

A GUIDE TO: **HEPATITIS C** **MAKING TREATMENT** **DECISIONS**

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The information in this guide is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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• *Foreword*

Making decisions goes hand in hand with having a chronic disease. There are lifestyle decisions, such as the use of alcohol, drugs, and caffeine. There are choices regarding diet, exercise, and sexuality. There are health considerations, such as the use of vitamins, herbs, and Chinese medicine. For those living with hepatitis C (HCV), the decision to undergo medical treatment may be one of the most difficult and complicated.

The decision is complicated because some of us don't notice any symptoms related to HCV. The medications to treat HCV often have side effects and we may be hesitant to trade the way we are feeling for the unknown. The decision is also complicated because success is not 100% guaranteed.

However, there has never been a better time to seriously consider HCV treatment. The latest HCV therapies have about an 80% success rate. Along with these improved success rates, medical providers have learned how to manage side effects better. Talk to your medical provider about current treatment options and whether it is appropriate to be treated now or to wait until something newer is available.

People rarely take a casual approach when considering conventional HCV treatment. For some, the question is not "if" but "when." Others are adamant in their opposition to treatment. However, for most, "to treat or not to treat" is a major issue that deserves serious attention. Unfortunately, there are folks who just cannot decide what to do. Their indecision may bring years of paralyzing anxiety and pain.

The purpose of this guide is to address some common elements used to make HCV-treatment decisions. We are assuming that you are making this decision along with advice from your medical provider. We hope this information will be useful in helping you to arrive at a decision that is right for you.

For those who have been through the treatment decision process, please let us know what strategies helped you to reach a decision. You may reach us at www.hcvadvocate.org

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INTRODUCTION

Some of us are information collectors; the more information, the better. Others want the condensed version. If you are a “get to the point” person, here are some tips for living well with HCV:

We are constantly making decisions. We are barely conscious of most of the decisions we make. Everything – from each word we speak to what we eat, how much, how fast and when – requires a decision. We decide where and how we sit, stand, and walk. How we react, and use our time involve decision-making. These decisions are so habitual that we hardly think about them.

Moods affect our decisions and may turn minor decisions into difficult ones. An example is having a day when we cannot find a thing to wear. We may be looking at the same clothes we looked at the day before, but a mood change can complicate this decision. The opposite is true as well. A life-saving decision can be made at lightning speed, such as slamming on the brakes when a pedestrian steps out into traffic.

The issue of HCV treatment is a major one, but it does not need to be made at lightning speed. HCV progression is usually slow, so the majority of people can take time to make a decision. How much time? That is between you and your medical provider. If you have very advanced liver disease, your provider may encourage you to make a decision sooner rather than later. People who have minimal liver damage may delay treatment for months or years. However, this delay can have serious ramifications since we know that people with less liver damage who are treated early have a better chance of responding to current therapies. Other factors may also trigger an early decision, such as facing future loss of insurance coverage or the desire to have an HCV-free pregnancy.

The average HCV patient with mild to moderate liver damage should not feel pressured to make a quick decision. There is time to gather information and come to a suitable decision. Treatment decisions should be made when the initial distress from diagnosis has passed and the mind is clear. Some experts believe that in certain conditions, those who are newly diagnosed with chronic HCV should wait 6 months before they make this important decision.

Decisions, Decisions

“There is no more miserable human being than one in whom nothing is habitual than indecision.”
– William James

COMPONENTS OF DECISION-MAKING

Decision-making is the subject of academic interest and research. Making decisions is often more than just a choice between “yes” or “no.” Consequences follow our decisions – some of them favorable and others not. This alone makes people reluctant to make choices.

Indecision has its own consequences. There are times when postponing a decision is the best choice. However, often this form of procrastination creates more harm than good. Not deciding is a decision. Further, it is a decision made from a position of powerlessness. Let us assume your doctor has recommended HCV treatment. Let us also assume that you have mild HCV progression and your doctor says the choice is up to you. You find yourself juggling a thousand different thoughts. You wonder how you can reach such a big decision.

We all have different ways of making decisions. What are the ways you make them? Do you jump in with both feet or do you test the waters? Do you like a lot of information or as little as possible? Do you talk to as many people as you can or to no one? Do you look ahead and ask yourself how you will feel if you never tried this? Knowing how you make decisions can bring insight. If you are interested in knowing more about various ways of making decisions, see Appendix A: Decision-making Styles.

- *Identify the Decision*

You cannot decide anything unless you know what you are deciding. Start by writing down all the decisions you are facing. For example, “Should I undergo HCV treatment?” or “If I undergo treatment, when should I start?”

