minimum 24 months) clinical benefits and risks of a four-month break in drug treatment followed by introduction of new antiretroviral drug treatment versus immediately starting a new antiretroviral drug treatment, in HIV-infected patients with multidrug resistant virus.

Participants must:

- be HIV-infected
- be 13 years or older
- sign an informed consent
- have evidence of MDR virus based on the results of GART
- have viral load level >10,000 copies/mL from the same blood draw as the qualifying GART specimen
- intend to initiate a new antiretroviral drug regimen at protocol-designated times
- be on a stable antiretroviral regimen between 14 days prior to the qualifying GART specimen collection and randomization

Participant must not:

- have received any vaccinations or have an acute illness within 14 days of GART specimen
- used IL-2 within 120 days prior to the date of the qualifying GART specimen or between that date and randomization
- have active OI requiring acute treatment
- be pregnant or breastfeeding
- be currently followed in the PIP study (CPCRA 057)

For more information, call 584-1971 and ask for a research nurse.❖

Ask the Experts forum is for HIV clinicians

Check out the Ask The Experts forum on the website of the AETC's National Resource Center at www.aids-ed.org.

Rather than a consultation service, it is intended as a resource and point of discussion for clinicians regarding the PHS AIDS/HIV Treatment Guidelines. In particular, it is useful in learning the rationale for recommendations, discussing nuances of the recommendations, and gaining insight into new versions of the Guidelines.

To access the forum, just log on to www.aids-ed.org and click on the Ask The Experts link.

Clinical Consultation for Health Care Providers

Delta Region health care providers can consult with HIV experts at university medical centers:

- Louisiana 504-903-0788
- Mississippi 601-984-6105
- Arkansas 870-535-3062

National Consultation Lines:

- National Warmline 800-933-3413
- National PEPLINE 888-448-4911



Research

Patients who first access care as inpatients are at higher risk

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The sites included the HIV Outpatient Clinic of MCLNO, two early intervention sites and a public hospital. A medical record review on patients who attended these sites from July 1995 through December 1999 and were enrolled in the Centers for Disease Control and Prevention Adult Spectrum of Disease (ASD) Study was conducted (N=3402). Logistic regression, Kaplan-Meier analysis and Cox proportional hazards regression were performed.

Of the 3402 HIV+ individuals, 805 (23.7%) received initial care through the public hospital inpatient services. The bivariate analysis indicated that the following covariates were associated with initial care through inpatient services: African-American race, female gender, older age (>45 years) and injection drug use (IDU) or no reported risk as the HIV risk factor. Clients first using inpatient services were also significantly more likely to have a diagnosis of AIDS at entry into the study and alcohol and/or drug (AOD) use. They were more likely to miss all scheduled outpatient visits in the six-month interval after study start (marginally significant).

A multivariate logistic regression model, including all of the significant unadjusted main effects in the bivariate analysis, was constructed. After backward elimination, all of the significant factors in the bivariate analysis remained independently associated with initial HIV care through inpatient services, except for female gender (table 1).

For the survival analysis, Kaplan-Meier analysis and Cox proportional hazards regression were performed. Risk of death or disease progression was analyzed for three different endpoints after adjusting for stage of disease: time from study entry to death, time from HIV to AIDS and time from AIDS to death. The risk of death or disease progression for patients first using inpatient services was significantly higher for all three endpoints. Table 2 shows the relative risk of death for individuals who had AIDS and first entered care through inpatient services—RR=1.65 (1.37, 1.99).

This study indicates that HIV+ individuals first entering care through public hospital inpatient services had a higher risk of death and disease progression than HIV+ individuals entering care through public outpatient services. The patients entering care through inpatient services were significantly more likely to be African-American, have IDU for the HIV risk factor and AOD use. They were also more likely to miss all scheduled outpatient visits in the six-month interval after study start. These factors could impede their access to and use of care. They were also older and this could lead to more health care problems that may impede treatment. Innovative and culturally acceptable approaches are needed to improve this group's access to early HIV care since the majority (66%) entered care with AIDS. It is important to further monitor survival trends over time among such groups in order to improve treatment and services.

