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Comprehensive update on antiretroviral therapy in HIV-infected children

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In the early years of the HIV/AIDS epidemic, approximately 20-25% of perinatally infected infants rapidly progressed to death within the first year of life, typically from pneumocystis pneumonia (PCP).¹ Antiretroviral therapy (ARV) provided as mono- or duo- therapy did not effectively change the natural history of perinatally acquired HIV. In adults, treatment with highly active antiretroviral therapy (HAART) consisting of three or more drugs, including a protease inhibitor (PI) and/or a highly efficacious non-nucleoside reverse transcriptase (NNRTI) inhibitor such as efavirenz (EFV), has dramatically increased life expectancy and decreased progression to AIDS.² PIs were first available to pediatric patients in 1996 and HAART therapy first appeared in national guidelines for HIV-infected

pediatric patients in 1998.³ However, children cannot be treated as small adults. Many ARVs are not available in a palatable liquid form, or have not been adequately studied in pediatric patients. Pharmacokinetic (PK) parameters vary greatly between pediatric and adult patients and often vary as well between distinct pediatric age groups. Adherence issues also differ between adult and pediatric patients.² Until adolescence, medication adherence is the sole responsibility of adult caretakers, who may face multiple barriers to administering complicated medication schedules to their children including dealing with their own illness.⁴ Due to the many complexities of treating HIV-infected infants and children, only experts in pediatric HIV should treat this population.

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Incarceration creates special issues for HIV clinicians

*Linton Carney, JD, and
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Although HIV/AIDS has affected many groups, perhaps the people most disproportionately affected are those who have been or are presently incarcerated. The United States leads the world in the number of its citizens living behind bars.

According to a report just issued by the United States Department of Justice, there were more than 2,000,000 people incarcerated in the federal and state systems as of December 31, 2002.¹ Overall incarceration rates are highest in the South, and according to 2002 figures, there were 36,171

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HIV-infected children cannot be treated as small adults

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Pharmacokinetics

Due to evolving organ function, pharmacokinetics change during infancy and childhood, with the greatest changes occurring during the first month of life. Aspects of developmental physiology which may affect drug therapy include drug bioavailability, renal and hepatic clearance, and changes in volume of distribution and plasma protein binding.

Drug bioavailability may be affected by multiple factors in the neonatal gastrointestinal tract. The newborn has a neutral gastric pH. In addition, delayed gastric emptying, increased intestinal transit time, and frequent feeding affects drug absorption in the neonate. Drugs such as nelfinavir (NLF) may be metabolized in the neonate by fetal intestinal CYP3A4.⁵

Renal clearance starts out quite low in the newborn and rapidly increases during the first month of life. In childhood, renal function approaches adult levels by age 3 to 4.⁵

Most hepatic metabolic functions are significantly reduced in the neonate and do not reach adult levels until later in childhood. Activity of many hepatic metabolic enzymes exceeds adult values in early childhood declining to adult values after puberty.⁵

Total body water is higher in the neonate and is higher in the preterm than full-term neonate, resulting in an increased volume of distribution and thus requir-

ing higher dosing of some drugs. Lower plasma protein concentration and protein-binding avidity requires other drugs to be dosed at lower levels.⁵

The PK parameters of multiple antiretroviral drugs in pediatric patients are known. The nucleoside reverse transcriptase inhibitor (NRTI) zidovudine (ZDV) has undergone extensive PK evaluation due to its use in prevention of perinatal transmission. Clearance of ZDV is diminished in neonates with total body clearance rates slower in the first 14 days of life and slower in preterm versus term infants. The resulting differences in half-life result in different dosing recommendations of neonatal ZDV based on gestational and chronological age. Other NRTIs such as lamivudine (3TC) and abacavir (ABC) have varied clearance rates between neonates, infants 1-3 months of age, and infants older than 3 months. The NNRTIs viramune (NVP) and efavirenz (EFV) are primarily hepatically metabolized. Therefore with hepatic enzyme maturation comes different rates of clearance in the various pediatric groups. NVP when given to the mother during the intrapartum period results in a long half-life in the newborn. After birth, neonatal dosing results in a much shorter half-life. Since hepatic clearance of this drug exceeds adult values in early childhood, higher dosing of NVP is needed until age 9 in HIV-infected children. Similar to NVP, EFV also requires higher dosing in young children. Since the protease inhibitor NLF was available in powder form quickly after its

release, much is known about its PK parameters in children. Like all PIs, NLF is hepatically metabolized and its kinetic features exhibit a great degree of inter-individual variability in adults. This variability is even more accentuated in children and particularly infants as hepatic function matures. Clearance rates generally are significantly higher in children than adults. Furthermore, clearance is not only affected by age but by weight, with children less than 25 kilograms requiring higher and more frequent dosing. Absorption is also variable since bioavailability of NLF is affected by food intake.⁵

Any new ARV introduced must have PK data collected in multiple pediatric age groups with particular attention paid to how changes in body mass, gastrointestinal absorption, plasma protein concentration, hormonal changes of puberty, as well as renal and hepatic clearance, affect PK parameters.

