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**REPORT OF  
THE ETHICAL ISSUES IN ACCESS TO HIV  
TREATMENT WORKGROUP**

**The New York State  
AIDS Advisory Council**

**September 1998**

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### APPENDIX I - Workgroup Participant List

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## 1. EXECUTIVE SUMMARY

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The demonstrated value and dramatic promise of new therapies for HIV treatment, specifically combinations of antiretroviral drugs including protease inhibitors that have allowed longer and healthier lives for many people with HIV, have elicited an equally dramatic ethical corollary: the difficulty of ensuring equitable access.

In response to reports that some patients lack information about treatment options or are denied access to these therapies because of presumptive judgements about their ability to adhere to the medical regimens, the Ethical Issues in Access to HIV Treatment Workgroup was formed by the New York State AIDS Advisory Council in mid-1997. The Workgroup consisted of a wide range of providers, consumers, ethicists, and other professionals who met in three all day sessions. The intent was to provide guidelines and recommendations for clinicians, policy makers, and health officials concerned that individuals and perhaps entire categories of people were not being given an opportunity to consider using the new drugs.

The Workgroup's primary operating premise was that every person with HIV should have access to medications at the point at which that person would be most likely to benefit. That determination, however, is not a straightforward clinical matter. Since multi-drug regimens are complicated and since even brief interruptions of medication schedules may encourage drug resistance, substantial effort is required to prepare patients to initiate treatment and to ensure they understand the importance of treatment maintenance. Support services, ranging from

minimal to extensive, may be required to enable patients to undertake and maintain treatment regimens. Side effects, the course of disease, new treatment advances, and many other variables also require that the patient be regularly monitored.

Therefore, a major contention of the Workgroup is that the new treatments demand highly collaborative, long term physician-patient relationships in which trust in the physician and belief in the potential benefits of therapy are critical factors. The terms compliance and adherence are inappropriate in this context in which patients are active participants in determining a workable treatment plan.

This report details barriers to and elements of an effective HIV treatment strategy, specifying the responsibilities of individual providers, community organizations, agencies, and funders and discussing factors likely to enhance the probability of treatment maintenance. The needs of special populations, such as inmates, children, and mentally impaired people with HIV, are noted. However, the Workgroup recognizes that while physicians have distinct ethical obligations regarding treatment education and referrals for support services they have also an obligation to withhold treatment that is medically inappropriate or treatment that, with all available supports, the patient is unlikely to maintain.

The Workgroup enumerated eight principles and 33 recommendations that were approved unanimously by the AIDS Advisory Council in November 1997. It is the hope of the Workgroup and the Council that this work will help to ensure that the benefits of present and future treatment advances accrue to all.

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## II. INTRODUCTION

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For the first time in the history of the HIV epidemic, health professionals have begun speaking, at first cautiously and now with greater confidence, of a new era in clinical care for people with HIV/AIDS. Deaths from HIV/AIDS are declining, and the rates of new AIDS cases are decreasing for many groups. <sup>1</sup> Inpatient admissions for HIV-related disease have declined, while the demand for ambulatory HIV services has substantially increased.<sup>2</sup> The use of combination antiretroviral drug regimens including protease inhibitors has begun to transform HIV/AIDS into a chronic disease, an illness requiring careful long term management. People with HIV can anticipate longer and healthier lives.

While this is exceedingly good news, the new therapies do not eradicate HIV infection nor do they herald the end of the epidemic. Critical problems remain. The new clinical treatments are expensive and require a serious commitment to difficult medication regimens. Treatments may be ineffective for some patients and inappropriate for others. Discontinuation or even minor disruptions of a treatment plan may produce drug resistance in an individual, which could contribute to future widespread drug resistance.<sup>3</sup>

Despite the difficulties of treatment with these multi-drug regimens, the benefits for those who respond are substantial, generating an ethical imperative to consider these medications in planning treatment for every person diagnosed with HIV disease.

In 1997, clinical and media reports<sup>4</sup> that some patients were being denied access to the new medications because of presumptive judgements about their ability to adhere to the medical regimens prompted the concern of the New York State AIDS Advisory Council. The Ethical Issues in Access to HIV

Treatment Workgroup was formed with a mandate to submit a report and recommendations to the full Council, which would in turn distribute them widely in an effort to address what was perceived as an acute public health problem, inequitable access to clinically valuable HIV treatments.

### **The Workgroup**

The Ethical Issues in Access to HIV Treatment Workgroup of the New York State AIDS Advisory Council consisted of 42 representatives of professional and academic disciplines, including HIV service providers and members of affected communities (see Appendix I).