REFERENCES

1. Kissinger P, Cohen D, Brandon W, Rice J, Morse A, and Clark R. Compliance with public sector HIV medical care. *J Natl Med Assoc.* 1995; 87:19-24.
2. Piette JD, Mor V, Mayer K, Zierler S, Watchel T. The effects of immune status and race on health service use among people with HIV disease. *Am J Public Health.* 1993;83:510-514.
3. Mor V, Fleishman JA, Dresser M. Variations in health service use among HIV-infected patients. *Med Care.* 1992;30:17-29.
4. Solomon L, Frank R, Vlahov D, Astemborski J. Utilization of health services in a cohort of intravenous drug users with HIV-1 serostatus. *Am J Public Health.* 1991;81:1285-1290.

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Table 1. Logistic Regression Predicting Initial HIV Care through Inpatient Services

	OR*	95% CI
AIDS Diagnosis (at entry)	2.48*	(2.09, 2.96)
Alcohol Abuse	1.70*	(1.32, 2.19)
Depression	.53*	(.42, .67)
Drug Use	1.47*	(1.20, 1.80)
IV Drug Use as Risk Factor	1.97*	(1.59, 2.43)
'Unknown' as Risk Factor	1.71*	(1.38, 2.12)
Race (African-American vs White)	1.82*	(1.10, 3.02)
Age (>45 vs <=45)	1.50*	(1.11, 2.01)

*OR is statistically significant (CI does not include 1).

Table 2. Risk of Death for AIDS Patients by Initial Health Care Utilization

	RR*	95% CI
Prescribed HAART Therapy	.27*	(.22, .33)
Race (African-American vs White)	1.42	(.78, 2.60)
Inpatient Services for Initial Care (Inpatient vs Outpatient)	1.65*	(1.37, 1.99)

*RR is statistically significant (CI does not include 1)



Mississippi's HIVRAN Project

HIV network makes high quality care available to rural patients

Harold Henderson, MD

The Mississippi HIV Rural Area Network (HIVRAN) is an organized network of care whose goal is to integrate and streamline HIV services in Mississippi between public health department clinics, rural primary care clinics, and the University of Mississippi Medical Center (UMMC) in Jackson. Such an integration of services is needed if the many barriers to care faced by HIV-infected persons are to be eliminated. These barriers include a shortage of qualified HIV clinicians outside the Jackson urban area, feelings of isolation by clinicians in rural communities, lack of insurance, and lack of transportation.

The HIVRAN is a computer network that grew out of a computer-based distance learning program funded as one of the Special Projects of National Significance (SPNS) at UMMC during the years 1994-1999. As part of the SPNS project, selected federally funded community health centers in Mississippi were supplied with computer equipment, and their clinical staff underwent intensive, comprehensive HIV training primarily through distance learning. By the end of the project period, relationships of mutual trust and respect had been solidified between the HIV care team at UMMC and the community health centers. Several of these expressed willingness to become established and known as clinics where HIV-infected persons would be welcome and receive

care. Most of these community health centers are located outside of Jackson in rural parts of the state, areas that historically had been lacking qualified HIV practitioners.

