

wise words

When to use anti-HIV therapy: the decision is yours to make!



making a decision about when to start anti-HIV therapy and what drugs to take can be a challenge. There's no one right answer about when to start or what therapies to use, but there are answers that are right for you. As you embark on this decision, think about your needs, as well as the medical facts, and how starting therapy—or even waiting—fits into your life. Take time to look at both the risks and the benefits of starting therapy as well as waiting to start.

There are many tools that can help you in making an informed decision about treatment. The Federal Guidelines for the use of anti-HIV therapy is one of these tools. The Federal Guidelines are just what they say, a guide. They provide informa-

tion, recommendations and suggestions on when to start treatment. They also outline the risks and benefits of treatment, what drugs to start with and options for changing therapy. The Guidelines are not a “one size fits all” solution, but rather a tool to assist you in making decisions.

On page 2 is a summary of the Federal Guidelines. Keep in mind that they are periodically reviewed and revised. You can also access the most current guidelines at www.hivatis.org.

In the following pages you'll find discussion points to consider if you're thinking about using anti-HIV therapy for the first time, to help you decide—for yourself—if starting therapy is right for you. You'll also find information on ways you can promote your own health. These are things you might consider exploring now, whether or not you decide to use therapy. Learning about anti-HIV therapy, the risks and benefits of starting now or waiting, and further developing for yourself your own decision-making process is central to making an informed decision.

Remember, this is your decision—take your time to make it.

Greetings Wise Women!!

My name is Shalini Eddens and I recently joined Project Inform as the new Program Manager for Project Wise. Project Wise was truly blessed to have the leadership of Angela Garcia. Earlier this year, Angela went on to continue her education. Her contributions to Project Wise and *Wise Words* will be remembered and appreciated. We wish her the very best.

I am optimistic and excited about the future of Project Wise. More importantly, I'm grateful to each of you for being such an important part of *Wise Words*. I invite your questions, comments or anything that keeps *Wise Words* your newsletter! Contact us at wisewords@projectinform.org, or 415-558-8669 x205.

This issue is for women who are considering therapy, specifically those with a chronic established infection vs. acute infection. A chronic infection means you were exposed to the virus over a year ago. An acute infection means within the last year.

These timelines are not written in stone—varying factors can influence an infection being acute or chronic. If you're unsure about the time of your infection, talk with your doctor.

I hope you can make this issue of *Wise Words* more personal to your life. Remember, the best decision is an informed decision—one that you made for **YOU!** Peace

Shalini Eddens

Shalini Eddens
Program Manager, Project Wise

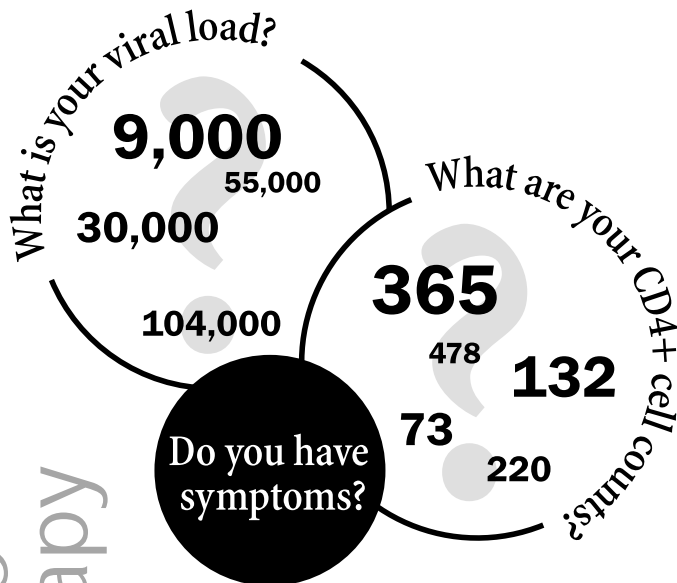
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federal guidelines for the use of anti-HIV therapy