Three all-day meetings were held, on June 2, July 7, and September 8, 1997, during which a wide variety of presentations were heard. Speakers outlined ethical issues, including individual rights and community risk; legal issues, including concerns about malpractice; and medical issues, including the biology of HIV replication, neurological impairment in people with HIV, and the requirements of drug regimens. Other participants addressed the patient education process in clinical settings, historical characterizations of non-adherent patients, drug utilization by category, drug administration in children, and program quality assurance in New York State. Consumers presented testimony describing the real life impact of medication schedules, difficulties with pharmacies and insurance, discrimination against substance users, and the particular problems of HIV-infected mothers, inmates, immigrants, the disabled, and other especially vulnerable populations. Researchers reviewed findings on the use of combination antiretroviral therapy and factors in successful adherence. Workgroup members considered articles from the professional and lay press and other documents and, lastly, summarized views on HIV treatment education, support services, and access.

In October 1997 the Workgroup presented a set of principles and recommendations to the Council, which were accepted unanimously at the November Council meeting.

Workgroup members were articulate and involved. Meetings were open to the public, and comments from observers were encouraged. Successive drafts of these guidelines were circulated, engendering lively and pointed critique. Every principle and recommendation was discussed, and where there was disagreement, statements were crafted to reflect diverse points of view.

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### **III. CENTRAL PRINCIPLES**

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#### **Universal access to HIV treatment**

In an attempt to assess barriers to care and their impact, the Workgroup, in the absence of a definitive survey, identified the following general problems based on the literature and on testimony from invited speakers:

1. People with HIV may often have less than optimal access to treatment information and HIV therapy because providers assume they would be unlikely to understand or be able to maintain a treatment regimen;
2. For some providers, these judgements may pertain to entire categories of people, including substance users, children, the homeless, inmates, immigrants, the mentally and physically disabled, and others, regardless of individual circumstances;
3. Some people with HIV lack stable environments, privacy, or control over their daily schedules, and/or have other problems that could make maintenance of drug regimens impractical or impossible, but, in many of these cases,

access to support services could enable treatment;

4. Physicians themselves sometimes do not have sufficient clinical information, patient education skills, or time to structure appropriate treatment plans or the ability to make support services available that would enable successful treatment maintenance.

In addition, many specific issues were brought to the attention of the Workgroup. For example, although there were indications that those with initial access to the new treatments were disproportionately white and male, women and people of color have substantially caught up in the use of combination therapies.<sup>5</sup> In addition, concerns were expressed that people with different insurance coverage (Medicaid, ADAP, private insurance) may have differential access to medications; and that medication side effects, caretaking responsibilities, and many other unpredictable factors can compromise even the most carefully designed and supported treatment plan.

At the outset, it became clear to the Workgroup that all recommendations would be founded on a primary operating principle justified by the dictates of both individual rights and public health responsibilities: every person with HIV deserves the best possible chance to benefit from the new treatments. Given the requirements of the new medications, this was further refined to mean that every person with HIV should have access to medications at the point at which that person would be most likely to benefit.

The group then undertook examination of the questions that clinicians and people with HIV face in determining how this can be accomplished. The problem of inequitable access quickly elicited a set of additional concerns:

- the need for a significant expansion of professional and public education about HIV treatment, as extensive as that at the start of the epidemic regarding transmission,
- the need to review and improve knowledge about how to prepare patients to initiate treatment and ensure successful continuation, and
- the need to examine and possibly reconceptualize the model of HIV provider-patient interaction.

### **A new paradigm of HIV care**

In the past, physicians providing HIV care were limited to palliative treatment or simple regimens that offered short term gain. In 1987, zidovudine (ZDV, also known as AZT) became available as the first antiretroviral treatment for HIV, followed soon by ddI, ddC, 3TC, and others. Combinations of these drugs were found to be more effective than monotherapy.

At the end of 1995, the first protease inhibitor was introduced. (Protease means protein cutter; thus, protease inhibitors prevent the cutting of HIV precursor protein strands into mature pieces of virus.) These drugs, used in combination with other antiretrovirals, have proven to be the most powerful HIV treatment developed to date, responsible for substantially increasing both the quality and length of life for people with HIV. <sup>6</sup> As of May 1997, there were fifteen antiretrovirals approved for combination use in treatment of HIV disease.

A typical antiretroviral-protease inhibitor combination of HIV drugs in 1997 cost about \$12,000 to \$15,000 per patient per year. The combinations are known collectively as HAART (highly active antiretroviral therapy), which generally refers to three, four, or five drug regimens aimed at decreasing viral load (the amount of HIV virus in the body) to undetectable

levels. High viral load is the most important predictor of progression to AIDS and death. Viral load and CD4 count (the number of CD4 cells per deciliter of blood) are currently the main parameters used in federal and state guidelines to determine when drug therapy should be initiated in individuals with HIV. <sup>7</sup>

However, clinical measures are not the only factors in determining the initiation of HIV drug treatment, and many issues affect the likelihood of successful treatment maintenance. (See "Elements of an Effective HIV Treatment Strategy" below.) An HIV regimen including HAART and prophylactic or therapeutic medications for opportunistic infections may actually involve multiple daily doses of seven or eight different drugs with varying nutritional requirements. New drugs are appearing regularly, requiring continuous review and revision of standards of care. Drug interactions, side effects, and long term impact are poorly understood.