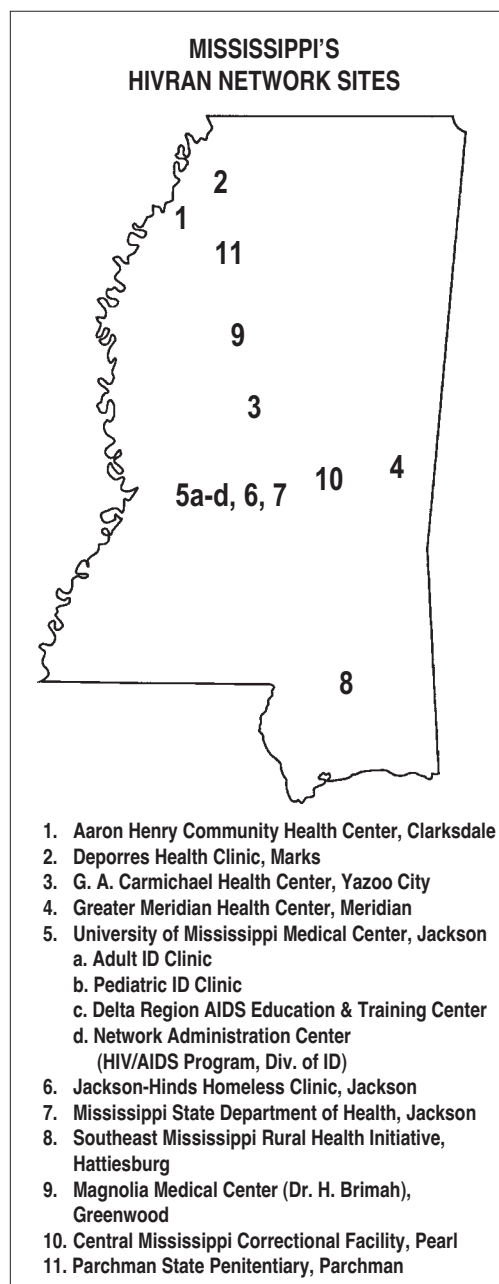
The current members of the Mississippi HIVRAN include UMMC, the MS State Health Department, the MS Department of Corrections, and several community based clinics located in various parts of the state (see map). Members communicate with each other frequently by e-mail and through a highly secured, shared database system. In addition, meetings of HIVRAN members are held in Jackson every two months to establish and fine-tune HIVRAN policies.

The primary objectives of the HIVRAN can be summarized as follows:

1. *Referral.* Persons who are newly diagnosed with HIV infection at a health department clinic can be referred via the secured computer to an HIV-experienced clinician in their particular area of the state. Infected persons would previously have been automatically referred to UMMC, the primary tertiary referral center in Mississippi, but can now be referred by the health department to a caregiver closer to their home. Patients who have been struggling to travel long distances to UMMC in Jackson can now be referred to a clinician located more conveniently to them. HIV positive inmates who have been incarcerated and are being released from prison can also be referred to a local caregiver via the HIVRAN, and their care can be transitioned rapidly. These referral activities have recently begun and are increasing.

2. *Consultation.* Community-

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based clinicians and case managers in the HIVRAN may consult with their counterparts at UMMC for help with complex HIV-related issues. Consults may be done using e-mail, fax, telephone, or through the computer network. This activity is just beginning.

3. *Educational support.* HIVRAN providers are offered regular educational updates and training on HIV and related topics, with full CME credits through the Mississippi Resource Center of the Delta ETC.

4. *Continuous Quality Improvement.* A CQI program for HIVRAN consultation and referral is currently being designed for implementation as part of the statewide network, to ensure that all members are delivering the latest standards of HIV care.

One measure of success of the HIVRAN to this point has been the award of three new Title III Ryan White grants, one involving a consortia of four community health centers and the other two each to community based clinics. All of these clinics are members of the HIVRAN, and the support received by these rural clinics as part of their membership in the network was a significant contributing factor to their receiving Ryan White funding. A continuing challenge remains issues of confidentiality and patient records. Currently, HIV positive persons are not entered into the computer network without their informed consent, and steps to maintain the integrity of patient records on the HIVRAN have been taken and continue to be reviewed.

The conclusion of the SPNS distance learning project in 1999

turned out to be merely the end of the beginning. The SPNS project has been successfully transitioned to an ongoing organized HIV care network, which is helping to make high quality HIV care available to persons living even in remote areas of Mississippi.