- ▶ No symptoms of HIV disease, with CD4+ cell counts between 200-350 and any viral load. Anti-HIV therapy should generally be offered, though controversy exists. Some experts believe it is often safe to wait until the CD4+ cell count falls to 200. Others believe this offers too little room to accommodate individual differences in how HIV disease progresses. In this case, they feel it's safer to start therapy at CD4+ cell counts of 350.
- ▶ No symptoms of HIV disease, with CD4+ cell counts above 350 and viral load above 30,000 copies by bDNA or 55,000 by RT-PCR. There are two unproven theories about treating early HIV infection in people without symptoms: aggressively vs. conservatively. For people who meet this definition, there are no data to suggest which approach results in longer survival. Very early, aggressive treatment might lead to longer life and greater preservation of the natural immune response against HIV. Or, it might lead to using up the limited supply of therapies too early in the course of disease. As well, it risks early exposure to possible long-term side effects from therapies. As a result, many experts would delay starting therapy and continue to monitor CD4+ cell counts and viral load until certain levels are reached. On the other hand, the risk of disease progression over the next three years is somewhat high (over 30%) in people who meet this definition. As a result, other experts prefer to start treatment without further delay, believing that preventing damage by the virus may be preferable to trying to repair what breaks later on.
- ▶ No symptoms of HIV disease, with CD4+ cell counts above 350 and viral load below 30,000 copies (bDNA) or 55,000 (RT-PCR). Many experts would delay therapy and continue to monitor CD4+ cell counts and viral load. The risk of disease progression over the next three years in this group is low (below 15%).
- ▶ Acute HIV Infection (very early, typically within days to weeks after initial infection) If infection is suspected, test for HIV using sensitive methods. (Note: technologies that measure viral load are not approved for diagnosing HIV infection and are discouraged for this use.) Experts agree that if treatment is offered this early, it should only be done in the context of a study. People interested in exploring very early treatment should be made aware of all its potential risks. The true long-term effect of early treatment is unknown because current studies are not yet complete. The hope, though, is that it might lead to a less aggressive course of disease. Whether or not this is the "right" approach remains unknown.

- ▶ Advanced stage disease (severe symptoms of AIDS, with any CD4+ or viral load level. All people with severe symptoms of AIDS are encouraged to be treated with anti-HIV therapy. In this case, therapy is shown to prolong life and improves symptoms. When starting therapy to prevent or treat serious infections (called *opportunistic infections*) at the same time as starting anti-HIV therapy, special care should be taken to avoid drug interactions. A person experiencing an opportunistic infection is generally encouraged to continue anti-HIV therapy.
- ▶ No symptoms of HIV disease, with CD4+ cell counts below 200 and any viral load. Anti-HIV therapy should be offered after considering the issues for making treatment decisions.

The following are the wise words of two women who have considered anti-HIV therapy at one point or another. They share the processes they went through in making their decisions, what helped and the challenges they faced.

WORDS OF EXPERIENCE FROM POSITIVE WOMEN

sarah

Sarah has gone back and forth about starting therapy. Her CD4+ cell count is just below 350 and her viral load fluctuates between 30,000 to 40,000 copies. Her provider recommended she begin therapy. She decided not to start anti-HIV therapy. Instead, she uses traditional Chinese medicine, herbs, acupuncture, eats well and only organic fruits and vegetables. She is healthy and feels great!

Q: What types of things did you think about when considering therapy?

A: As I was going through the motions of investigating, while my heart told me not to take it (anti-HIV therapy) my doctor and other people told me to start taking them. A lingering feeling of the gamble if I take it or if I wait is always at the back of my mind. It's a constant struggle.

Q: What kinds of resources did you use to help you think through the decision?

A: I spoke to friends and Project Inform. I read a lot and used the internet or got information from places like TheBody.com, Kaiser Family Health Foundation, Centers for Disease Control, National Institute of Health, and BETA (San Francisco AIDS Foundation's treatment publication).

Q: What type of advice would you give to a woman considering therapy?

A: The decision that they make is theirs; other people shouldn't tell you what to do. Understand the medications and what they do. Flush out all your concerns, expectations and fears. You need a lot of education!

diane

diane was diagnosed with HIV in 1988 when only one drug was available—AZT (zidovudine, Retrovir). Her doctor tried everything he could think of to stall the progression of the virus and put her on a 30-day cycle of AZT at 1,200mg/day. That's 3 pills every four hours all day. This is twice the currently recommended dose of AZT, but was still used by many doctors in 1988, especially in people who didn't have AIDS. Diane recalls her experience: "It was a very negative introduction to meds for me and it really scared me."

In 1992, Diane's CD4+ cell count dropped to 500. After three times of her labs showed CD4+ cell counts below 500, her doctor suggested therapy.