Adverse Events

In general, clinical trials have shown that ARVs are well tolerated in pediatric patients. The adverse event profile is relatively similar to that of adults with few exceptions. Gastrointestinal side effects such as nausea, vomiting and diarrhea are approximately as frequent in pediatric patients as in adult patients. The incidence of rash is similar between children and adult patients treated with NNRTIs. Central nervous system complaints with EFV, however, are less frequent in children than adults.^{1,6-8}

Long-term adverse events of HAART in children have been evaluated in a few studies. Lipodystrophy has been reported to occur in ~30 % of pediatric patients treated with antiretrovirals.² Risk factors for developing lipodystrophy in HIV-infected children may include treatment with PIs, a favorable virologic response to HAART or HIV infection itself. At least one study suggests that stage of pubertal development may have the greatest influence on development of this syndrome of fat redistribution. In the study by Taylor et al, new lipid abnormalities and lipodystrophy appeared only in pediatric patients who started HAART therapy while progressing through puberty.⁹ Very long-term toxicity data on infants starting ARV therapy under 12 months of age is underway.

Efficacy

Differences in the natural history of disease acquired perinatally as opposed to adult infection need to be considered when evaluating the efficacy of ARV therapy. As opposed to primary adult infection, perinatal infection typically results in very high viral loads in the first year of life with a slow fall over the next one to two years. Lymphocyte counts are also much higher in normal infants and children than in adults and slowly decline to adult levels by age 6. Therefore when evaluating immunologic function in infants and children under 6 years, it is necessary to use percentage rather than absolute numbers of CD4 cells.³

In the last decade multiple clinical trials of HAART therapy have been completed both inside and outside the US. More re-

cently many of these trials have included infants under 3 months of age. In an open label trial completed by the Pediatric AIDS Clinical Trial Group (PACTG), 57 children ages 3.8-16.8 years, 55 of whom had been previously treated with NRTIs only and two of whom were ARV naïve, were treated with a combination of EFV, NLF and NRTIs. An intention-to-treat analysis revealed 76% and 63% of patients had viral loads of < 400 copies/ml and < 50 copies/ml, respectively at 48 weeks.⁶

Due to the many complexities, only experts in pediatric HIV should treat this population.

In an open label trial of the Pediatric European Network of Treatment of AIDS (PENTA), 20 infants under 3 months of age were treated with stavudine, didanosine and NLF. In this trial only 37% and 21% achieved viral load suppression of less than 400 copies/ml and <50 copies/ml, respectively at week 48. Only 26% had viral loads <400 copies/ml at week 72.¹ Another multicenter open-label trial performed in both developed and developing countries showed better virologic results when a more potent protease inhibitor, lopinavir/ritonavir (LPV/r) was used. In this trial, 100 infants 6 to 12 months of age received LPV/r together with stavudine (d4T) and 3TC in ARV-naïve or LPV/r with NVP

and one or two NRTIs if ARV-experienced. Two different doses of LPV/r were used initially with all patients switched to the higher dose once the PK/adverse event profile was known. In this trial, 79% and 66% achieved viral loads of <400 copies/ml and < 50 copies/ml, respectively by week 48. ARV-naïve and PI-naïve patients had better virologic responses than PI-experienced patients.⁷

Another PACTG open-labeled study in 52 infants and children stratified therapy into early (< 3 months of life) and delayed (> 3 months of life) therapy groups. All of the patients were PI and NNRTI naïve. Within these two groups the patients were further stratified into one of three treatment groups: ZDV, 3TC and NVP; ZDV, 3TC, NVP and ABC; or d4T, 3TC, NVP and NLF. Fifty percent of these patients reached a viral load < 400 at 48 weeks of therapy. Forty-four and 42% had viral loads <400 copies/ml and <50 copies/ml, respectively at 200 weeks. In this study, better virologic responses were seen in children treated at < 3 months of age (60% with viral load <400 copies/ml at week 200) and in those treated with d4T, 3TC, NVP and NLF (72% with viral load < 400 copies/ml at week 200).⁸

An observational study of HAART therapy in infants and children performed in the UK and Ireland demonstrated that after six months of starting HAART, virologic responses were better in older children.¹⁰

Immunologic responses were overall less impressive in the above studies since a larger percentage of treated infants and children had CD4 percentages

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Adherence issues differ between adult and pediatric patients

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in the normal range at baseline. However, improvements were seen in CD4 absolute numbers and percentages with the greatest changes seen in younger children, children with lower baseline CD4 counts, and ARV-naïve patients.^{1,6,7-8,10}