Do this if it is a priority decision. You may have another major health problem that takes priority, such as cancer, major depression or alcoholism. You may have a sick child or parent who needs your attention right now.

It is better to think about decisions when you are not distracted. Take breaks from thinking about it. It might be helpful to make a pact with yourself to take a break from thinking

Identify the Decision

“We are given one life, and the decision is ours whether to wait for circumstances to make up our mind, or whether to act, and in acting, to live.” – Omar Nelson Bradley

about treatment for a set period of time. If so, be sure to set a date to revisit the decision process. Sometimes decisions emerge when we are not thinking about them.

Note: *Bedtime is a poor time to be worrying. Beds are for resting, sleeping and sex. Make your bed a worry-free zone. If you find yourself worrying instead of sleeping, try the following:*

- Gently remind yourself that this is not a useful time to worry. Suggest to yourself that you find time tomorrow to think about your situation. If your mind wanders back to worrying a hundred times, gently bring it back a hundred times. With practice, you will find yourself worrying less at bedtime.
- Get out of bed and go into another room. Read or do something that is not stimulating.
- Listen to calming music or a meditation tape. If you sleep with someone, use a headset so as not to wake him or her.
- Visualize being in a relaxing place, such as on a beach or in a forest.

• *Identify the Choices*

Write down all the options, even the choices you reject. Using treatment as an example, here is an illustration:

- Start treatment
- Don't start treatment
- Get a second opinion before deciding
- Wait until newer treatments are available

A good decision relies on good data. Ask your medical provider to suggest good sources of information. Your community may have a health information library. Support groups may be good resources. Talking directly to other people who have tried treatment is a way to learn about actual experiences. Try to hear many stories rather than just a few. If you talk to someone who had an easy treatment or someone who had a difficult time, you do not get the full picture. Chat rooms are less likely to be reliable sources of information, since they tend to attract people who need a place to deal with problems. People who are having an easy treatment are less motivated to use chat rooms.

Identify the Choices

"It does not take much strength to do things, but it requires great strength to decide what to do."

– Elbert Hubbard

- *To make a sound decision, you need to know the following*

Confirmation that you have chronic HCV infection. Has your medical provider conducted a viral load test (a blood test that confirms the presence of HCV)? Tragically, patients have been treated on the sole basis of a positive HCV antibody test. About 15 to 25% of those exposed to HCV carry antibodies but are HCV-negative. In addition, it needs to be ruled out that this is not an acute infection (occurring in the past 6 months). Acute infections are handled differently than chronic ones (infections longer than 6 months).

Genotype – These strains of HCV determine the length of your treatment and the dose. Knowing your genotype can help you assess the potential for a favorable response.

Viral load – This may be used to decide which medicine to use and to estimate your potential for a favorable response.

Baseline labs – These may be used to decide which medicine to use and to estimate your potential for a favorable response.

Liver biopsy results – You may or may not have this information. Some doctors perform routine liver biopsies, while others only biopsy certain patients. Liver biopsy results may be used to decide if treatment is needed at this time and to estimate your potential for a favorable response.

Your medical provider’s reasons for recommending or not recommending treatment.

Treatment regimen – What HCV medication does your medical provider want you to take? What is the dose and duration of treatment? Your medical providers suggest a 12-week trial period for genotype 1 patients. Is this part of your proposed plan? Some providers do not use a trial period for genotype 2 and 3 patients. This is because the treatment period is shorter and the chances of a favorable response are good. *(Note: Treatment is based on the latest research. If your medical provider suggests a treatment duration or dose that is different from what you expected, discuss this. Your provider might make recommendations based on new information.)*

Health history – In order to make a safe recommendation, your provider needs a thorough medical history. HCV treatment should be avoided or used cautiously with patients who

Collect information

“Nothing is more difficult, and therefore more precious, than to be able to decide.”

– Napoleon Bonaparte

have certain health problems. (See Appendix B: *Warnings and Cautions Associated with HCV Medications*)

Medication package insert – This information is required to be included with all medication. It lists potential risks, side effects and who should not use the drug. Compare your health history with the warnings. Do you have any conditions that carry warnings? (See Appendix C: *Reading Prescription Information*)

What are the potential risks of the treatment? (See Appendix D: *Side Effects of HCV Medications*)

What are the potential benefits?

What are the potential risks if you are not treated?

How will your medical provider manage side effects? How much experience does he or she have? Is your provider readily available if you need help with side effects?