All of these factors, in addition to the threat of resistance to one or many drugs when treatment is interrupted or discontinued (See "Treatment Maintenance" below), have prompted a close reexamination of HIV management. Access to care no longer means simply ensuring that a person with HIV receives a prescription. In the context of new HIV medications, it is being redefined to require much greater provider involvement, a proactive role for health professionals in facilitating the initiation and ensuring the long term continuation of difficult HIV treatment regimens.

This requires that physicians spend time explaining treatment requirements, helping a patient determine how these requirements can be met in the context of the individual's life, and providing referrals for services that will allow the patient to begin treatment and give him or her the maximum opportunity to benefit. This may include helping the patient secure housing, regular meals that are nutritionally adequate and medically

appropriate, refrigeration for medications, substance abuse treatment, or other services. This labor intensive preparation must be followed by vigilant monitoring of the patient's clinical status and response to medications.

Thus, among the earliest and most important issues the Workgroup addressed was the language used to describe physician-patient interactions involving treatment. While traditional medical paternalism has been modified somewhat by shifts toward greater consumer health education and autonomy, the paradigm in which physicians prescribe and patients adhere to or comply with physician instructions is still dominant. Although there have been some changes in language, many articles in the medical literature addressing the problem of compliance/adherence still use punitive terms to characterize patients who take medication irregularly or do not complete a course of treatment.<sup>8</sup> Patients are said to have failed a course of treatment; they are labeled noncompliant regardless of the reasons for discontinuing treatment. Non-compliance is seen as a form of deviance.

While physicians have always devised treatment plans in accordance with individual circumstances, current HIV therapies demand more collaborative interaction. The involvement of the patient in treatment decisions is not only desirable for successful HIV treatment, it is essential. Patients must understand the careful scheduling and nutritional requirements of medications as well as the danger to themselves, and possibly to others, of discontinuities in treatment. Vastly expanded patient education and a sustained trusting relationship between physician and patient are required to structure and support a plan that is medically appropriate and feasible, has the confidence of both parties, and can be maintained over time.

Thus, terms like compliance are, in the view of the Workgroup, counterproductive. Fortunately, this term has generally disappeared from common usage in clinical settings, but health care workers and others interacting with patients should guard against its use. Adherence is a term that is less pejorative and is in much more common usage today. Still the Workgroup felt that people with HIV need not be compliant or adherent. They must be active participants in the process of evolving an effective treatment plan and committed to maintaining it. In assuring treatment success, personal responsibility is as important as professional skill. The Workgroup suggested consideration of the term "treatment maintenance" to better encompass this concept.

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#### IV. ELEMENTS OF AN EFFECTIVE HIV TREATMENT STRATEGY

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##### **Professional, public, and patient education**

As standards of clinical HIV care rapidly evolve, both physicians and consumers have difficulty keeping up with the most current information. However, it is clear that health officials have an obligation to disseminate new treatment information promptly, and health care providers have an obligation to stay up to date.

Consumer education is a more complicated matter. The Workgroup discussed a number of issues that can impede accurate public and patient knowledge about HIV treatments:

- C Many people do not know their HIV status.
- C People newly diagnosed with HIV may not be able to process treatment information.
- C Most people, in any clinical setting,

remember only a fraction of the information given orally by providers.

- C Information that is not linguistically or culturally appropriate, or that is not tailored to the age, gender, educational level, and circumstances of the patient, is not absorbed.
- C Some people with HIV do not trust and do not often seek medical care.
- C Some patients do not want information and do not want to participate in medical decisions, preferring that physicians be paternal and dictatorial.
- C Programs often do not have the resources to engage in extensive education of community organizations and institutions, to employ peer educators, or, particularly in a managed care environment, to engage in time-consuming, one on one treatment education efforts.
- C People in prisons and other institutions, those who have neurological impairment, children, especially those in foster care, and other populations with special needs have no less of a right to appropriate HIV treatment but experience much higher barriers to information and treatment.

Some of these factors are common to all types of medical treatment, but they are critical in HIV care. HIV treatment information is complicated and the consequences of misunderstandings can be serious. Further, since HIV has become a chronic disease, treatment education must continue over the course of the patient's life.

Attempts are being made to solve these problems. In one educational model, a team of providers takes responsibility for patient education over time, repeating and reinforcing messages and encouraging patient initiatives in gathering and questioning information.<sup>9</sup> Other ideas

include devices such as visual teaching aids, take home materials, forums, pill organizers, and buddy systems to enhance understanding and commitment to treatment.

However, more can and should be done. Providers must be trained to teach more effective ways of transmitting information. Peers, family members, counselors, case managers, social service liaisons, and health professionals can encourage people to learn their HIV status. Anyone who interacts with an HIV-positive person and who is granted confidential knowledge of the patient's HIV status can be employed to help communicate and reinforce treatment information.