Predictors of virologic response varied among the above studies. Some^{6,8} but not all^{1,10} showed a negative correlation with high baseline HIV-1 RNA levels and virologic response. Baseline CD4 counts and proviral HIV-1 DNA load were not predictive.⁸

Resistance

Development of drug resistance mutations on HIV therapy has been associated with HIV disease progression in children.¹¹ In the clinical trial using LPV/r as the PI, NRTI and NNRTI but not PI resistance mutations were found in viral rebound isolates.⁷ When NLF was the PI used, 25% of infants selected resistance mutations to NRTIs and PIs.¹ Primary mutations to NRTIs and NNRTIs were seen in one study and were associated in decreased virologic response. In this study many of the resistance mutations seen at baseline were to agents to which neither the infant or infant's mother had been exposed.⁸ Information about both genotypic and phenotypic drug resistance in children is limited to small studies. More research is needed to evaluate the prevalence of vertically transmitted

resistant virus, risk of developing resistance mutations during perinatal prophylaxis therapy, and the effect of these mutations on virologic response in infants and children on HAART.

Adherence

Research in adults treated with HAART has revealed that > 95% adherence is needed for long term virologic suppression. Adherence rates of 70% to 90% can result in drug resistance and virologic failure.¹² Factors affecting adherence rates in children include age of the patient, whether the caretaker is a foster parent, biological parent or relative, palatability of medication, complexity of medication schedule, disclosure of HIV status to the patient, HIV knowledge base of the caretaker, and psychological and medical needs of the caretaker. In an observational, cross-sectional multi-center study, quantitative adherence was evaluated with structured interviews. Poor adherence was associated with children's awareness of their HIV diagnosis, poor palatability of medications, number of daily doses, and whether or not medication had to be taken with food. Adherence was better in children on HAART and when the caretakers were foster rather than biological parents or relatives.¹³ Many adherence strategies can be employed. In addition to education and use of adherence tools such as star charts and pillboxes, home visits may be needed with some families. In a randomized, non-blind-

ed pilot clinical study, a home-based nursing intervention group was compared to a control group that received standard clinic setting adherence counseling. HIV knowledge and medication refill history was better in the group receiving home-based nursing intervention.¹² Not all families need home visits and some families may not be receptive to having a stranger enter the home for adherence counseling but home-based intervention is an addition to the adherence tool arsenal.

Current European and US guidelines vary slightly in recommending when to start HAART therapy in infants and children. The current 2004 guidelines by the Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children divide treatment strategies based on age, clinical and immune status. In children less than 12 months, the group recommends treating all symptomatic children and children in immune categories 2 and 3 (CD4 <25%) and consider treatment in asymptomatic children with normal immune status (CD4 ≥25%). In children 12 months and older, the group recommends treatment in all children in clinical category C (AIDS) and/or immune category 3 (CD4 <15%). Most experts would treat older children with moderate to mild symptoms, mild to moderate immune function (CD4 15-25%), and/or viral load ≥100,000 copies/ml. Asymptomatic older children with normal clinical and immune status and with viral loads < 100,000 copies/ml would be



monitored and not treated. However, some experts would treat asymptomatic older children with viral loads between 50,000 and 100,000 copies/ml.³ The PENTA guidelines are similar to US guidelines, but are slightly more conservative in their recommendations for HAART in infants.²

Due to success of perinatal transmission prevention programs in the US, significantly fewer children are becoming infected. In the face of shrinking numbers of infected children in the US and other developed countries, physicians will have less experience treating HIV-infected children. Considering the unique problems encountered when treating HIV-infected children and infants such as varying PK parameters of ARV drugs, only physicians experienced in pediatric HIV should treat HIV-infected children. Despite declining perinatal HIV infections in the developed world, pediatric HIV infection remains a global problem. More research on ARVs in children is imperative, for it is not unreasonable to consider HAART therapy in the developing world. Recent studies suggest that even in resource-poor countries, HAART therapy can be successful.^{14,15}❖

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Legal

HIV infection adds to challenges faced by former inmates

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prisoners in Louisiana, 12,655 in Arkansas and 22,001 in Mississippi.²

While definite numbers are hard to come by, approximately 2% of the incarcerated population in the various state systems (over 22,000 inmates) and 1.1% of the incarcerated population in the federal system (over 1,500 inmates) were known to be infected with HIV at the end of 2002. According to the same report, female inmates were more likely to be infected than male ones: 2.8% versus 1.9%. In addition, almost 6,000 prisoners had progressed to an AIDS diagnosis, representing 0.5% of State inmates and 0.4% of those in the federal system, a combined rate three and one half times the rate for the general population. Higher rates of HIV prevalence were also detected in the 2002 Survey of Inmates in Local Jails. Among all inmates who reported ever having been tested for HIV, 1.3% were HIV-positive. However, the rate for females was almost twice that of males, 2.3% versus 1.2%. In addition, almost 3% of Hispanic persons reported being HIV-positive, as compared to 1.2% of African-American inmates and 0.8% of white inmates.³