"I asked him if I take meds until my T cells (CD4+ cells) go above 500, can I stop? He said no, that I would be taking meds for the rest of my life. It felt like the beginning of the end. I felt like I was being punished. I had not disclosed my status and didn't know how to deal with that. I knew there were a lot of side effects.

"At some point, I began to realize that the pills were not my enemy. I was supporting my body, they (the pills) are like this superpower. At the same time, they were also harming my body. They reminded me that I was sick! So I had to make friends with my pills. The more I learned about what the meds were doing, the more I could understand it. I started to embrace them."

Q: What advice would you give to women considering therapy?

A: Ask every question you possibly can, as many times as you can, until you completely understand it. Understand that the drugs are not perfect. They are a tool in your toolkit along with the healthy eating and taking care of yourself. They are a component in a whole picture. Find a buddy who is also on meds. It is possible to live your dreams with HIV, and taking meds can be part of the success!

Q: How did you deal with side effects?

A: Side effects are as unique as the individual. They don't happen 100% of the time, they happen 10-20% of the time (and not in everyone). Talk out your fears about side effects. Take a few days off if you can at the start to get used to the drugs. Have someone around—you may feel sick. Talk to other folks, and talk with them about your fears. Never put a handful of pills in your mouth ... one at a time between bites of food (*only for drugs taken with food*). Drink water with a splash of juice to ease the nausea that may come with the taste of the pills.

Q: Do you have any other advice?

A: Find a buddy to cheer you on! Numbers (like CD4+ cell counts and viral loads) are guides. Even if you are far from taking therapy, it's okay to start researching and asking questions now so you're not overwhelmed when you come closer to making that decision.

Walking your way through making a decision

When considering therapy, there are many issues to keep in mind. Though research has not defined an absolute standard time to start anti-HIV therapy, some criteria can assist you in making a decision tailored to your needs. This road map highlights these criteria and may help you in this process. It may be a good idea to bring this with you to your doctor's appointment for discussion. Remember, take your time and don't feel pressure to make the decision today.

1

Your readiness and belief in therapy

Before you start any kind of medical treatment make sure that you're ready. Take time to reflect and contemplate how taking therapy is going to impact your life. Ask yourself questions like: Do I feel ready? What kind of expectations do I have? Do I have a support system or someone I can talk to about therapy? Am I scared? If so, of what am I afraid of? Explore your own beliefs and fears about therapy. Ground yourself in knowledge rather than fears. Talking to other people about their treatment decisions can be extremely beneficial, but remember ... what works for one person does not always work for another.

2

Viral Load

What is your viral load? _____

Has your viral load *trend*...

- gone up more than 3-fold (i.e., an increase from 10,000 to 30,000) or
- gone down over your last few tests?

30,000 or below
(generally considered low)

Therapy is generally not recommended, but if you're experiencing symptoms or have very low CD4+ cell counts, considering therapy might still be warranted.

30,000-50,000

Federal guidelines suggest considering therapy if your CD4+ count is also below 350. However, if your CD4+ cell count is high (above 350), it's reasonable to wait.

Viral load readings, especially in the first 3–5 years after infection with HIV, may be different in women and men. While viral load readings of 30,000–50,000 is generally considered moderate/low in men, this might be high for a woman and signal a more pressing need for intervention.

100,000 or above (considered high)

Increased risk of disease progression. Federal Guidelines strongly suggest and encourage anti-HIV therapy.

For more information, read Project Inform's *Blood Work: A Useful Tool for Monitoring HIV*; *Wise Words #3*; and *Vaginal Candidiasis*.

3

CD4+ Cell Counts

What is your current CD4+ Cell Count? _____

Over your last few tests, has your CD4+ cell count *trend*...
 gone up or gone down?

Is your CD4+ count generally declining or is mostly stable, with just modest movement (100 points or less) up and down? A stable CD4+ count, as long as it's above 200, has less risk of progression than one that's steadily declining.

CD4+ cell count above 500
(normal range 500–1,500+)

Maintain good healthy habits (nutrition, exercise, monitor disease progression and labs).

Therapy is generally not recommended. If your viral load is high and/or you're experiencing symptoms, therapy might still be warranted. However, if the CD4+ count is declining rapidly and consistently, and the viral load is high, some doctors might recommend treatment or more frequent monitoring.