Most importantly, education can become the first step in the process of establishing the relationship between patient and provider that will create and improve the chances for successful treatment. The establishment of trust in the provider and the medical system, belief in the potential for treatment benefit, and understanding of how treatment requirements can be integrated into the patient's life are the foundation for effective therapy.<sup>10</sup>

### **Support services**

Once HIV status is determined and discussion is underway about treatment options, it may become evident that the patient is willing to undertake medically appropriate treatment, but lacks prerequisites that would make this possible. Homelessness, institutionalization, substance use, inadequate health insurance, insufficient food or access to cooking facilities, family crises, work schedules, interruption of social service benefits, immigration problems, and many other issues may compromise access to HIV treatments. Adolescents, pregnant women, children, the disabled, prison inmates, and other populations and individuals also have distinct barriers to information and care.

For some people with HIV, appropriately



timed work breaks or the acquisition of simple skills like meal planning could make the use of new HIV medications possible. Others may require more elaborate structural changes to stabilize their lives.

It is a fundamental tenet of this report that many people assumed to be incapable of maintaining treatment schedules could be successful with the proper support.

Physicians and other health care providers who take the extra step of making referrals and creating conditions in which regular medication schedules can be maintained will enable many people with HIV to benefit from treatment. Funding agencies and organizations can build into programs a consciousness of the need to support HIV treatment regimens. They can facilitate, for example, access to housing and refrigeration, appropriately planned meals and work arrangements, sufficient supplies of medication at regular intervals, access to medications during times of crisis such as arrest or hospitalization, coordination of HIV care with substance abuse and mental health treatment, language translation of treatment information, enrollment for Medicaid, ADAP, or other funding support, and access to any number of other services that would allow the initiation and maintenance of HIV treatment.

An effective treatment plan is a unique creation and a work in progress, incorporating non clinical elements that make clinical improvement possible and undergoing constant revisions keeping with each individual's health status and life events.

### **Treatment maintenance**

Although it is unknown exactly how many doses of a drug can be missed before it becomes clinically significant, there are some preliminary reports that missing even a few doses can affect treatment response. Missed doses of medication allow

proliferation of the virus and an increased frequency of mistakes in viral replication. That increases the chances that some mutations will be drug resistant and will multiply rapidly.<sup>11</sup> Since drug resistance is transmitted with the virus, there is legitimate concern that inadequate viral suppression in individuals could lead to widespread resistance rendering the new HIV drugs ineffectual, in a scenario similar to that of antibiotics and TB medications.

Early use of ZDV, in which physicians prescribed intermittent or lower doses when side effects were intolerable, is thought to have contributed to later ZDV resistance. In one report, ZDV resistant strains of HIV accounted for up to 15% of new infections, although a portion of wildtype HIV may be ZDV-resistant. In another small study, 30% of patients who had never taken 3TC were resistant to that drug.<sup>12</sup> Although, in general, there is insufficient data to determine the causes or extent of HIV drug resistance, there is clinical agreement that the commitment of patients to maintaining an HIV treatment plan is as critical as their preparation and decision to initiate it.

However, in work on other diseases requiring self-medication, researchers have reported that only about 40-50% of patients complete a course of medication for an acute illness. Only 25% complete a course of antibiotics, and about 40-75% maintain medication schedules for chronic disorders such as hypertension, asthma, epilepsy, and diabetes.<sup>13</sup> Even participants in clinical trials such as ACTG 076 (which found reduced maternal-fetal HIV transmission with administration of ZDV to pregnant women and infants) averaged only about 60%. Thus, with average compliance among the population at large at about 50-60%<sup>14</sup>, providers of HIV care face an uphill struggle in persuading patients to perfectly maintain HIV medication schedules.

Although there is a history of interest in non-

compliance, relatively little is known about predictive factors for maintaining therapy. Regarding HIV, neither risk behaviors nor demographic factors reliably predict treatment maintenance.<sup>15</sup> Substance use and mental illness seem, in some reports, to correlate with irregular medication schedules. Past non-compliance is also often a poor predictor of present or future behavior in individuals.<sup>16</sup> Studies indicate that even physicians who know patients well cannot predict better than chance who will maintain treatment regimens.<sup>17</sup>

Efforts to combat multiple-drug-resistant tuberculosis using directly observed therapy (DOT) to ensure regular drug administration among people who may not otherwise complete treatment have been proposed by some as a model to prevent large scale drug resistance. However, DOT is not possible with triple combination HIV treatment that involves many doses of a variety of medications each day. While the TB epidemic illustrated the dangers of drug resistance, it also demonstrated that when patients are given adequate supports, including information, encouragement, and treatment plans that accommodated practical life style issues, were able to maintain effective self-medication schedules and complete therapy.<sup>18</sup>

Studies have further shown that the following objective elements are associated with the highest rates of treatment maintenance: simple, inexpensive regimens, frequent clinical appointments with incentives to keep them, individualized one-on-one patient education, persistence in conveying information, and tools such as pill dispensing systems to prompt treatment maintenance.<sup>19</sup> Other factors, such as pill size, access to food, ability to eat, drug interactions, and concomitant illness are also clearly important.