The education, training, and consultation activities of the HIVRAN fall closely in line with the activities of the AIDS Education and Training Centers, and funding support for the HIVRAN is now maintained through the Delta ETC. The HIVRAN promises to be a powerful tool in the fight to eliminate those barriers to HIV care in Mississippi mentioned at the beginning of this article.❖

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substernal in location, radiating to the left arm or jaw and relieved by rest in ten minutes or by nitroglycerine in three minutes.

Digestive. Lab results, biopsy and charting of weight loss are required.

Genito-urinary System. SSA requires laboratory findings and a report of the deterioration of renal (kidney) function, as well as charting the weight loss.

Hemic and Lymphatic System (blood disorders). Laboratory findings and pathology reports are required.

Skin. SSA requires information that the lesions have not responded to prescribed treatment.

Endocrine System. The endocrine system impairments involve diabetes and thyroid disorders. Health care providers must provide laboratory findings and x-ray evidence.

Neurological. Neurological disorders such as epilepsy require an EEG as well as laboratory findings that the prescribed medication is at a therapeutic blood level. Any evidence of alcohol consumption while on seizure medication will result in an automatic denial of the claim.

Mental Disorders. Mental impairments are particularly difficult to establish as independently disabling under SSA's rules. The health care provider needs to provide extremely detailed information concerning the patient's presenting problems, treatment and daily activities.

Neoplastic Diseases. The health care provider must provide a pathology report along with detailed information concerning location of the neoplasm, metastases (if any), treatment, and response to treatment. Certain cancers are more amenable to treatment than others. For example, oat cell carcinoma is considered disabling but non-metastatic breast carcinoma is not.

Last, and probably most importantly, keep communication open with the claims examiners at the Disability Determination Unit of Social Security. Frequently, the claims examiners lack only minor information in order to render a decision favorable to your client. However, unless they can get this information from the healthcare provider, the claim may be delayed by having to purchase this information through a consultative examination. Greater weight is generally given to medical evidence provided by a treating clinician than to evidence supplied through consultative examination.❖

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Legal

Social security disability rules are clarified for HIV clinicians

by Iska Beck, JD

There are common misconceptions among both providers and patients about who is or is not considered disabled from Social Security's perspective. This article provides an outline of requirements for a finding of disability under Social Security rules and regulations for adults; impairments for children are rather different and are not covered.

The Social Security Administration (SSA) defines disability as (1) the inability to engage in any substantial gainful activity (2) by reason of any medically determinable physical or mental impairment(s) (3) which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months. This is a threshold issue for disability and SSA is very serious about the duration requirement. If the applicant's medical condition is only temporarily disabling, like a broken leg which is expected to heal within twelve months, the applicant is not disabled.

The rules governing all aspects of Social Security issues and claims can be found in the Code of Federal Regulations and the United States Code. Anyone wishing to see a complete listing of impairments can contact SSA or look the regulations up in a law library. While the list is not exhaustive for all known medical conditions, an applicant who has a listed condition invariably has an easier time in qualifying than one who has a more unusual medical condition or a combination of medical conditions.

SSA considers a wide variety of evidence in making a disability determination. Keep in mind, however, that this is a medical disability program which requires evidence of medical treatment; simply put, a patient will never get Social Security disability without treatment. While SSA will consider a client's self-reporting testimony, they are more interested in objective medical evidence found in medical reports. Also, it is not enough for a treating clinician to write a note saying a patient is disabled without giving a detailed description of the disability.

There are thirteen categories, or "listings," of impairments for adults. All of AIDS Law's clients will be evaluated, at least in part, under the immune system listing. The immune system listing covers both

overactive and dysregulated immune system disorders (like lupus, systemic sclerosis, scleroderma, Raynaud's phenomena polymyositis and dermatomyositis) and immune suppressed disorders like HIV/AIDS.

Because HIV suppresses the immune system, all other body systems are potentially vulnerable to attack by opportunistic infections. As such, many of the listed impairments refer the SSA examiner to other body systems for evaluation of disability, such as neurology, neoplasm (cancers), skin, blood, cardiac or genitourinary. The potential for HIV to affect all systems makes the determination of disability difficult for all involved, claimants, SSA examiners, representatives and the court system.