Perhaps as a result of the South's high rate of incarceration, almost half of the State inmates with HIV were incarcerated in the South. In Louisiana there were 503 HIV-positive inmates, 224 in Mississippi, and 100 in Arkansas. Louisiana's rate of 2.5% was higher than the national average, while Mississippi's rate of 1.9% tracked the national average and

Arkansas's rate of 0.8% was substantially lower.⁴

Many incarcerated persons entered prison already infected due to prior high-risk behavior. Among jail inmates who reported past drug use, 1.5% were infected, but the rate doubled to 3.2% for those who reported injecting drugs, and escalated to 7.5% for those who had shared needles.⁵ Nevertheless, prisons also offer excellent conditions for the spread of infection. Many prisoners are serving time for drug-related crimes and continue to use behind bars. Sexual relations between inmates are also common, and while much of it is consensual, rape is used to establish domination over other inmates. Prisoners also have very little control over their environment and often cannot take steps to protect themselves. They are also subject to institutional policies that can limit access to information about HIV, or to other means of protection like condoms and clean needles.

While some of these inmates are either serving life sentences or will die behind bars, most of them will obtain release and re-enter the general population. People who return to care after incarceration can present special challenges for clinicians, who in turn need to be aware of some of the legal issues that relate to incarceration and HIV/AIDS.

Returning to Society

In Louisiana, Arkansas, and Mississippi, former inmates face numerous obstacles in returning to society. For example, in Louisiana convicted felons lose the right to vote, and cannot vote until

the completion of their sentence, regardless of whether the sentence has been suspended or they have been released on parole or probation.⁶ It is also a crime in Louisiana for a person who has been convicted of most felonies, including drug violations, to possess a firearm or carry a concealed weapon, unless the person has applied for a permit after the end of his or her complete sentence, including probation or parole.⁷ A felon also may not serve as the executor of an estate being probated.⁸ Former inmates face similar obstacles in Arkansas and Mississippi. For example, in Mississippi, a felon may only possess a firearm if he has either received a pardon or a certificate of rehabilitation from the state.⁹ In Arkansas, a felon faces the risk of having his/her professional license revoked due to past imprisonment.¹⁰

Social Security and VA Benefits

However, one of the most problematic areas involves eligibility for public benefits. Prior to 1980, many inmates in prisons continued to receive Social Security benefits if they had qualified as disabled prior to their incarceration. However, in 1980 and 1983, Congress enacted legislation to bar prisoners convicted of felonies from receiving Social Security benefits, and in 1994 the ban was extended to include people placed in public institutions who are found not guilty of a crime by reason of insanity or who receive a similar verdict or finding. The same law also expanded the ban to incorporate any crime punishable by imprisonment of more than a year.¹¹ Note, too, that Social Security regulations provide that



any grounds for disability that arise from or are aggravated by the commission of the offense (but not any subsequent incarceration) cannot be considered in determining whether someone is disabled.¹²

Clients who receive veterans' benefits also face having their benefits reduced if they are convicted of a felony, but only if they serve more than 60 days in a state, local or federal institution.¹³ In addition, instead of a total cessation of benefits, the benefits are only reduced according to a formula set forth in the statute.¹⁴ The reduction in compensation also ends as soon as the veteran is released from incarceration.¹⁵

Clinicians need to inform clients that their Social Security benefits will not automatically start again upon their release, and that they must start the application process again at the district office. In some cases, clients may have a written determination from Social Security indicating the medical bases for their pre-incarceration award (this is only true of clients who had a hearing before a Social Security administrative law judge; clients who were approved for benefits at the district office merely receive notice that they have been approved). Reference should be made to that determination in helping the client complete the new application. However, depending upon the length of the incarceration, the basis for the client's claim for disability may have changed. For example, until 1999 morbidly obese people were deemed disabled due to a specific Social Security regulation/listing that has now been abolished. On the other hand, some clients may have qualified in the past for exhibiting opportunistic infections that present day standards of care now render much less disabling.

In addition, Social Security examiners are much more aware now that HIV infection is not a death sentence, and that medical advances have allowed many infected people to carry on normal lives, including working for a living. Thus, clients who have responded well to treatment while incarcerated are unlikely to prevail in obtaining benefits without some independent grounds to establish disability.¹⁶

In making this assessment, clinicians should be on the lookout for deficient records from the

**Clinicians can help
by being aware of
the obstacles and by
developing strategies
to overcome them.**

patient's period of incarceration. And since prisoners can only sue about medical treatment if they can prove "deliberate indifference", as opposed to negligence for free patients,¹⁷ their treatment while behind bars may not have been of the highest standard.

