Part of the burden of HIV disease is having to make extraordinarily difficult decisions about medical treatment: when to begin and halt treatment, whether to join clinical trials and how faithfully to follow them, and whether to try alternative therapies and how to interpret experience with them. For many other health-related decisions, there is broad consensus in the medical community about what people ought to be doing. It is common for medical providers to do whatever it takes to get patients to take actions consistent with this consensus. This might involve overt advocacy for the medical standard and more subtle deprecation of alternatives.

HIV-related treatment decisions are often less tidy. They involve gambles with varied consequences and great uncertainty. Rarely can medical providers confidently predict the outcomes of treatments or even in the age of protease inhibitors and triple combination therapy, prescribe a standard approach. New medicines are inherently less certain than old ones, and treatments “in the pipeline” may seem the most uncertain, yet the most promising.

Under these circumstances, the best that health professionals can do is to help patients to understand their choices. The goal is no longer to advocate for fixed treatments but to give patients the best shot at achieving the outcomes they value in a way that leaves them feeling empowered. This article first looks at the decision-making process, and then applies it to HIV-related treatment dilemmas, with the goal of helping mental health and medical practitioners guide people with HIV. This strategy may seem formulaic and does, in fact, employ a formula, but it is most importantly a structured tool to help clients clarify values and a complement to more typical counseling approaches.

**Decision-Making Theory**

Although HIV-related decisions are varied, they share common elements. Each presents possible actions, possible consequences of taking those actions, and uncertainties about which of those consequences will actually occur. Decision theory offers a calculus for identifying the best course of action. Using it, however, requires clearly characterizing a decision’s components. Provider and patient must define options sharply enough to assign probability estimates to each possible consequence and to reveal the—often difficult—tradeoffs that these consequences imply. For example, how much suffering of type X will a person tolerate over the next six months in order to achieve a 10 percent increase in the probability of being alive five years from now with a comparable quality of life?

Corporate or government decisions with large financial stakes often undergo detailed decision analyses conducted by well-paid consultants. This luxury is seldom available for the life-and-death decisions of ordinary people. Even if it were, not everyone would be comfortable trusting their fate to calculations, especially those based on uncertain data.

But the principles underlying decision analysis can help people with HIV disease to structure their decisions so that they can get further into their dilemmas before throwing up their hands and going with their guts. Knowing in detail what it means to make a calculated decision allows people to decide how calculating they want to be. These potential insights can be organized according to the core concepts of “options,” “uncertainties,” and “consequences.”
Editorial: In Decision
Robert Marks, Editor

Indecision is a familiar state of being for me. I am all too aware of the options, and am quick to interrogate them one after another, critiquing and discarding them, and adopting them after careful re-examination.

It must be true for some people with HIV disease, whose choices involve much higher stakes than mine do, that they too experience indecision in response to an abundance of information and a paucity of certitude. Organizations like ACT-UP and Project Inform and publications like AIDS Treatment News, GMHC’s Treatment Issues, and the San Francisco AIDS Foundation’s BETA have made the science of HIV infection accessible, revealing HIV-related treatment in all its complexity to people with HIV disease and their loved ones.

The resulting population of lay-experts has the advantage of being able to identify and understand the treatment options and the burden of being able to dissect and assess each one. Is there a template to help them make treatment decisions, a guide for the all-too-initiated?

The answer is, of course, not an unequivocal “yes.” This issue of FOCUS looks at HIV treatment decision making with the goal of illuminating this process. It provides a bird’s-eye view of the two sides of the decision equation—the provider’s and the patient’s—a perspective that can help counselors help their clients.

The anchor of the issue is an introduction to decision-making theory. Baruch Fischhoff and Julie Downs apply decision science to HIV treatment dilemmas, an exercise absent from the AIDS literature. As they stress, the result is not a cut-and-paste formula—though I am bound to disclose that there is math involved—but a lens through which to perceive and master the decision-making process. In some ways, understanding this process may be as important as understanding the science behind each treatment.