CD4+ cell count 200-500

If you are in this range, you may want to consider therapy, especially if you have developed symptoms associated with immune dysfunction. Examples include shingles (zoster), and recurrent and aggressive yeast infections. When no symptoms are present, most doctors would consider delaying treatment at least until the CD4+ count consistently falls below 350.

Guidelines suggest considering therapy when CD4+ cell count is consistently at or below 350

If your CD4+ cell counts are above 200, and you experience recurrent fungal infections (thrush, etc.), preventive therapy for pneumocystis carinii pneumonia (PCP) is recommended.

CD4+ cell count 200 and below

There is an increased risk for developing serious and life-threatening infections (*opportunistic infections*) and therefore the Federal Guidelines highly recommend anti-HIV therapy.

If you choose not to use antivirals at this point, talk with your provider about preventive therapies against common infections, like mycobacterium avium complex (MAC), cytomegalovirus (CMV) and toxoplasmosis. Monitor your lab values, weight, minor symptoms and overall sense of well-being.

If your CD4+ cell count and/or viral load levels change drastically from one test to another, discuss this with your provider. Large sudden changes are often the result of lab errors or other health factors (like a flu shot or stress).

For more information, read Project Inform's *Blood Work: A Useful Tool for Monitoring HIV*.

4

The goal of HIV treatment

Take time to understand how therapy works. Get informed so you have solid foundation in understanding the goal of treatment. Learn about all of your possible treatment options. It's important to understand the risks and benefits of both *starting* and of *waiting*. If you start therapy now, what are the possible side effects and how will you monitor to make sure therapy is working for you? If you wait to start, or decide not to start at all, what is your risk of HIV disease progression?

Take time to talk with your doctor about his/her opinions and experiences with treatment and other people who you trust and have an understanding of therapy.

For more information, read Project Inform's *Anti-HIV Therapy Strategies*.

Opportunistic Infections

Have you had any opportunistic infections (OIs) like MAC, PCP or CMV?

- Yes.** If you have an active OI, talk to your physician about treating that OI before you start anti-HIV therapy.
- No.** If you have had a major OI, aggressive anti-HIV therapy is almost always recommended after treating the OI.

9

Drug Interactions

Are you currently on any other therapy (contraceptives, methadone, anti-depressants, etc.)? Yes No

There are known drug interactions between a variety of drugs, and even herb-drug interactions. These can worsen side effects and/or cause one or both therapies to be less effective. For example, some protease inhibitors can decrease the level of ethinyl-estradiol (chemical in oral contraceptives), making them less effective.

If you decide to take therapy, take all the medications, vitamins, supplements and/or alternative therapies that you're taking to your next doctor's appointment. Whenever you add or change a therapy or supplement, be sure to talk with all your health practitioners (and pharmacist) to make sure these products may be taken together safely.

For more information, read Project Inform's *Drug Interactions*.

5

What about side effects?

There are many side effects from anti-HIV therapy. It's important that you are aware of them and learn how they can be monitored and managed. Not everyone on therapy experiences side effects (only 10–20% of people have serious ones). It's not uncommon for people to have some short-term side effects like nausea and headaches during the first 4-6 weeks of therapy. After this adjustment period, often short-term side effects diminish. Therapies can have long-term side effects too, including body changes (called *lipodystrophy*) and changes in lab results like cholesterol.

For more info, read Project Inform's *Drug Side Effects: Lipodystrophy Syndrome(s); and Mitochondrial Toxicity and Lactic Acidosis*.

8

If you come to the decision that you want to start therapy, here are 4 other points to consider before starting and as you develop your strategy.

6

Adherence

Adherence is crucial to treatment being effective. Adherence means taking medications exactly as prescribed by your provider. If anti-HIV medications are not taken according to instructions, the risk of developing drug-resistant HIV increases. Drug-resistant HIV may not respond to the anti-HIV drugs and, as a result, treatment options become limited. Numerous factors can influence adherence: the responsibility of children, your housing status, busy and demanding work, potential side effects from anti-HIV drugs, being in a domestic violence situation and many others.

Take a moment to reflect upon the various factors that can make taking your medications correctly challenging. Discuss this with your provider as you develop a treatment strategy. In addition, use those sources of support which will motivate you to stay adherent.

For more information, read Project Inform's *Adherence: Keeping Up With Your Meds and Drug Dosing Schedule*.