An HIV diagnosis alone is not enough to establish disability.

SSA will look initially at the T-cell or CD4 count, as a measure of whether the patient has a sufficiently suppressed immune system to be at risk for opportunistic infections, but not all opportunistic infections are considered equally disabling. Additionally, the SSA examiner is instructed to evaluate information concerning fatigue, weight loss, night sweats, pain, restriction of daily living, difficulty in maintaining social functioning and difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

It is critically important that patient files are fully documented. The report by the health care provider is given greater evidentiary credibility than a consulting clinician's report purchased by SSA.

Questions which measure fatigue are usually phrased in terms of "How far can you walk before you must rest?" and "Are you able to clean a complete room in your home before resting, or only part of a room?" Some of the Administrative Law Judges prefer to measure fatigue in terms of "how many minutes can you walk before tiring?" Another common issue tied to fatigue is sleep disturbance, whether the patient is able to sleep through the night and if not, what causes the patient to awaken. It is extremely important for the health care provider to document this information as SSA is more likely to accept this type of report from the health care provider rather than by only the patient's testimony.

Reports of pain by a patient also need to be referenced in the medical records. This includes pain from any separate orthopedic condition, from herpes or from neuropathy. If neuropathy exists, the record should state whether the pain is limited to the feet or extends to the hands as well. If pain in the hands would limit a patient's ability to use a computer or to write, this fact should be recorded in the patient's file since such limitations definitely limit the ability to engage in sedentary work. Many applicants for Social Security disability who are unable to return to past work still have their claims denied because SSA considers them able to perform lighter duty or sedentary work. If a patient is restricted to less than a full range of sedentary work, SSA will usually award disability.

Psychiatric components such as restrictions of daily activities, difficulties in maintaining social functioning, forgetfulness, memory loss, and difficulties in completing tasks in a timely manner also serve to limit a patient's ability to engage in sedentary work. Questions such as "Do you have trouble remembering to take your medications?" or "Do you have to write down reminders to yourself?" are usually an easy way to begin questioning patients who are frequently extremely embarrassed by their current memory losses.

The other 12 adult listings and the types of evidence follow. Please note that furnishing the evidence does not mean the patient will win, but without the evidence the patient will almost surely lose.

Musculoskeletal. The health care provider will need to describe any non-union of a fracture or range of motion of the affected area of the body by degrees.

Special Senses and Speech. Provide findings on visual fields and visual acuity needs. For a hearing loss, provide test results.

Respiratory. Interpretation of chest x-rays and results of pulmonary function studies along with laboratory findings must be provided.

Cardiovascular System. For cardiac impairments where there is chest pain, a diagnosis of angina without a specific description of the chest pain will be considered inadequate. The doctor must describe the chest pain in the terms SSA wants, i.e., the pain is squeezing, burning,

See Social Security page 8



Mental Health

How can clinicians determine whether patients are malingering?

Jill Hayes Hammer, PhD

Substance abuse, HIV/AIDS, and other physical and emotional conditions often co-occur, a fact which is surely not shocking to any clinician reading this article. IV drug use is reported to be the cause of one-third of cumulative AIDS cases in the United States, and approximately 20-50% of HIV and AIDS patients are diagnosed with a co-occurring mental illness. How to treat individuals with comorbid disorders and how to determine when an individual with HIV/AIDS has “real” pain or other complaints and when a patient is exaggerating or malingering pain complaints to obtain prescription medications is the focus of this article.