Options

The first step in the process of decision making is to define the options. In practice, individuals rely on health professionals to identify the field of alternatives. This process is not perfect, because practitioners may not wish to discuss treatment options that they cannot provide or do not trust, or with which they are not familiar. Under ideal circumstances, clinicians would lay out all the options, along with the reasons why they favor some and cannot (or will not) advocate others. This is particularly important because options that individuals perceive as “omitted with intent to conceal” may, ironically, acquire more credibility than clinicians may believe they deserve.

The clinician’s rationale provides patients with an orderly framework for determining choices. This increases the chance that unconventional treatments receive the same scrutiny as mainstream ones.

Getting all the options out on the table should also mitigate the natural tendency to neglect “opportunity costs,” that is, the chances that are forgone when one course of action precludes others. For many people with HIV disease, the greatest risk from treatment may not be its direct side effects, but having to forgo other treatments or interfering with natural healing processes.

Once the options have been identified, they must be understood. Technical jargon provides one obvious threat to comprehension. A more subtle risk arises when people with HIV disease attain fluency in the language of treatment, without fully understanding the technical terms or their implications. For example, patients might not realize that what seems like a single treatment option—for instance, “protease inhibitor”—is actually a family of possibilities. As a result, they may not appreciate the clinician’s ability to tailor treatments to patient needs by varying doses or ameliorating side effects. Nor may they understand the opportunities in awaiting the outcomes of research or field trials that might make

Ironically, for many people, the new treatment “paradigm” has not made the choices obvious. In his article, Steven Deeks identifies a range of concerns that complicate treatment decisions: from side effects and toxicity to overwhelming treatment regimens. In a discussion of the approaches clinicians take when advising their patients about treatment, Deeks distinguishes between the limited guidelines of “cookbook” medicine—past recipes employing CD4+ cell counts, symptom profiles, and limited drug combinations—and broader principles of the new paradigm. These fundamental principles enable us to harness the new conception of HIV infection, more precise measures of progression, and a wider array of treatments.

These articles cannot lead to crystal-clear decisions. Too many questions about the new treatment approach remain unanswered, and every individual facing these choices has different goals and values. But, the authors, like therapists, have equipped us with the tools to help clients reach informed decisions: principles, information, and process.
treatment options look different. In response, clinicians should be aware of common misconceptions, aggressively solicit questions about options, and encourage patients to bring friends to appointments to help them process information.

**Uncertainties**

Once clients understand their options, they can focus on how likely it is that the consequences of these options will come to pass. In expressing likelihoods, we often describe events using terms such as “rare,” “uncommon,” or “likely.” But, there is no real substitute for expressing this information numerically. While clinicians might be uncomfortable speaking precisely about issues that are poorly understood, only numerical terms communicate uncertainty in the standardized way needed for decision making. If science can say no more than that the side effect rate from a treatment is anywhere from 3 percent to 30 percent, then clients are better off knowing this range than they are with vague descriptors like “possible.”

To give them an intuitive feeling for where these numbers come from and why they are so uncertain, patients need to understand something about the underlying science. This context should help them to interpret their own “post-decision” experience, so that they can tell when things are going awry and when the decision might need revisiting. It may also enable them to follow public discussion of the issue, so that they have a better chance of distinguishing among scientific evidence, anecdote, and rumor.

The research literature finds that people are good at remembering—and keeping a rough count of—individual occurrences that they themselves have witnessed. However, most of us place too much confidence in small samples and are easily misled by unrepresentative samples. The literature also finds that misconceptions can co-exist with correct beliefs, undermining their usefulness. Once identified, though, these “bugs” in people’s “mental models” can often be corrected with common-sense explanations. For this to happen, clinicians need to consider carefully what additional information is really necessary to help their patients. Finally, patients need to know about opportunities for reducing uncertainty, for example, by running tests to determine susceptibility to side effects or by acknowledging clinical trials that may produce relevant results in the near future.

**Consequences**

Treatment dilemmas often pose irreconcilable tradeoffs. For example, does one want a drug that extends life at the price of persistent nausea and disrupted sleep? The full set of consequences that patients need to consider might include changes in health status, self-esteem, personal relations, and finances. For effective decision making, these consequences must be as specific as possible, so that patients know exactly what they are evaluating. For instance, a possible future health state could include more energy, less nausea, less pain, weight gain, decreased viral load, and an increased CD4+ cell count.