However, subjective elements seem to be at least as critical. These include patient beliefs about the benefits of the drug, perceptions of

the severity of the disease, symptoms of illness at the moment, understanding of the regimen, fear of side effects, trust in the doctor's clinical judgement, type of interaction with the physician, belief that the provider is interested in the patient's welfare, patient involvement in the treatment process, comfort and convenience of the setting, and peer support.<sup>20</sup> Development of a cooperative relationship with the physician has been cited as the single most important variable. Clearly, that is less likely to occur if medical visits are brief, impersonal, and infrequent.

The prominence of subjective elements supports the contention that each person and each episode of illness is distinct. Categorical assumptions do not apply. Recent attention to reasons for missing doses has emphasized that patients bring their own set of beliefs and decision making capabilities to medical encounters and to discrete events in the course of therapy. Taking or not taking a dose of medication or discontinuing an entire regimen is a specific decision undertaken by an individual in a specific context for specific reasons. This view argues that refusing, interrupting, or stopping therapy is not deviance or non-compliance, but a rational course based on the patient's beliefs and information.<sup>21</sup>

Thus, it is strategies to enhance positive beliefs and increase information that are likely to most significantly improve treatment maintenance. More data are needed on how to best establish clinical relationships that incorporate these strategies, which will lead to the need for more resources, including time and training, so that providers can develop the skills and have the opportunities to provide effective HIV education and care.

Further, pharmaceutical companies should be encouraged to develop drugs that are simpler to administer, reducing the size of pills, frequency of dosage, and nutritional

restrictions, and constructing regimens that are appropriate for children. Techniques for maintaining regimens in children should be further explored.<sup>22</sup>

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## V. ETHICAL STANDARDS FOR ACCESS TO HIV TREATMENT

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In determining the primacy of universal access to HIV treatment, the Workgroup established and built upon the following ethical foundation:

1. It is unethical for providers to deny information about potentially beneficial treatments to any person with HIV;
2. It is unethical to deny access to HIV treatment based on the patient's membership in any category or group, past or current risk behaviors, or past behavior concerning medications;
3. Health professionals have an ethical responsibility to provide access to primary care, HIV speciality care, and support services that could enable persons with HIV to benefit from treatment;
4. Physicians have an ethical responsibility to provide care at the point when the patient is most likely to benefit and, simultaneously, to safeguard the patient and the public from harm by doing everything possible to prevent interruptions or cessation of treatment. Thus, physicians are ethically bound to delay or withhold treatment, if necessary, until the patient is able to maintain a treatment regimen;
5. In the event that certain treatments are withheld, physicians have an ethical responsibility to explore other treatment options, provide appropriate care to the patient, and offer to refer the patient to another provider.

Members of the Workgroup agreed that medical and legal interests were compelling and complementary. Physicians and public health professionals have obligations to provide optimal care to patients and to prevent both individual and large scale drug resistance. Similarly, legal concerns center on preventing group-based discrimination in access and preventing harm to individuals or communities.

A number of additional issues emerged in discussion:

- C Patient education was interpreted to include the requirements of treatment regimens as well as the risks and benefits of initiating or delaying treatment;
- C It was agreed that the cost of treatment should not be a factor in whether treatment is universally offered. However, financial issues such as savings from inpatient care, the cost implications of drug resistance, and other concerns should motivate insurers to insist on appropriate time and money for treatment education, particularly in managed care settings;
- C Since HIV treatment requires consideration of the patient's entire social context, many types of groups, including social service, religious, and community organizations should play a more active role in encouraging HIV prevention, testing, and treatment education, and in facilitating access to support services;
- C While maximum patient participation in determining the treatment plan is encouraged, the physician is still the ultimate arbiter of medical decisions.

Finally, the Workgroup acknowledged that even with simpler regimens, ideal patient education, and supported clinical care relationships, the special needs of some individuals and populations may make the

initiation and maintenance of HIV treatment difficult.

For example, prison inmates, detained immigrants, and other institutionalized people with HIV do not have control over their own schedules, meals, transfers, access to physicians or health information, coordination of care, participation in support services, or any other health related issues and, therefore, often have no way to initiate treatment or prevent interruptions. Health professionals have a particular obligation to these individuals to formulate the most effective treatment plan possible and arrange services that will enable the person with HIV to benefit from treatment.

About 20% of people with HIV develop dementia, and many have other types of cognitive deficits. Self reporting about medication schedules is unreliable, particularly when there is mental impairment, and such patients may not know when they are unable to follow a medication schedule. Ethical decisions about HIV treatment in this context are particularly

difficult.

Medication regimens, difficult enough for adults, are nearly intolerable for children. Side effects and unpredictable behavior complicate treatment. Often, there is insufficient respect for the family decision making that governs treatment of children with HIV. Trusting relationships with providers and family involvement in the treatment process can help prevent parental decisions that are medically inappropriate for the child.