Malingering refers to the intentional production of false or grossly exaggerated symptoms and is often difficult to diagnose, as it is a disorder of exclusion rather than inclusion (American Psychiatric Association, 1994). Similar to the criminal justice system model whereby an individual is innocent until proven guilty, care providers, rightly so, believe the veracity of the histories and reported symptoms provided by a patient until faced with overwhelming evidence that the patient is not being truthful. Helpful in determining whether or not an individual is malingering are the following red flags:

- Repeated requests for prescription medication without clinical indicators or signs
- Anger and rage when denied these medications
- History of drug abuse and/or dependence

- History of legal difficulties
- Presence of Antisocial Personality Disorder
- Evidence of secondary gain
- Variability in the way the patient presents with different providers
- Improbable symptoms inconsistent with any known medical syndrome
- Refusal to submit to urine drug screens

When the drug-abuse-or-dependence-history flag is raised, what do you do? Many individuals with current or previous drug dependence experience chronic pain and other physical and emotional difficulties and need treatment. Lu, Passik & Portenoy (1992) reported that inadequate management of pain, as well as untreated anxiety, depression, insomnia, and problems of adjustment may lead patients to self-medicate. However, many patients without chronic pain malingering to obtain prescription drugs to abuse, sell, or trade. In fact, most researchers would agree that approximately 35-53% of patients with chronic pain either malingering or exaggerate symptoms when seeking disability compensation (c.f., Gervais, Allen, Green, Cunningham & Iverson, 1998; Gervais, Russell, Green, Ferrari, Pieschl & Allen, 2000). So, how do you tell which is which? The following case examples illustrate this conundrum.

Max was a patient at an HIV clinic. He had a CD4 count of 50 and no opportunistic infections. He complained of back pain and neuropathy—two subjective complaints that are hard to verify. Max was specific in requesting

Dilaudid for pain. Discussions with the primary care physician revealed that no red flags were raised, due to Max’s extremely poor health. The primary care provider prescribed Dilaudid, but Max missed follow-up primary care and neurology appointments, yet would call to request refills for pain medications. The social worker suspected the patient was using drugs and discussed this with the primary care provider who ordered a urine drug screen. Max tested negative for Dilaudid and positive for cocaine. The police arrested Max after learning that he sold Dilaudid. The street value of the previously prescribed medication was approximately \$6,500.00. He used this money to buy cocaine. Upon Max’s return to the clinic, the physician discontinued the Dilaudid, and the patient never returned to the clinic.

In another case, Danny admitted using IV drugs, including heroin and others. His CD4 count was less than one hundred. He asked for pain medications secondary to reported severe stomach and gut pain. In this case, because of his active drug use and because one of the side effects of heroin withdrawal is cramping, he was not prescribed any pain medications. Danny was later diagnosed with CMV colitis, necessitating a colon resection.

A thorough assessment should first be conducted including a review of the patient’s substance use history. Some clinicians may be hesitant to discuss this topic with patients as they may feel asking will offend, embarrass, or anger the patient. However, there are ways to ask which will not



offend or embarrass most people. Learning the street names for drugs is also a must. For example, do you know what a “blunt” or “clickum” is? Using these terms rather than “marijuana cigarette” or “marijuana cigarette laced with PCP” results in increased patient honesty. When substance abuse is strongly suspected, reliable information can be obtained from asking questions that over-estimate the amount of use. For example, “how many rocks do you smoke a day... twenty, thirty?” This line of questioning allows the patient to normalize his or her behavior. Additionally, ask about the desired effects of the drugs used, thus allowing the clinician a window into why drugs are being used, what types of treatments could be effective, and what could be the underlying etiology for the drug use. Requesting a consult from a mental health clinician helps clarify the etiology of the pain complaints, whether due to personality factors, mental illness, or unremitting pain (Lu, Passik & Portenoy, 1992).

In situations where clear evidence indicates a patient is malingering, the diagnosis should be made. Confronting the patient in a caring supportive manner, one in which respect for the individual is conveyed, is the best approach. Arguing and getting upset with the patient helps neither the patient nor the clinician.