Highlighting these tradeoffs and making them a matter of individual choice can make the decision process an opportunity rather than a burden. Providers should help patients understand the real-life effects of potential consequences. One way of doing this is to relate them to a patient’s past experiences or to those of people whom the patient knows. Many patients may have experienced similar side-effects from other drugs or have dealt with episodes of regret or social pressure; these experiences can inform the process. Patients who have friends with HIV disease may be all too well acquainted with the consequences of treatment. Patients who have neither direct nor vicarious experience may benefit from meeting people who have, or by reading accounts that describe what it was like for them—recognizing the difficulty of imagining physical or psychological states.

Throughout this process, it will be a challenge for patients to realize that it is their values that matter when weighing alternative outcomes. This process can be frustrating, but, ultimately, it can lead to personal growth, as people determine what really matters to them and assert control over their lives.

**Putting It All Together**

Although it may be unnerving to consign one’s fate to a formula, it can still be instructive to “run some numbers,” in order to get a sense of the combined influence of the uncertainties and consequences associated with each option. The logic of these computations is straightforward: calculate the expected utility of each option, then choose the option with the highest score (or, one of the best, if the very best cannot be clearly distinguished). Expected utility

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**References**


Clearinghouse: The New Paradigm

References


is computed by taking each possible outcome of an action, estimating how good or bad it would be (its “utility”), assessing the probability of its occurrence, multiplying the two (to get the expected utility associated with that outcome), and then adding the products from all the outcomes (to get the overall expected utility of the action).

For example, one might array the possibilities along a rating scale anchored by the very best and very worst possible outcomes (equal, say, to +100 and -100, respectively). Using this approach, Peter might rate as +100 the dramatic decreases in viral load produced by Combination X. He might rate peripheral neuropathy -5 because it had proven to be mild, causing only modest discomfort for most people. However, if Peter had once had a severe case of peripheral neuropathy and feared repeating this experience, he might rate the condition -25. The critical point is that Peter gets to assign values that make sense to him.

This process may be useful even if a person has no intention of being bound by the mathematical results. Doing some calculations can help get a fix on complex issues that might otherwise overwhelm a person. Simply writing things down can reduce the risk of neglecting an issue. It can summarize a person’s thinking for others who might provide advice and support. Discussing the analysis can clarify the patient’s and clinician’s respective roles in selecting the appropriate treatment.

Finally, creating a record can protect one, in the future, against “hindsight bias,” the tendency to exaggerate how predictable the outcomes of a decision were when it was made. It can also protect against “outcome bias,” the tendency to evaluate decisions by how things turned out, rather than by how wisely the situation was analyzed when the choice was made. Either bias can add a needless element of regret. When people engage in careful and thoughtful decision-making processes, their decisions should be more systematic and less vulnerable to biases.
Principles of HIV-Related Medical Care
Steven G. Deeks, MD

The use of antiretroviral therapies to treat HIV disease has, until recently, been based on clinical guidelines. For example, recent guidelines suggested that as CD4+ cell counts fall to 500, patients should begin treatment with zidovudine and, after a year or two, switch to didanosine. However, since the field has evolved so dramatically over the past year, such clinical guidelines—cookbook medicine—are no longer appropriate. Instead, clinical decision-making is increasingly based on much broader principles of therapy.

As part of this shift, clinicians and researchers have articulated new goals for HIV-related antiretroviral treatment. For most of the past decade, antiretroviral therapies aimed at delaying disease progression. Today, the goal of treatment is to stop progression: to fully suppress viral replication. The logic is relatively simple. By preventing HIV from replicating, mutations in its DNA cannot occur, making viral resistance to any combination of drugs impossible. Since these combinations prevent resistance, they can work indefinitely and halt disease progression. For some patients, this goal may be achievable. The challenge is to find potent combinations that patients can tolerate and which result in enduring suppression of viral replication.

To understand resistance, it is important to understand mutation. Mutation refers to specific changes in the HIV "genome" or DNA. Every time HIV replicates in an individual's body, it makes mistakes and mutates. Occasionally, a mutation allows HIV to replicate more easily in the presence of a particular antiretroviral treatment. Since the treatment is effective in blocking the replication of other strains of HIV—only those that have not mutated—the resistant strain quickly takes over and becomes the dominant strain. Once resistance develops, it is probably permanent, and the more often mutation occurs, the more difficult it becomes to find an effective drug regimen.