When clients reapply for benefits, Social Security will look at their treatment history as well as their work activities during their incarceration. If clients have performed strenuous labor while incarcerated, this fact will be evaluated by Social Security. In addition, if clients have received any vocational training, particularly for sedentary work, these new skills may make them more employable and thus less likely to obtain benefits. Although clients may claim in their new application that

they have remained disabled during their incarceration, as a practical matter SSI claimants will receive monetary benefits only from the date of the new application, while SSDI benefits would start from the date of release from incarceration. (Note, however, that a pre-release onset date may benefit an SSDI claimant because it would commence the 25-month waiting period for Medicare coverage.)

Even clients who are deemed disabled by Social Security may face barriers to receiving full benefits. Under the so-called "fleeing felon" rule, clients who have serious criminal charges pending against them will not be eligible for benefits until the charges have been dismissed or otherwise resolved.¹⁸ Note that a charge that was originally a misdemeanor may have turned into a felony if the client failed to appear in court to respond to the charges against him/her. Some clients may also receive notice from Social Security that their benefits will be reduced in order for Social Security to recoup overpayments made to them while they were incarcerated.¹⁹ Clients may seek a waiver of the overpayment, which will keep them in benefits status until their case is reviewed if the request for the waiver is made within 10 days. However, to get a waiver the client must show that the overpayment was not his fault. Since the law is very clear that it is the recipient's duty to inform Social Security that he has been incarcerated, many of these requests for waiver are not granted.

Other Benefits

In Louisiana, since 1997 anyone convicted under federal or state law of any offense that is deemed a felony and involves drug

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possession, use or distribution is ineligible for TANF (food stamps) for one year from the date of conviction or the date of release from incarceration, whichever is later.²⁰ Individuals convicted of a drug felony in Mississippi after August 22, 1996, are permanently barred from receiving food stamps.²¹ Arkansas has adopted an analogous approach, but has modified the ban to cover only felons convicted of drug manufacturing or distribution.²²

If the client lives in or is seeking housing through the local public housing authority, or Federal housing programs authorized under the United States Housing Act of 1937,²³ a prior criminal record or activity can be grounds for rejection. In addition, federal regulations require a public housing authority to reject anyone who has been evicted from any other federally funded housing program for criminal drug-related activity for a period of three years after the eviction.²⁴ An exception can be made, however, if the applicant can prove that he or she has completed an approved substance abuse recovery program. For Section 8 assistance, public housing authorities may refuse applicants they deem unsuitable for the program, including people previously evicted for serious lease violations.²⁵ Rent support under Section 8 programs can also be terminated if the tenant is evicted for a serious lease violation, which of course includes criminal or drug-related activity.²⁶

On the other hand, clients who have been incarcerated are not deemed ineligible for benefits under HOPWA programs,²⁷ although a client's propensity

for violence may be considered, particularly in the group home setting. In addition, if a client is incarcerated while receiving HOPWA support, the support will terminate not only for the client but also for his/her family members. Note, however, that HOPWA regulations provide a grace period (not to exceed one year) for family members in the event of the client's death,²⁸ so perhaps a similar grace period could be sought by family members displaced by the incarceration of the client eligible for HOPWA support.

Confidentiality and Transmission Liability

Recent CDC prevention guidelines have stressed the responsibility of clinicians to discuss partner notification and risk reduction with their patients.²⁹ This requirement may place additional responsibilities on clinicians who treat people recently released from incarceration. Patients who were first diagnosed behind bars may not have disclosed their status to their families and partners on the outside. The client may fear that disclosure may cause loved ones to reject him/her, or the client's reluctance to disclose may merely arise from the desire to return to the way things were before incarceration.³⁰ However, failing to disclose to a partner before having sexual relations is against the law in Louisiana, Mississippi and Arkansas,³¹ and could result in a swift return to incarceration in all three states. Note also that sharing needles to inject drugs is prohibited by the same laws.³²

Conclusion

Former inmates will face an array of obstacles as they

transition from the institutional setting. Navigating the system of housing, public benefits, and legal liability can be overwhelming for any former inmate, but when that individual is also infected with HIV or has AIDS, the challenges become more numerous. Clinicians can aid these individuals by having an awareness of these obstacles and by developing a strategy to overcome them. These small, yet significant, steps may guarantee the health and overall stability of a former inmate living with HIV and AIDS. ♦

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FOOTNOTES

¹United States Dept. of Justice, NCJ 205333, December 2004. hereinafter, DOJ 2004. Data on prisoners are from the National Prison Statistics (NPS-1); data for jail inmates are from the 2002 Survey of Inmates in Local Jails.

²Council of State Governments, www.csg.org.

³DOJ 2004.

⁴Id.

⁵Id.

⁶La. Constitution, Art. 1, Section 10; La. R.S. 18.102 A(1).

⁷La. Constitution, Art. 1, Section 11; La. R.S. 14:95.1.

⁸La. Code of Civil Procedure, Art. 3097.