The Workgroup concluded that much information that would inform ethical decision making is lacking and, consequently, many questions remain. What constitutes optimal patient education? Under what circumstances is it appropriate not to prescribe? What is the risk of community harm from failure to maintain treatment regimens? Members of the Workgroup urged that research and experiential data on these issues be continuously monitored.

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## **VI. \* PRINCIPLES AND RECOMMENDATIONS**

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As new types of treatment for HIV infection appear they have provided dramatic benefits to people with HIV, redefining both the course of HIV disease and standards of HIV care. Combination therapy with protease inhibitors may be such an advance, with the potential to improve quality and length of life for people with HIV.

- h** Responding to reports that individuals and entire groups of people with HIV may not have access to current HIV treatments, and
- h** Acknowledging the obligation of providers and patients to utilize drugs responsibly,

The members of the New York State AIDS Advisory Council's Ethical Issues in Access to HIV Treatment Workgroup hereby delineate the following principles and recommendations regarding access to HIV treatments:

### **KNOWLEDGE OF HIV STATUS**

- 1. The first step in gaining access to HIV treatment is learning one's HIV status. All health care providers and all social service, religious, and community organizations have a public responsibility to widely and strongly encourage HIV counseling and testing.**

Every person should understand basic information about HIV transmission and be encouraged to learn their HIV status, especially if they are sexually active, pregnant, planning a pregnancy, or engage in behavior that puts them at high risk for HIV.

### **ACCESS TO HEALTH CARE SERVICES**

- 2. Every person with HIV should have access to basic health care services as well as HIV specialists as needed.**

Many people with HIV still lack access to primary care services and/or to providers with HIV expertise. Health officials and providers share the responsibility of ensuring that people with HIV get appropriate, up to date medical care.

### **ACCESS TO HIV TREATMENT INFORMATION**

- 3. Health care providers have an ethical obligation to inform every person with HIV about all potentially beneficial treatments. Information is broadly defined to include a full explanation of the requirements of treatment regimens and the benefits and risks of initiating or delaying treatment.**

Health care providers have a responsibility to stay informed about clinical developments in HIV/AIDS and to discuss treatment options with patients or make referrals for this purpose. Treatment information should also be available through health education campaigns and methods that do not directly involve providers and should take into account culture, gender, age, language, education, and other differences among individuals and populations.

\* Approved unanimously by the NYS AIDS Advisory Council, November 1997

## **PATIENT-PROVIDER COLLABORATION**

- 4. Determining an HIV treatment plan should be a collaborative process undertaken by a patient with HIV and a health care provider. As part of the long term process of HIV care, patients have a responsibility to play an active role in shaping treatment decisions that fit the circumstances of their lives and to maintain treatment regimens, and providers have a responsibility to work with patients to explore treatment options and to identify and reduce barriers to care.**

The greatest chance for successful treatment occurs when patients have participated in treatment decisions and when both patients and providers believe in their potential benefits. Moreover, an ongoing positive relationship is essential for effective HIV care. Readiness to begin a treatment regimen may entail a prolonged process of preparation, including frequent reviews of information as well as resolution of possible impediments to treatment success. A decision to initiate treatment will require the continued active involvement of the provider to monitor the person's tolerance for the medications, access to support services, maintenance of the regimen, and clinical status. A decision to postpone treatment will require regular reevaluation and may require consultations with or referral to other providers. Providers should guard against criticism, judgement, threats, or punishment of patients who are not ready to initiate or maintain treatment. Similarly, patients have a responsibility to be active participants in treatment discussions, to use support services, to maintain treatment regimens, and to be honest when they do not. Providers doing their best to educate patients, arrange support services, and encourage treatment maintenance cannot succeed unless patients wish to be informed, ask questions when information is unclear, offer feedback, and make a commitment to follow a treatment plan.

## **SPECIAL POPULATIONS**

- 5. Providers have additional responsibility to carefully determine and facilitate the most appropriate treatment plan when a patient is unable to fully participate in treatment decisions, such as in the case of children or the mentally ill, or when a patient does not have control over his or her participation in services to support treatment maintenance, such as in the case of prison inmates, immigrants in INS custody, or others in institutional settings.**

Providers should enlist others as needed to devise an HIV treatment strategy for patients with special barriers to care, structuring other forms of care to incorporate HIV therapy and support services and educating other caregivers and personnel about the importance of maintaining HIV treatment regimens.

## **HIV TREATMENT SUPPORT SERVICES**

- 6. Every patient with HIV should have access to support services that will enhance readiness to begin therapy and provide the maximum opportunity for effective treatment and maintenance of the treatment regimen. Providers should be informed about factors that enhance treatment maintenance and support services available to the patient.**

Every person with HIV deserves the chance for successful treatment, which is dependent on many factors. While medication side effects and other unpredictable issues affect treatment maintenance, many factors that limit treatment options or prevent continuation of treatment can be remedied by social and medical support services, which it is the responsibility of government agencies and all components of health care systems, including providers, insurers,

and managed care organizations, to provide. Besides patient education, provider follow-up, access to basic health services, and funding for treatment, services should include those that address obstacles to care experienced by individuals and groups such as the homeless, prison inmates, the mentally ill, immigrants, the disabled, women, children, adolescents, and drug users. Providers have a responsibility to actively refer patients for services that will facilitate the initiation and continuation of treatment.