What are the chances of being a responder to HCV treatment? What are the chances of being a long-term (sustained) responder? (See Appendix E: *HCV Treatment Response Rates* and Appendix F: *Factors that Influence HCV Treatment Response*)

What are the possible outcomes if no treatment occurs? Ask for these outcomes to be stated in statistical terms, e.g., the chances are one in five that cirrhosis will occur within so many years.

Insurance coverage – Verify the extent of coverage in your medical insurance plan.

Treatment costs – What is the cost of HCV treatment? Insurance or not, can you afford the costs associated with HCV treatment? How often will you have lab tests done and what is the co-pay? Can you afford the medical appointment and medication costs?

Other costs – People react to treatment in different ways. Some people never miss a day of work, while others need to take some time off. If you need to take time off from work, do you have sick pay? Would it be a financial burden if you missed any work? Will you have difficulty taking time off for medical and lab appointments?

How will this affect your life? What are your thoughts and feelings about this?

How will this affect others? What are their thoughts and feelings about this?

What kind of support do you have? Is it enough?

Are you confident about your medical provider? Would a second opinion be of benefit?

Evaluate the timing. Is this a particularly stressful time? Are there events in your life that may conflict with treatment? For instance, if you are planning a wedding or caring for an ill parent, tell your medical provider this. Is this a particularly good time?

Are you or your partner planning on becoming pregnant anytime during or six months after treatment is stopped? If so, either you must delay treatment or pregnancy until it is safe to do so.

Do you have any reasons why self-injection might be a problem, such as blindness, needle-phobia, or severe arthritis in your hands? If so, address this with your provider.

If you value the opinions of others, do you know their opinions?

THE DECISION IS YOURS TO MAKE, but seeking advice is a way to gain insight. Sometimes others see points that we miss. Naturally, your medical provider's advice is important. Perhaps you have family and friends whose opinions you respect. Are there people in your life who have given you good advice in the past? If so, invite them to give you feedback.

Attend a support group. Although reading about treatment is important, there is probably no better way to learn about it than by meeting people who are going through it or who have completed treatment. Talk to as many people as you can. If you only talk to one person, you might get a favorable or unfavorable opinion. A single experience is not enough data for this significant decision.

- * List the reasons you would like to try HCV treatment. (See Appendix G: *Motivations and Potential Benefits of HCV Treatment*)
- * List the reasons you are reluctant to try HCV treatment. (See Appendix H: *Concerns, Fears and Potential Risks of HCV Treatment*)
- * Are you a person who often feels regret? If so, ask yourself which choice(s) you are less likely to regret? Imagining the future, which choice(s) would you more likely to regret?

EVALUATE THE OPTIONS

- *Here is another way to evaluate your options:*

List all choices in one column. List the reasons for and against alongside the choices. Rate these choices. Doing this exercise on paper may be all you need to help you decide. Alternatively, you can total your ratings and see if a clear choice emerges.

	Benefits and reasons for this choice	How important is this benefit? Rate on a 0 to 5 scale, with 5 being extremely important	Risks and reasons against this choice	How important is this risk? Rate on a 0 to 5 scale, with 5 being extremely important
Choice 1				
Choice 2				
Choice 3				
Totals				

If you feel you have sufficient information, you may be ready to make a decision. For some people this is straightforward. Others may have a hard time with this. When faced with indecision some find it useful to follow the advice of their medical provider. They may ask the question, "If you were in my shoes, what would you do?" This is a fine strategy, but remember you are making the decision – not your doctor. Make a choice, but do not make it under pressure from others. If you feel pressured by others, tell them this. Sometimes people do not realize they are doing more harm than good. They are probably worried. The best way to handle this is to request their support, keep them informed, and ask for time and space to make your own decision.

Verify that your decision is consistent with your decision-making style. If you normally take the advice of experts, but this time you are not, perhaps there is a reason. If you do no research about HCV treatment but are normally a person who thoroughly investigates cell phone services and car purchases, what is the reason behind this?

If you have a spiritual or religious practice, you might find it helpful to apply this to your decision. Even if you do not, spend some time in solitude and reflect on your decision. Even if you are scared about it, does it feel "right?" Remember, you don't have to like your decision but you do have to live with it.

- *Create a Plan: Carry it Out:*

If you have made a decision, congratulate yourself. Now it is time to formulate a plan so you can carry out your decision. Identify what you need to help you meet your goal. The same resources that helped you make your decision will probably help you make your plan. Your medical provider, support group, literature, family and friends may provide useful ideas.