⁹Miss. Code. Ann. § 97-37-5(1).

¹⁰For example, a felon can lose his or her license to practice medicine. Ark. Code Ann. § 17-95-409(a)(2).

¹¹42 U.S.C. Section 402(x)(1); 20 CFR 404.468.

¹²20 CFR 404.1506

¹³38 U.S.C. Section 5313, 38 C.F.R. Section 3.665; Hall v. Dept. of Veterans' Affairs, 83 F.3d 532 (11th Cir. 1996).

¹⁴Id.

¹⁵Id.

¹⁶"Social Security disability rules are clarified for HIV clinicians," HIV Clinician, Summer 2001, Vol. 13, No. 3, p.9.

¹⁷Revere v. Mass. Gen. Hospital, 463 US 239, 243-4 (1983); Estelle v. Gamble, 429 US 97, 104 (1976).

¹⁸42 U.S.C. Section 1382.

¹⁹20 CFR 404.501 and 404.535.

²⁰La. R.S. 46:233.2

²¹Miss. Code. Ann. 843-17-5.

²²Food Stamps Certification Manual, http://www.accessarkansas.org/dhs/webpolicy/Food%20certification/FSC12000_new.htm.

²³42 U.S.C. 1437d, 24 C.F.R. 960.966.

²⁴24 C.F.R. 960.205(3)(d).

²⁵24 C.F.R. 982.307 (a); 24 C.F.R. 982.555 (e) (2000).

²⁶24 C.F.R. Section 982.552 (b)(1); 24 C.F.R. Section 982.553(a).

²⁷24 CFR Sec. 574.3, defining "eligible person".

²⁸24 CFR Sec. 574.310(e).

²⁹New guidelines: clinicians should incorporate HIV prevention into ongoing care of patients" HIV Clinician, Fall 2003, Vol. 15, No. 4.

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³¹"The three faces of criminal exposure in Delta Region states," HIV Clinician, Fall 2000, Vol. 12, No. 4.

³²Id.



Nursing

How can clinicians help motivate their clients to change?

Deborah J. Konkle-Parker, PhD,
FNP

Teaching about healthy behaviors for health promotion is a classic nursing role. In HIV, this may include encouraging adherence to medicines, safer sex, disclosure, and the myriad of healthy behaviors suggested for us all: attaining and keeping a healthy weight, getting exercise, etc. So often, however, we feel that we are speaking into the wind, as change is often not seen.

Motivational interviewing (MI) is an approach to counseling for behavior change that is generating excitement and research in a multitude of behaviors (http://motivationalinterview.org/library/outcome_files/frame.htm for a review of literature). This approach is a client-centered approach, avoiding confrontation, but using reflective listening to allow the client to make self-motivational statements that encourage change. An important basic concept is that each person is in a stage of readiness to change which may not lend itself to immediate change in the health behavior, but which might lead one closer to causing the change to happen.

MI was developed by Miller and Rollnick (2002) for use in counseling substance abusers, in opposition to the confrontational style advocated at that time. It is an approach that is directive in moving the client toward healthier behaviors, but does so in a client-centered way. There are five basic principles to MI:

- Express empathy
- Develop discrepancy
- Avoid argumentation
- Roll with resistance
- Support self-efficacy

Using open-ended questions and empathic reflections, the counselor elicits the personal goals important to the client, and allows the client to identify the discrepancy between these important goals and current behavior. "So you said that you would really like to be able to continue taking these current medicines because they are easy to take. You also talk about your fears of getting resistant to these medicines and having to take other medicines that will be much harder." The response to this reflection

often indicates the client's concerns, and often involves self-motivational statements, where the client talks about the need to change behavior to meet his or her personal goal. Self-motivational statements are always reinforced with praise and positive feedback.

The expression of ambivalence to behavior change is encouraged, and used to generate self-motivational statements. "You say that, on a scale of 1 to 10, you are at a 5 in terms of how important it is for you to take your medicines regularly every day. What makes that a 5 rather than a 3 or 4?" "You have said that it is difficult for you to take the medicines on a regular basis, but you continue taking the medicines anyway," again waiting for a response that will involve self-motivational statements by the client.

Rolling with resistance involves highlighting successful responses to challenges, rather than being tempted to problem-solve or confront the client for lack of change. "You have been missing three doses per week. What keeps you taking your medicines so well on the other days?"

Providing the client with objective feedback is an important part of MI. The purpose of this is to strengthen motivation by potentially setting up a discrepancy between current behavior and where he/she would like to be. "Your last viral load is 4600, and your CD4 has remained stable since the last time. According to what you told me, you are taking about 85% of your medicine doses. What do you think of this information? Is there any of it that is important to you?"

At the end of the session there is an opportunity to develop the plan of action. Using reflection and summarizing what the client has indicated to that point, specifically in relation to the behavior change in question, the client is then asked, "And where do you plan to go from here? What changes do you plan, if any, by the next time I see you?"