Hit Hard: Use Three Drugs

“Hit hard, hit early” describes the evolving paradigm of HIV treatment. The first principle, “hit hard” is becoming widely accepted: in order to fully suppress the virus, patients should initiate treatment with combinations of drugs all at the same time. Typically, these combinations include two nucleoside analogs, for example, zidovudine (ZDV; AZT) and lamivudine (3TC) plus a powerful protease inhibitor. These drugs should be taken at their full doses and started within no more than a couple of weeks of each other. The goal of this approach is to render HIV unable to replicate and force it into a “dormant” state.

It is no longer appropriate to start off with a single drug like ZDV. In such cases, the virus is able to mutate and become resistant to the drug in a matter of weeks. In fact, many experts recommend against therapy with two similar antiretroviral drugs—such as the popular combination of ZDV and 3TC—since this tentative, less aggressive approach allows HIV to replicate and still easily mutate. Adding a protease inhibitor to a failing regimen is tantamount to making the treatment a futile one.

The following newsletters and other publications are devoted to HIV-related treatment issues:

- *AIDS Treatment News*, P.O. Box 411256, San Francisco, CA 94141; 800-TREAT12 or 415-255-0588; aidsnews@aidsnews.org.

- The *Bulletin for Experimental Treatment for AIDS (BETA)*, published by the San Francisco AIDS Foundation, PO Box 2189, Berkeley, CA 94702-0189; 800-959-1059.

- Project Inform publishes fact sheets on a variety of treatment-related topics, 1965 Market Street, Suite 220, San Francisco, CA 94103; 800-822-7422 (national hotline), 415-558-9051 (SF hotline), 415-558-0684 (fax).

Resources

- Treatment Issues, published by the Gay Men's Health Crisis in New York, 129 West 20th Street, 2nd Floor, New York, NY 10011.

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See also references cited in articles in this issue.
to using that protease inhibitor alone, resulting in mutation and rapid resistance.

A corollary to the “hit hard” principle is that compliance with medication regimens is crucial to the overall goal of complete viral suppression. To prevent resistance, the virus must be suppressed continuously. While it is clear that missing a few doses every month or so is safe, the more doses missed, the more likely it is that the virus will have a chance to replicate in the absence of the drug and become resistant. If a drug must be stopped in response to side effects, it is best to switch immediately to a replacement at its fully prescribed dose. Taking low doses allows HIV replication in the presence of the drug and is no longer an appropriate response to side effects.

In short, there is substantial clinical evidence to support the principle to “hit hard.” Patients who are not taking antiretroviral drugs have two options: suppress the virus completely or leave it alone. Patients currently on non-aggressive but effective regimens, such as ZDV plus 3TC, can continue as long as they are doing well. However, if they experience a decline, they will probably need to switch to two other nucleoside analogs plus a protease inhibitor.

**Hit Early?**

The second fundamental principle is that clinicians should initiate treatment as early in the disease process as possible, even for patients with normal CD4+ cell counts. Although the premise to “hit early” is based on some clinical data, it is more controversial than the “hit hard” approach. It is difficult to justify exposing otherwise healthy individuals to the expense, potential toxicity, and complexity of medical regimens.

Hitting the virus early in the disease process is based primarily on three theoretical concerns. First, when a person is initially infected with HIV, the pool of virus in the body is relatively homogeneous. After years of replication and the inevitable mutations that follow, the body becomes host to multiple strains of the virus. Second, early in the disease process, HIV spreads throughout the body, seeding different organ systems such as the genitals and the brain. Treating HIV in these “sanctuaries” may be difficult as HIV disease progresses. Third, early treatment will likely prove beneficial because HIV-related immune destruction may not be reversible. Until research confirms otherwise, a patient can expect antiretroviral therapy to do no more than maintain the immune system at the level it was when he or she began that treatment (even if CD4+ cell counts increase).