## **ACCESS TO HIV TREATMENT**

- 7. No individual should be denied access to any HIV treatment because of membership in any category or group, past or current HIV risk behaviors, or past behavior concerning medications, factors which do not reliably predict the ability to maintain a new treatment regimen. Health care providers have an ethical obligation to offer all medically appropriate HIV treatments at the point when a patient is most likely to benefit.**

In the context of education, support, understanding of potential benefit, and ongoing relationships with trusted providers, many patients can maintain a treatment regimen, even if they have not in the past. New circumstances present a fresh opportunity for treatment success. Treatment decisions should be based, therefore, not on categorical assumptions but on individualized assessment of clinical health status, the likelihood of benefit, the availability of support services, the person's interest in and readiness to begin the treatment regimen, and, in view of these, the probability of treatment maintenance. Referral to another provider is an appropriate choice if the provider and patient cannot agree on a treatment plan or a strategy to prepare a treatment plan.

## **RESPONSIBILITY TO INDIVIDUAL AND PUBLIC HEALTH**

- 8. Physicians have a responsibility to consider HIV treatment decisions in light of the potential for both individual and public health risk from discontinuous or inadequate HIV therapy. The decision to postpone or discontinue HIV combination therapy does not decrease a physician's obligation to provide a full range of HIV care to a patient, to explore other treatment options, and to reconsider previously inappropriate treatment plans.**

Although in the general practice of medicine, maintenance of treatment regimens is frequently imperfect, the consequences for lapses in HIV medication schedules or inadequate viral suppression by HIV therapy regimens are potentially serious. Individual patients may develop drug resistance which compromises their future treatment, and there is a potential public health danger of widespread drug resistance resulting from infections with resistant HIV strains. Although data on these possibilities are currently inadequate, studies are expected to further clarify the risks. Providers should stay informed about these issues and consider them in treatment decisions. Further, in HIV care, no treatment decision is final. Circumstances, course of disease, available medications, and responses to medications change rapidly. Thus, providers should evaluate other treatment options in the event that combination therapy is unsuccessful or inappropriate, reevaluate treatment decisions frequently, and reconsider regimens that may not have been possible earlier.

# **RECOMMENDATIONS FOR UNIVERSAL ACCESS TO HIV TREATMENT**

## **EDUCATION**

1. Since lack of awareness of HIV infection is the greatest barrier to treatment, health providers should encourage all clients to learn their HIV status in anonymous or confidential test settings that provide pre- and post-test counseling by trained counselors and appropriate referrals for care. According to current New York State HIV care guidelines, HIV counseling must be provided and HIV testing medically recommended to all pregnant women.
2. Health officials should undertake statewide efforts to ensure that information on the most current HIV treatment options is disseminated in a timely manner to all providers of HIV care.
3. All physicians and other health professionals who provide clinical HIV care should consider it part of their responsibility to regularly update their knowledge of HIV treatment options, correct prescribing practice, and strategies for lack of clinical response or intolerance.
4. Training and/or other forms of support should be available to ensure the ability of HIV care providers to clearly explain complicated treatment requirements and to devise with patients treatment plans appropriate to each person's needs and circumstances.
5. In health care settings, educational models should be employed in which HIV consumer information is repeated during several sessions, providers work in teams to reinforce messages, and follow-up is emphasized.
6. Newsletters, handouts, seminars, outreach programs, buddy systems, pill organizers, reminder devices, and many other techniques and strategies to provide information and promote treatment success may be effective and should be considered.
7. The full range of resources should be employed in HIV treatment education, including peer educators, all variety of health professionals, family members, community and religious organizations, and entire communities, all of whom can play important roles in establishing a consistent environment of support for treatment maintenance.
8. HIV treatment education should be designed to encourage people of any age, gender, or cultural background to explore their options with health care providers.
9. Specific obstacles to HIV care faced by drug users, pregnant women, children, immigrants, the disabled, the mentally ill, prison inmates, and other groups should be addressed in educational materials and outreach services.
10. HIV treatment education should be regularly evaluated for consistency, effectiveness, and relevance to current therapies.