A team of clinicians including members from primary care and mental health, working together with a substance abuse treatment program is often the most helpful. Establishing a treatment contract with the patient that spells out the services to be provided, the caregiver’s expectations about the

patient’s behavior, and what will occur if the patient violates the contract’s requirements is essential. Behavioral violations could include missing appointments, requests for early refills, “loss of prescriptions, misuse of prescription drugs, disruptive behavior in clinic or hospital, or use of illicit drugs during hospital stays” (Friedland, GH, unpublished manuscript, p. 3). In this author’s experience, relapse prevention plans based on risk factors and other variables learned through clinical and collateral interviews are necessary for successful treatment. Table 1 is an example of a treatment plan.

The behavioral contract and the level of monitoring necessary should be based on the perceived level of relapse risk, as well as the medication’s potential for abuse. Educating both patients and family members about responsible prescription drug use is useful in attempting to eliminate abuse of the medication. Treatment of comorbid psychiatric disorders is a must as mental illness is a risk factor for relapse. Toxicological testing is often helpful in determining if a patient is using drugs and also serves the dual role of discouraging drug use.

Finally, a caution: a malingering diagnosis should never be made lightly. In the medical setting, a misdiagnosis of malingering could deny an honest person benefits, medications, and treatment. Furthermore, misdiagnosis could allow for deterioration in the original condition because of lack of treatment. A diagnosis of malingering can be stigmatizing and can follow a person through his or her medical chart for the foreseeable future. ❖

REFERENCES

- American Psychiatric Association. (1994). *Diagnostic and statistical manual of mental disorders* (4th ed.). Washington, DC.
- Gervais, R.O., Allen, L.M., III, Green, P. & Cunningham, S. (1998). The effects of coaching DSM-IV Pain Disorder patients on the Computerized Assessment of Response Bias. *Archives of Clinical Neuropsychology*, 14(1), 97-98.
- Gervais, R., Green, P., Russell, A.S., Pieschl, S., & Allen, L.M., III (2000). Failure on symptom validity tests associated with disability incentives in fibromyalgia patients. *Archives of Clinical Neuropsychology*, 15, 841-842.
- Lu, H.U., Passik, S.D., & Portenoy, R.K. (1992). Management of chronic pain in the patient with substance abuse. In G.M. Arnoff (Ed.), *Evaluation and Treatment of Chronic Pain* (3rd ed., pp. 421-432). Baltimore, MD: Williams & Wilkins.

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Table 1. An example of a treatment plan

RISK FACTOR	SHORT-TERM GOAL	LONG-TERM GOAL
Drug use	Weekly appointments; urine drug screens; substance abuse treatment	Patient remaining drug free
Peer group endorses drug use	Peer counselor or AA sponsor	Development of a drug-free peer group
Co-morbid major depression	Psychiatric care and counseling	Maintenance of mental illness through mental health care



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▲ A Retrospective Cohort-Based Survey of Patients Using Twice-Daily Indinavir + Ritonavir Combinations: Pharmacokinetics, Safety, and Efficacy [Burger DM, et al. JAIDS 2001;26:218]

▲ Mode of Delivery and Postpartum Morbidity Among HIV-Infected Women: The Women and Infants Transmission Study [Read JS, et al. JAIDS 2001;26:236]

▲ Association of Cancer with AIDS-Related Immunosuppression in Adults [Frisch M, et al. JAMA 2001;285:1736]

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▲ HIV-Associated Non-Hodgkin's Lymphoma: Incidence, Presentation, and Prognosis [Little RF, et al. JAMA 2001;285:1880]

▲ HIV Lipodystrophy: A Review [Kravcik S. HIV Clin Trials 2000;1:37] [Alexander CS, et al. AIDS 2001;15:601]

▲ Viral burden in genital secretions determines male-to-female sexual transmission of HIV-1: a probabilistic empiric model [Chakraborty H, et al. AIDS 2001;15:621]

▲ Nevirapine or efavirenz combined with two nucleoside reverse transcriptase inhibitors compared to HAART: A meta-analysis of randomized clinical trials [Torre D, et al. HIV Clin Trials 2001;2:113]

▲ Breast Feeding Safer Than Mixed Feeding for Babies of HIV Mothers [Wise J. BMJ 2001;322:511]

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