This approach can be helpful in leading the client to motivate him or herself to change, rather than others trying to motivate the client to change. A web site that can give much more information is <http://motivationalinterview.org/>.

Some readings that might also be helpful are:

- *Motivational Interviewing*, 2nd edition, by William R. Miller and Stephen Rollnick (2002), a book that describes well the theory;
- *Health Behavior Change: A Guide for Practitioners* by Stephen Rollnick, Pip Mason, and Chris Butler (1999), a book that describes the use of MI in brief medical visits; and
- DiLillo, Siegfried, and West (2003), *Incorporating Motivational Interviewing into Behavioral Obesity Treatment, Cognitive and Behavioral Practice*, 10, 120-130, an article that nicely describes the technique in relation to counseling about obesity, but generalizable to other behaviors. ♦

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Dental

Dental services in the RWCA: Implications for reauthorization

Nicholas Mosca, DDS

Congress passed the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in 1990 to improve the availability of care for persons with HIV/AIDS. When the CARE Act was passed, AIDS was universally fatal, treatments were limited, fear of acquiring disease was widespread, and public hospitals and safety net clinics were overloaded with HIV-infected patients in major metropolitan cities. The CARE Act was named for Ryan White, an Indiana teenager who died in 1990, just a few months before the legislation was passed. In 1995, Congress amended and reauthorized the CARE Act at a time when more treatments were becoming available and a nationalization of the epidemic occurred. The CARE Act was amended and reauthorized again in 2000, with a greater emphasis on access to medical treatment in the era of HAART (Highly Active Anti-Retroviral Therapy). From FY 1991 through FY 2005, Congress has spent nearly \$18 billion for HIV/AIDS care and services through the Ryan White CARE Act. Current funding is about \$2 billion.

The DHHS Health Services and Resources Administration (HRSA) through its HIV/AIDS Bureau (HAB), administers the Ryan White CARE Act. Title I of the CARE Act provides resources to U.S. metropolitan areas most severely affected by HIV/AIDS, defined as areas having a population of at least 500,000 and at least 2,000 reported AIDS cases in the two previous years. Title II of the CARE Act authorizes grants to U.S. States and Territories that have between 500 and 1,999 AIDS cases over a 5-year period. Title II also provides earmarked funding for the AIDS Drug Assistance Program (ADAP), which is used to purchase medications or prescription drug benefits for low-income persons with HIV/AIDS, using eligibility criteria that vary with each state or territory. About 80 percent of persons eligible for ADAP have incomes at 200 percent of the Federal Poverty Level (FPL) or less. Title III funds grants for outpatient medical services in underserved communities, and is awarded directly to primary care providers. Title IV funds grants awarded to organizations that target health services to women, in-

fants, children and their affected family members.

Early studies of access to dental services by persons with HIV infection indicated that dental care was a common unmet need and the use of dental care was low. The availability of dentists willing to treat persons living with HIV was cited as a major barrier to care. These findings would assist the American Association of Dental Schools, now known as the American Dental Education Association, to successfully advocate for inclusion of the HIV/AIDS Dental Reimbursement Program under Part F of the CARE Act, linking dental services delivery with the education and training of the dental provider through accredited dental schools and post-doctoral education by covering the non-reimbursed cost of providing oral health care to HIV-infected patients at their institutions.

The HIV/AIDS Dental Reimbursement program (DRP) was initially funded at \$7.5 million in FY 1997 and is a retrospective payment program. Congress gradually increased DRP funding to \$13.5 million in FY 2002, and subsequently decreased funding to \$13.2 million in FY 2005. Programs may apply to receive funds for non-reimbursed costs only. In FY 2004, HAB awarded 63 grants to dental education programs in 24 states and territories, totaling \$9.8 million to reimburse dental education programs for some of the costs of providing oral health services to persons living with HIV/AIDS. Some programs have received reimbursements as high as 75 percent of their actual costs but the percentage varies. For example, the University of Mississippi School of Dentistry's annual reimbursement was about 50% of its actual costs. The total appropriations for the DRP from FY 1997 - 2005 are about \$94.5 million. A comparison of DRP funding with total Ryan White CARE Act funding shows that less than 0.5 percent is spent on the dental reimbursement program. Since 2000, fewer dental education institutions have applied for the dental reimbursement grants. In FY 2003, eligibility for DRP funding was extended to dental hygiene training programs as a result of changes introduced in the 2000 Ryan White CARE Act reauthorization.