Once you have made a decision, trust your instincts. Do not second-guess yourself unless you have clear reasons to. However, treatment decisions are reversible. You can change your mind at any point. Do not make an impulsive decision. Also, do not make it when in a bad mood. The saying, "this too shall pass" may help you weather hard times until you regain your determination.

You may need to revise your plan along the way. Some patients plan to take time off

"Once you make a decision, the universe conspires to make it happen."

- Ralph Waldo Emerson

from work during treatment, only to find out that this was unnecessary. The opposite may also be true. Assess your needs as you go along. Everyone reacts differently to HCV treatment. However, most patients report that if they were prepared for the worst that it seldom was as bad as they anticipated. The key to getting through treatment is to make sure that you have as much support as possible from family, friends and others in your life.

After you have carried out your plans and have the benefit of hindsight, you may be delighted with the results. You may also be disappointed. If you are, try not to have regrets. Most of us have them, often for what we have not done rather than for what we have done. If you can, acknowledge your regrets, but do not dwell on them. Dwelling on regrets is like paying rent on a home you no longer live in. The past is past and those who focus on the present tend to have more contentment and peace in their lives.

COMMITMENT

Commitment is often overlooked, but it is a powerful tool in successful decision-making. The following quote, by William H. Murray, describes the power of commitment:

“Until one is committed, there is hesitancy, the chance to draw back, always ineffectiveness. Concerning all acts of initiative and creation, there is one elementary truth the ignorance of which kills countless ideas and splendid plans: that the moment one definitely commits oneself, then Providence moves too. All sorts of things occur to help one that would never otherwise have occurred. A whole stream of events issues from the decision, raising in one’s favor all manner of unforeseen incidents, meetings and material assistance, which no man could have dreamt would have come his way.

I learned a deep respect for one of Goethe’s couplets:

‘Whatever you can do or dream you can, begin it.
Boldness has genius, power and magic in it!’”

– William H. Murray, *The Scottish Himalayan Expedition*, 1951

“May boldness and commitment carry you through your HCV expedition.”

– Lucinda K. Porter

APPENDIX A

*Decision-making Styles**

People have different decision-making styles. It may help you to know what your style is so you can apply it to health decisions. Here are some examples:

- *Impulsive Deciders* – Those who take the first alternative that is presented, with little thought or evaluation; “Leap without looking.”
- *Fatalistic Deciders* – Those that cast their fate to the wind; “What ever will be, will be.”
- *Compliant Deciders* – Those who follow someone else’s plan, rather than making their own decision, even when it doesn’t agree with their own beliefs; “If that’s OK with you, then it’s OK with me.”
- *Delaying Deciders* – Those who delay thought and action on an issue: “I’ll cross that bridge later.”
- *Agonizing Deciders* – Those who spend much time and thought on gathering data and analyzing alternatives, only to get lost amidst all the accumulated data; “I can’t make up my mind.”
- *Planning Deciders* – Those who develop a strategy based on a rational approach, with some balance between the thought and feelings; “I’m weighing the facts.”
- *Intuitive Deciders* – Those who decide based on feelings, but which cannot be verbalized; “It just feels right.”
- *Paralytic Deciders* – Those who accept responsibility for a decision but are unable to approach it: “I know I should do so, but I just can’t face up to it.”
- *Escapist Deciders* – Those who avoid responsibility for a decision or make up a socially acceptable answer to deflect an inquiry. For example, if undecided about medical treatment but considering it, when asked by someone what they are doing about their HCV the response might be: “I’m looking into HCV clinical trials.”
- *Play-it-Safe Deciders* – Those that pick the option with the perceived lowest level of risk: “I’d like to wait to see if new HCV treatments develop, but I’m going ahead with the current options.”

“Health is not valued till sickness comes.”

– Thomas Fuller

- *Deviant Deciders* – Those that ask the advice of others, then do the opposite of what they suggest: “I did it my way.”

Within these styles, there are two broad categories. Lillian Dinklage identified them as “Inner Reliant” and “Outer Reliant” Deciders. **Inner Reliant** Deciders hold themselves accountable for their decisions. **Outer Reliant** Deciders attempt to shift accountability to others. These two categories apply to all the decision styles. For example, an Impulsive Decider can be either Inner Reliant or Outer Reliant.