The extreme example of “hitting early” is the practice of initiating combination therapy in patients who have been recently infected, that is, within the three months preceding treatment. However, the number of people who know they are infected within a month or two of contracting HIV is very small. Barring this knowledge, clinicians use quantifiable measures of infection—viral load and CD4+ cell counts—to determine when to start therapy. Today, there is clear consensus that people with a viral load greater than 10,000 to 30,000 copies of HIV RNA per milliliter and CD4+ cell counts of less than 350 should definitely begin treatment. People who have viral loads above 10,000 and CD4+ cell counts below 500 should probably begin treatment. People who have CD4+ cell counts above 500 should probably not begin treatment unless viral load is above the 10,000 range.*

Some virologists and clinical experts have gone beyond these guidelines, advocating that every seropositive patient should be aggressively treated with three-drug combinations. For people whose CD4+ cell counts are relatively high and whose viral load is relatively low, this may not be an attractive option: it is understandable that an otherwise healthy, asymptomatic person might delay treatment when confronted with the possibility of a lifetime commitment to ingesting a handful of pills—each of which can cause a variety of side effects—three to four times a day. In such cases, experts recommend close monitoring of viral load and CD4+ cell counts. Until there are better data, deciding when to initiate therapy is dependent on individual preferences and personal experience.

Clouding the issue is the fact that the science of treatment is advancing daily, and decisions made today might be regretted six months from now. A year ago, clinicians routinely recommended starting treatment with two drugs, and adding a third when HIV disease progressed. Today, many clinicians regret this approach, since it appears now to encourage drug resistance. For healthy people with early stage disease, waiting for science to catch up remains a reasonable option. Those in the middle and late stages of AIDS, however, cannot afford to wait. Hitting hard is important at whatever point therapy is initiated, but hitting
very early may be too stringent a criterion to be held up as a standard.

Are All Combinations Created Equal?

Combination therapy and the advent of the protease inhibitors have reinvigorated HIV antiretroviral therapy. However, with 10 drugs currently available, there are hundreds of possible combinations. When they confront the daunting task of identifying the best combination for a particular patient, clinicians consider side effects, drug interactions, dosing regimens, cost, and the possibility of viral resistance.

Combination therapy usually includes two nucleoside analogs such as ZDV and 3TC plus a protease inhibitor. Among the protease inhibitors, there are now four options. In the United States, indinavir (Crixivan) has been the most popular of these. However, it can cause kidney stones and requires adherence to a complicated regimen. Indinavir must be taken every eight hours on an empty stomach, forcing patients to be ruled by an alarm clock.

Ritonavir (Norvir) is a powerful drug. It is the only protease inhibitor with convenient twice-daily dosing. But, ritonavir has significant side effects, particularly during the first few weeks of treatment. (Many of these side effects may be prevented by escalating dosage gradually over two weeks.) In addition, ritonavir interacts with a number of other drugs further complicating treatment. The third option, saquinavir (Invirase), is safe and well-tolerated, but it is not as potent as the other options, primarily because only 4 percent of the drug is absorbed. Recently approved by the Food and Drug Administration, nelfinavir (Viracept), the fourth option, appears to be safe, well-tolerated, and potent.

Recent research suggests that patients may now have a fifth option: the combination of ritonavir and saquinavir. Because of unique interactions between these drugs, they can be administered at low doses and are particularly effective. Over the next year, other options are certain to emerge.

The nucleoside analog drugs include ZDV, 3TC, didanosine (ddI), zalcitabine (ddC), and stavudine (d4T). The combination of ZDV and ddI or ZDV and 3TC may be the best combination for patients who have never received therapy in the past. However, in the HIV epicenters such as San Francisco, Los Angeles, and New York, many if not most people with HIV disease have already taken ZDV and the other nucleoside analogs. Theoretically, such patients may already be resistant to these drugs. For them, it is difficult if not impossible to apply the principle—articulated below—of starting three “new” drugs. In these cases, clinicians must apply experience and knowledge of resistance to select the optimal combination.

Changing Therapy

A clinician may suggest changing a drug for a variety of reasons, including side effects and difficulties with compliance. However, the most common reason is drug failure, typically manifesting as an increasing viral load. In these instances, it is possible that a patient’s virus has become resistant to his or her medical regimen. In response, the fundamental principle is to avoid replacing a single drug. If a combination has truly “failed,” and the development of drug resistance is a genuine concern, it is probably best to change the entire antiretroviral regimen.