In addition to Part F, oral health services can be supported by all four titles of the CARE Act. Data regarding FY 2000 dental expenditures for Titles I, II and III was prepared for HRSA by Positive Outcomes, Inc. In FY 2000, Title I metropolitan areas allocated about \$16 million in funds for dental care, representing only about 2.9 percent of total Title I funds spent for all HIV/AIDS services, including ambulatory/outpatient medical care, medications, substance abuse treatment/counseling, food bank/home delivered meals, nutritional supplements, etc. Four Title I metropolitan areas did not allocate any Title I funds for dental care in FY 2000. About \$5.4 million in Title II funds were allocated to dental care, representing only 2.2 percent of total Title II allocations. Over \$6 million in Title III grant awards was budgeted by grantees for dental care, however, wide differences in allocation of funding was noted, from \$300 (or 0.18 percent of total grantee award) to \$107,865 (or 27 percent of total grantee award).

In FY 2002, HAB deferred a portion of Part F DRP appropriations to initiate the Community-Based Dental Partnership (CBDP). The CBDP funds eligible dental education programs to increase access to oral health care for persons with HIV and enhance dental provider training in community settings. In FY 2003, a total of \$2.9 million in funding to 12 institutions in 10 state and territories was awarded, including programs in LA (LSUHSC) and MS (UMMC). Due to budget restrictions, no new grants were awarded in FY 2003 or FY 2004 but the original 12 institutions continued to receive funding. Funded activities include dental student education and hands-on clinical rotations at federally qualifying health centers and public hospitals, and HIV-dedicated service learning training for existing dental providers in community settings. Some grantees have also developed stronger two-way patient care relationships with existing Title III grantees through this program. In 2005, a limited competition for currently funded programs and new applicants proposing to serve the same communities being served by the existing grantees was announced.



The current CARE Act is scheduled to expire and requires reauthorization at the end of September 2005. CARE Act programs are considered the payer of last resort for health services, and diminished resources in states due to Medicaid cutbacks and reduced state contributions to ADAP may make it difficult to allocate additional funding for dental services.

The 2005 reauthorization must assure that adequate funding remains for current services while addressing the broader context of a changing epidemic. One proposal is to make funding of Ryan White Title allocations based on reported HIV infections instead of reported AIDS cases. Another proposal is to mandate coordination of CARE Act services across health care delivery systems, thus ensuring that available resources are expended efficiently and accountably. Many consider HIV a chronic disease and amendments will focus on assuring the equitable availability of health services for minorities with HIV. The highest rates of growth in HIV cases geographically are in the Southeast among African-Americans. Many PLWH also have co-morbidities, such as hyperlipidemia and heart disease, Hepatitis B and C, or substance abuse and mental health problems. Because of the Dental Reimbursement Program's unique linkage of dental care with provider education and training, there are curriculum implications for dental educators to consider regarding these co-morbidities. Educators must develop new models of training that integrate oral health care delivery into HIV health care systems. Another dental consideration is the need to gather standardized data on utilization, cost, cost-effectiveness, outcomes of treatment, and measures of cultural competency in delivering oral health care. HAB should be urged to provide funds to dental education programs participating in the DRP and the CBDP to address this need.

Dental educational institutions and community-based dental partners must assure that any changes to the Ryan White CARE Act will continue to guide and enhance the delivery of dental services to persons with HIV disease. Working closely with Association of State and Territorial AIDS Directors (ASTAD), ADEA, the ADA and others, the dental community will be able to advocate effectively for improvements. ❖

Nicholas Mosca is Dental Director of the Mississippi Department of Health.

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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 601-984-5542
- Arkansas 870-535-3062 x104

National HIV Telephone Consultation Line:
800-933-3413

National Clinicians' Post-Exposure Prophylaxis Hotline (PEpline):
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Delta AETC

CONTINUING EDUCATION PROGRAMS

NEW ORLEANS, LOUISIANA

A clinical preceptorship for nurses and clinical service providers: Comprehensive Management of the Patient with HIV Disease—May 9-11, 2005. 21 contact hours. Contact: Danielle Pierce, 504-903-0788 or dpierce@lsuhsc.edu

JACKSON, MISSISSIPPI

A multidisciplinary preceptorship for physicians, dentists, pharmacists, nurses: Comprehensive Management of HIV Disease—May 26-27, 2005. Contact: Jessie Lindsay, 601-984-5542 or jlindsay@medicine.umsmc.edu

NEW ORLEANS, LOUISIANA

A clinical preceptorship for MDs, NPs, PAs: Care and Management of the Patient with HIV Disease—September 12-13, 2005. 13.5 CMEs from AAFP. Contact: Danielle Pierce, 504-903-0788 or dpierce@lsuhsc.edu

NEW ORLEANS, LOUISIANA

A clinical preceptorship for dentists: Oral Health Management of the Patient with HIV Disease—October 3, 2005. 7 hrs CDE. Contact: Danielle Pierce, 504-903-0788 or dpierce@lsuhsc.edu

PINE BLUFF AND LITTLE ROCK, ARKANSAS

Clinical preceptorships for primary care providers—ongoing by request. To arrange, contact Derrick Newby, 870-535-3062 or dnewby700@aol.com

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