## **SERVICES**

11. The State of New York should ensure that every person with HIV has access to basic health services as well as to providers with HIV expertise. Mechanisms should include improved outreach and other strategies to improve access incorporated into the design of primary care and HIV special needs plans.
12. HIV treatment support services to enable people to begin and maintain complicated medication and nutrition regimens should be available to every person with HIV and should become part of a new standard of HIV care. Support may include housing, supportive residences, day treatment programs, nutritionally appropriate food, mental health treatment, harm reduction and other drug treatment programs, access to Medicaid, ADAP, or other funding for medications, accommodations in scheduling meals or work to fulfill treatment requirements, or other forms of assistance as necessary. Interruption of access to support services and benefits compromises access to HIV treatment, endangering the immediate health and future treatment options of individuals and potentially creating more widespread public health problems.
13. While a particular constellation of support services will depend on individual need, some services should be population-specific, designed, for example, for the homeless, pregnant women, adolescents, children, the mentally ill, drug users, immigrants, inmates, the disabled, or others.
14. Providers of HIV care should take responsibility for helping patients gain access to and successfully continue medically appropriate treatment, a process that includes identifying barriers to care, and making referrals for support services and follow-up. The state should make available regional lists of support services to aid in this process.
15. The state should review all existing HIV support services to determine the role they can play in encouraging HIV treatment maintenance and should use its regulatory authority to remove barriers to HIV services and encourage HIV treatment maintenance in all systems of health care delivery.
16. Medications should be viewed as one part of a comprehensive health plan in which all elements are interdependent. Thus, clinical monitoring, nutritional counseling, secondary prevention education, and other components should be coordinated.
17. Hospice and palliative care should be available for terminally ill persons with HIV who have exhausted all treatment options.

## **TREATMENT PLANS**

18. An HIV treatment plan should be customized, created with and for a specific HIV patient with the goal of prescribing drug therapy when and in the manner in which the person is most likely to benefit.
19. Patients should have an active role in structuring an HIV treatment plan that both patient and physician can support and in which both have confidence, although physicians should not relinquish the essential responsibility of determining what is medically appropriate.

20. An HIV treatment plan should not be based on presumptive judgements about people in any racial, ethnic, gender, age, risk, or other category, nor on the clinical setting, funding mechanisms, or the person's past history of treatment maintenance, but instead on clinical health status, the availability of support services, the person's interest in and readiness to begin the treatment regimen, and, in view of these, the probability of treatment benefit and continuation.
21. Since treatment decisions reflect a particular set of circumstances which require regular reevaluation, a treatment plan is a work in progress. Discussions about treatment options and about the effectiveness and appropriateness of the current plan should be an ongoing process, a routine part of every HIV care visit. This will require expanding the usual time allotted for patient care to establish the dialogue needed to identify possible obstacles to the initiation of treatment, to review laboratory monitoring tests, and to allow the patient to report on medication side effects, changes in circumstances, misunderstandings about the regimen, or other issues that interfere with the maintenance of treatment.
22. For HIV combination therapies, a decision about whether to begin treatment should entail careful consideration and discussion with the patient of the potential benefits of therapy at a given clinical stage, the requirements of treatment regimens, support services that may be required, the risk to the individual of a delay in treatment or of later drug resistance if treatment is discontinued, and possible alternatives if the regimen is unsuccessful.
23. It may be appropriate to postpone or discontinue combination therapy in select cases if, despite a provider's diligent efforts to provide comprehensive HIV treatment education and access to support services, the patient demonstrates an inability to initiate or maintain a treatment regimen. In that case, combination therapy may not be in the best interest of the patient at that time, since irregular dosages of HIV medications can compromise immediate or future treatment benefits and potentially contribute to an increased public health danger from drug resistant HIV strains.
24. Any decision to postpone or temporarily discontinue treatment should follow full discussion with the patient about the reasons for delaying treatment, the steps necessary to initiate or resume treatment, and the option of a second opinion or referral to another provider.

## **FUNDING**

25. The State of New York should ensure that adequate long term funding is provided for provider education and evaluation, HIV medications, support services, mechanisms and devices to promote treatment maintenance, and the extra provider time required to do expanded patient education and follow-up. This should be reflected in care reimbursement rates, as well as grant funded and entitlement programs.
26. In addition to funding for HIV medications, managed care plans and third party insurers should provide funds for patient education about HIV treatment, support services, regular clinical monitoring, and other components of a plan to ensure treatment maintenance.

## **INTERAGENCY COLLABORATION**

27. New York should ensure that programs for people with HIV in the Divisions and Departments of Health, Education, Insurance, Corrections, Social Services, Mental Health, Substance Abuse, and other agencies at all levels are coordinated and duly reflect the principles and recommendations of this document.

## **RESEARCH**

28. Data should be examined to determine whether any demographic, economic, geographic, temporal, or other variable is correlated with inequitable access to HIV combination therapies and, if so, corrective action should be taken.
29. Models of treatment support should be studied to determine the most effective methods of helping patients to maintain treatment regimens.
30. Studies should look at the consequences of treatment discontinuities for individuals and populations and at the basic science and variables of drug resistance.
31. Resources should be directed to the development of less complicated and less expensive forms of HIV treatment and those appropriate to children.
32. Research should examine and disseminate information on the interaction of HIV treatment medications and other prescription, non-prescription, and street drugs.
33. As each new HIV treatment is developed and marketed, the issue of access should remain a serious concern not only to those within the AIDS and health care provider communities but to all who monitor the ways in which social and economic interests and assumptions shape health care services.



**ETHICAL ISSUES REGARDING ACCESS TO HIV TREATMENT  
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