(*Adapted from the work of Lillian Dinklage, as referenced at <http://careerservices.rutgers.edu/OCAmakedecision.shtml>)

APPENDIX B

*Warnings and Cautions Associated with HCV Medications**

People who should not be treated with current HCV medications:

- Women who are or who may become pregnant during and up to 6 months after treatment is stopped
- Men with female partners who are or who may become pregnant during and up to 6 months after treatment is stopped
- Those with autoimmune hepatitis
- Infants
- Anyone allergic or hypersensitive to interferon or ribavirin
- Patients with decompensated (a very advanced stage) liver disease
- Patients with certain blood disorders, such as sickle-cell anemia or thalassemia major
- There may be exceptions to the above list. For instance, HCV patients with decompensated liver disease who are being treated in academic medical centers.

People who should not be treated for HCV until an underlying condition is stable:

- Anyone who is suicidal, violent, or has thoughts of harming self or others
- Anyone with active heart disease
- Anyone with uncontrolled thyroid disease
- Those with uncontrolled diabetes
- Many medical providers will not treat patients who have an active problem with chemical dependency.

Warnings – Patients need to be closely monitored for these serious conditions. Anyone who has one or more of these conditions may not be a candidate for treatment unless the condition is stable:

- Pancreatitis
- Colitis
- Lung disorders
- Autoimmune diseases
- Kidney diseases
- Cardiovascular diseases, including high blood pressure
- Endocrine disorders
- Anemia
- Diseases of the eye
- Neuropsychiatric problems
- Bone marrow toxicity
- Allergic reaction
- Infections
- “Flare-up” of hepatitis, especially in patients who have hepatitis B viral infection
- Low white blood count
- Low platelet count

**Note: Although rare, liver failure and death have been associated with HCV treatment.*

APPENDIX C

Reading Prescription Information

Your doctor gives you some information about medication for hepatitis C virus infection (HCV). The information could be simple or complex, depending on the level of printed material and your ability to understand medical language. Nevertheless, even the most basic material also includes a neatly folded copy of the professional information. This is often printed on white paper in very small print. It requires training and a magnifying glass to read it.

This piece of paper is the *Package Insert (PI)*. It is also called *product or prescribing information*. The Food and Drug Administration (FDA) requires all manufacturers to include this with their drugs. Listed below are tips on how to crack the medical code

in the PI. These will tell you what to look for, what to avoid, what to fear, and what not to fear.

If you do not have the PI's, you can get a copy from the HCV Advocate website. They can be found at www.hcvadvocate.org/hepatitis/factsheets.asp#FDAInserts.

Most medications have information written specifically for patients. This will give you a broad overview of the most important information and is a good starting point. When a drug is advertised in a consumer magazine, this is what usually appears in small print on the backside of the advertisement. After you read the basic information, you may want to read the entire PI.

Using ribavirin (Copegus® and Rebetol®) as an example, let us take a PI tour. The first things you will read are the drug's trade name, generic name and manufacturer. What follows next in this case is a box with bold type. This is called *black box* information. This has to be predominately displayed and carries a serious message. In ribavirin's case, there are warnings about pregnancy complications and cardiac disease. If you do nothing else, read and understand every word in the black box. If any of it applies to you, do not take that drug unless your medical provider has adequately explained why you may take it. Not every drug has black box information.

Next is the *description*. This is the most complicated part and can be ignored for now until you are ready to tackle concepts that are more challenging.

Clinical study information is provided next. This is the data that proves why the drug works. It may be helpful to skip this for now and then return to it after you have read the rest of the PI. You can also ask your medical provider to summarize the parts that apply to you.

The *indications and usage* section lists the medical conditions the drug treats. It may surprise you to learn that interferon and ribavirin were originally used for other conditions. However, the indications for the *pegylated* (longer acting) interferon alfa-2a and alfa-2b are for HCV treatment. The indications may change per FDA approval. For instance, Pegasys is approved for treatment of hepatitis B and HIV/HCV co-infection. The shorter acting interferon, Intron-A, has indications other than for HCV. Sometimes physicians will use the pegylated interferon instead. This is called an *off-label use* and it is legal although insurance will not always cover the drug's cost.

The *contraindications and warnings* sections are high priority. In *contraindications*, all the patients who should not take the drug are discussed. Also listed are situations

in which patients can take the drug but need to be closely monitored. If the PI has a black box in the beginning, this information will be repeated in the *warnings* section along with additional cautions. Again, if you think information in this section applies to you, talk to your medical provider **before** you start taking the drug.