Co-infection

Have you been diagnosed with Hepatitis C (HCV)? Yes No

Some anti-HIV therapies, especially protease inhibitors and non-nucleoside reverse transcriptase inhibitors, can increase liver enzymes and/or cause hepatitis. Liver enzyme levels should be carefully monitored soon after starting anti-HIV therapy.

Are you taking treatment for HCV? Yes No

A 1–2 month gap is suggested between starting HIV and HCV treatment.

Treating HIV or HCV first will depend on the stage of liver disease and your CD4+ cell count and/or (HIV) viral load.

For more information, read Project Inform's *Hepatitis C*.

7

four ways to access meds



ADAP



PAPs



experimental



clinical study

Most people in the United States get their medications through insurance—either public insurance like Medicaid or Medicare, or private insurance. A comprehensive insurance plan that pays for doctor’s visits, hospital and home care, prescriptions and other services is the best way to get quality HIV care. But what do you do if you don’t have and can’t get complete coverage?

If you can’t afford or obtain private insurance, you may have other options. In addition to Medicaid and Medicare, states and even some localities may have services to help you obtain insurance or access care. Some pro-

grams, however, don’t cover prescription drugs. For example, Medicare (the national insurance program for the elderly and some disabled persons) doesn’t cover prescriptions. A description of some of the main drug assistance programs follows.

If you have questions about these programs or need information about how to qualify and participate, call Project Inform’s Hotline at 1-800-822-7422. The Hotline will help you explore your options and link you to local resources. For more information on Medicaid and AIDS Drug Assistance Programs, visit www.aidsinforyc.org/network/access.

1

AIDS DRUG ASSISTANCE PROGRAM

The AIDS Drug Assistance Program (ADAP) is a federal and state program that provides HIV-related medications to uninsured and underinsured people who can’t otherwise afford them. All 50 states, the District of Columbia, Puerto Rico, Guam and the Virgin Islands have ADAPs. Benefits and eligibility vary from state to state. Due to inadequate funding, some ADAPs may experience shortages that limit services in the upcoming year. You can sign up at offices in various locations.

2

PATIENT ASSISTANCE PROGRAMS

Patient Assistance Programs (PAPs) are run by drug companies. They provide prescription drugs to people without means of getting the drug. The eligibility criteria are not public but do include income limits. PAPs can be more difficult to use because each company has a separate program with its own application process. You have to re-apply fairly often. Usually, your doctor or medical advocate has to fill out paperwork. Some companies also charge a small co-payment each time you get your drugs. You can sign up by contacting the company that makes the drug you need.

3

EXPERIMENTAL DRUGS

EXPERIMENTAL DRUGS: Sometimes you may need or want an experimental drug not yet approved by the Food and Drug Administration. Because less is known about experimental drugs, it’s important to consult closely with your doctor before making decisions. There are two ways you can get these drugs. **EXPANDED ACCESS PROGRAMS** are run by drug companies. They allow people who meet certain medical criteria to get experimental drugs. You sign up through your doctor’s office. **COMPASSIONATE USE** typically does not have pre-set criteria. Working with your doctor, you can apply to get the drug, and the company then decides on a case-by-case basis.

4

CLINICAL STUDIES

Clinical studies may be run by drug companies or academic institutions. They are research studies and not meant to provide ongoing treatment or care. However, there may be good reasons to consider enrolling. Work closely with your doctor and make sure you read and understand the study’s *informed consent* form. Informed consent is a document that details the study, known risks of the experimental drug and your rights as a research subject. It can be technical and confusing. Be sure your questions are answered before you sign and enter the study.

it's never too early to take charge of your health

Developing a comprehensive health plan is something that's better done sooner rather than later. This means a plan that addresses health as it concerns your whole being. It includes the health of your body (biological health), mind (psychological health), spirit (spiritual health), and community (social health).

Each area is connected to one another. So, improving health in one has benefits in other areas too. Studies show that people facing life-threatening illnesses who address health holistically live longer and have a better quality of life. Some people think holistic means excluding things, like medicines. Instead, it is an inclusive approach that uses medicines as needed, but also addresses other needs.