Unfortunately, there is little clinical data to guide clinicians when resistance to a protease inhibitor develops. For example, we do not know if a virus resistant to one protease inhibitor will respond to a second administered subsequently. Until such data exist, clinicians should consider a patient’s first regimen—including a protease inhibitor—as the patient’s best chance for “complete” viral suppression.

Conclusion

Over the next few years, researchers and clinicians will publish guidelines on how to treat patients using antiretroviral therapies. These guidelines will represent the best recommendations at the time and will be valuable as clinical tools. While experience suggests that these guidelines will change with time—incorporating new medications and treatment options—it is likely that the broader principles of therapy will evolve more slowly and that preventing drug resistance will remain the cornerstone of future treatment decision making.

Comments and Submissions

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Recent Reports

Viral Load


Although CD4+ cell count remains the best predictor of the development of opportunistic conditions, plasma HIV RNA level, or “viral load,” appears to be the best predictor of long-term clinical outcome for people with HIV disease, according to an overview of appropriate clinical use of viral load testing. Viral load can indicate risk of disease progression, timing and efficacy of antiviral treatment, and treatment failure.

Viral load—which is quantifiable in virtually all HIV-infected people—is useful because it exhibits a wide dynamic range, correlates significantly with clinical stage, and provides data that can inform treatment decisions. High viral load corresponds to lower baseline CD4+ cell counts, more rapid declines in CD4+ cell counts, and more rapid disease progression.

The CD4+ cell count remains an essential index for making decisions about opportunistic infection prophylaxis and for evaluating the immunological effects of antiretroviral therapy. CD4+ cell count alone, however, is inadequate to determine prognosis and to measure response to antiretroviral therapy, and is subject to substantial variability.

Viral load, as is CD4+ cell count, is expressed as a quantity per milliliter of blood, in this case the number of copies of HIV RNA. Initially, clinicians should obtain two viral load readings two to four weeks apart and subsequent measurements every three to four months. At critical decision points, for example when changing treatment, clinicians should increase frequency to every three to four weeks.

Studies have shown that patients whose viral loads exceed 100,000 within six months of seroconversion were more likely than those with lower viral load to progress to AIDS within five years. Patients who maintained viral loads of less than 10,000 did not progress to AIDS during the next five years. High viral load (from 30,000 to 50,000) warrants the start of therapy, regardless of CD4+ cell count. The minimal response indicating effective antiviral treatment is a three-fold reduction in viral load, a magnitude that reflects biologically significant changes in viral replication.

Protease Inhibitor Review


Long-term studies of the protease inhibitors have only recently been completed and, therefore, results have not undergone peer review. But since there is such a demand for protease inhibitors, this technical review of conference and meeting presentations provides a rational approach to prescribing these drugs.

The review explains how protease inhibitors work, their interactions with other drugs, and their safety, efficacy, and cost. Protease is an enzyme that acts as a “molecular scissors,” cleaving large protein chains into smaller ones that enable HIV to mature. Protease inhibitors block the part of the protease molecule that clips these chains, thus preventing HIV from maturing.

The annual cost of treatment with a protease inhibitor, two reverse-transcriptase inhibitors, and viral load testing is well over $10,000. The federal ADAP program was meant to fill a gap by paying for medications for those with advanced HIV disease until they qualified for Medicaid. But the prospect of providing long-term medication support for tens of thousands of people has provoked a crisis in the program. Likewise, Ryan White CARE Act services, which are aimed at those with advanced disease, may become less necessary, but only if combination therapy is affordable.

Next Month

As studies of protease inhibitors are too recent to have been published in peer-reviewed journals, so it is that "data" on psychosocial adjustment to the new treatment paradigm arises from first-person accounts. In the May issue of FOCUS, Ron Henderson, Director of Training and Education at Health Initiatives for Youth in San Francisco, describes his own experience dealing with the shift in AIDS care and recounts the stories of four others facing different situations but similar decisions.

Also in the May issue, Jeffrey Moulton Benevides, PhD discusses life as a San Francisco therapist treating people whose lives and perspectives of life are rapidly changing.
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