The key to creating a solid long-term plan is to make gradual improvements, ones that you can sustain and fit into your lifestyle. There's no one right way to do this—no perfect recipe. In fact, tailoring a plan that you feel good about and matches your beliefs about health and well-being is central to success.



the body

Project Inform provides many resources about biological health and HIV. This includes information on anti-HIV therapy and preventing and treating serious infections. It also includes information on nutrition, stress reduction and strategies for understanding your test results and monitoring your health regularly. Building a strong foundation of biological health will strengthen your body, reduce side effects of therapies and increase the likelihood that you will benefit from therapies. Also, if you choose not to use therapies, strengthening your body will help it fight disease and remain healthy.

get enough sleep

Eight hours a night is recommended. This isn't possible for everyone, especially women with young children and infants. But if you only sleep five hours a night, then five hours and fifteen minutes is an improvement!

reduce stress

Chemicals released in the body when you are stressed out weaken your immune system. A

recent study suggests that stress decreases the benefit of anti-HIV therapy. Taking time for yourself, meditating, talking with friends about what's going on in your life and seeking support are all ways to promote health and reduce stress.

eat well

HIV hangs out in lymph tissue. 80% of the lymph tissue in the body is in the gut, where food and nutrients are absorbed into the body.

the mind

It's easy to see how improving the body might have a positive impact on your psychological health as well. Reducing stress not only strengthens the immune system, but it also clears the head! Many people with HIV experience depression, especially people who are co-infected with HIV and hepatitis B or C. A disproportionate number of people live with both HIV and mental illness.



Some mental illnesses may be caused, sustained or worsened by HIV. Seeing a therapist, especially one with HIV experience, can help you manage the unique challenges of living with HIV. Seeking support groups with professional facilitation is another option. Resolving tensions or resentments, dealing with your fears, addressing depression and diagnosing and managing mental illness all help to improve your psychological health. This includes finding space and time to reflect on your life and your mental and emotional health.

Eating three balanced meals daily is a good way to improve nutrition. Taking vitamins is probably not necessary if you're eating well, and it's likely true that the best way to get vitamins is from food. Still, adding a multi-vitamin to your daily diet is not harmful and could be helpful! Improve your diet gradually, in ways you can sustain and fit into your life. Sudden and dramatic changes in diet can cause stomach upset and other problems.

exercise

Blood and other fluids move more effectively through the body when our hearts beat faster and when muscles move. Keeping things moving helps your cells get to where they need to be, moves oxygen throughout your body and helps keep you healthy. Aerobic exercise—like walking, running, swimming and biking—is particularly good for keeping things moving. Again, gradual improvements are key to success. If you never go to a gym, then committing to stretching a few minutes each day is one way to start. You could also simply take a walk around the block and then extend your walking distance over time.

continues on page 8 ...

the community

Social networks are critical to promoting health and well-being. These include friends, family and the people in the various communities you identify with. Improving social health might mean changing the relationships you have, like ending relationships that are harmful. It might mean nurturing and strengthening existing or new relationships. Social health is about cultivating a network of people around you who support you in exploring and achieving your potential. They help you in difficult times and speak with you openly and honestly. Social health is also about giving back to the community. This might include volunteer work, becoming involved in civic activities or starting a buddy network of people who help each other.

the spirit

A number of studies suggest that people facing life-threatening diseases who have a strong spiritual foundation live longer and have a better quality of life. Whether that foundation rests in Judaism, Christianity, Buddhism, Islam, native spiritual beliefs or religions of nature may be less important than nurturing a spiritual well-being that supports your beliefs in a personally meaningful and life-affirming way. There are many spiritual paths to explore. For one person this may be Catholicism; for another it may be Wicken. For someone else it may be a personal spiritual path of expression not associated with an organized religion.

These are just a few places to start thinking about in building a holistic foundation of health. You might find it useful to keep a diary. You could record things like your lab work, menstrual cycles and changes, how you're feeling and any symptoms or health conditions you're experiencing. You could also outline what you're doing to promote your health in various areas.

Project Inform is mostly a resource for biological health, as it relates to treating HIV and its related conditions. Biological health is only one aspect of overall health, however, and information about therapies and ways to treat HIV is not the entire picture of biological health. It also includes general healthcare, routine physicals and age-appropriate screening (like mammograms to detect breast cancer, bone density screening for osteoporosis, etc.), addressing substance use and addiction to name a few.

Resources for exploring and promoting psychological, spiritual and social health are available in your local community. How you address health in these areas will likely be as unique as you are. There's no one holistic health plan that's best for everyone. The first step to defining what's best for you requires you to define health for yourself.

Wise Words

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