Precautions come next. This is important because it gives more information about the safety of the drug. In the PIs for Copegus® and Rebetol®, we are alerted to more possible risks. The black box information is restated and informs us about what lab tests medical providers should order before and during treatment. For example, an ECG (a simple and painless heart test also known as an EKG) is recommended. Advice to patients is in this section, such as to drink lots of water and take medication with food.

The *drug interactions* section is included here. Read this section. Listed here are the drugs that are known to interact with the drug you are considering. If you are taking a drug that is on the list, tell your provider. Fortunately, the list is very short for HCV drugs. Also included in the *precautions* section is information about special groups of people. This addresses pregnancy, nursing mothers, *pediatric* use (infants and children), *geriatric* use (older adults) and if the drug works differently between genders.

Try to read the *adverse reactions* section. When you want to know the drug's side effects, go to this section. The *adverse reactions* section may scare you but actually its bark is worse than its bite. This is where everything that is known to have happened is listed and informs patients about the drug's risks. Look for the most common adverse reactions. Ask yourself how common these are.

PROBABLY THE BEST way to find out about drug side effects is to talk to other patients who have experience with that medication. Support groups are great resources for this. You can also talk to your medical provider or pharmacist and ask what sorts of feedback they are hearing from patients. Be cautious about relying on the Internet for patients' stories; negative experiences are more likely to appear than positive ones. It is important to get a full range of reports on which to base your decisions.

Using Copegus® as an example, you will learn that in research studies, one or more serious adverse reactions occurred in about 10% of patients. The most common life-threatening or fatal events related to this drug (when used with Pegasys®) include depression, suicide, relapse of drug abuse/overdose, and bacterial infections. This may sound frightening. The good news is that each of these events occurred at a frequency of **less than 1%**.

Just about everyone reported one or more adverse event. The most common of these were depression, irritability, anxiety, fatigue, headache, muscle aches, fever and chills. Again, this sounds pretty awful. However, keep in mind that if a research patient was irritable for one day that counts as an adverse event. Just because nearly everyone reported an adverse reaction does not mean that these reactions were constant or intolerable.

Sometimes information about adverse reactions includes numbers and percentages. Looking at Rebetol® (when used with PegIntron®), we find that 31% of patients reported depression. That means that roughly one-third of the study patients reported at least one episode of depression. That does not tell us for how long or how severe the depression was. However, we also learn that 14% of the study patients discontinued treatment for any number of reasons. This casts a more favorable light on the 31% depression figure because no more than 14% (and probably less) of patients had depression severe enough to cause them to stop treatment.

Although percentages can be reassuring, keep in mind that these numbers were derived from clinical trial patients. Research usually uses the healthiest patients. If you are already depressed, then your risk for increased depression could be higher than the percentages listed in the PI.

The final portion of the PI supplies information about overdose, discusses *Dosage and Administration*, states how the medication is supplied and how it should be stored. This is important to know. Peginterferons are injectable drugs that have special storage requirements. Knowledge about dosages gives you guidelines for how much medication is recommended and for how long. However, patients are unique and medications are not “one size fits all.” Physicians and mid-level practitioners may prescribe different doses to different people for different reasons. If your dose differs from the printed guidelines, ask your provider to explain the reason for this.

APPENDIX D

Side Effects of HCV Medications

This list is based on product information from the most widely prescribed HCV medications.

Check the product information for each medication for the more specific data. Overall neuropsychiatric problems were reported in approximately 3 out of 4 patients. Together, fatigue and headache were reported by two out of three patients.

All side effects are temporary and will gradually go away after treatment is stopped. This may take weeks or months and rarely up to a year. The exception is thyroid problems, which may be permanent. Obviously, death is not reversible. Death occurred in less than 1% of study patients. Information for one of the drugs stated that of the five deaths, two were from suicide, one from suicide/murder, one from a motor vehicle accident, and one from sudden death. Information from the competitor stated that the most common potentially life-threatening or fatal events were bacterial infections, depression, suicide, and drug overdose or relapse. HCV medications may have induced or aggravated these events.

Nearly everyone has one or more side effects during HCV treatment. These may be intermittent, nearly constant, relatively minor or major. Although this list looks frightening, keep in mind that the majority of patients completed therapy. The discontinuation rate was between 10 and 14%. It is also important to remember that in the years since these clinical trials, strategies to manage side effects of HCV therapy have greatly improved. The key to managing side effects is to treat them as soon as possible, before they become worse.

Side effect	Approximate chances of occurrence*
Fatigue and weakness	65 – 66%
Taste changes (usually a metallic taste)	44%
Headaches	43 – 62%
Body, muscle, and joint aches	40 – 56 %
Fever (usually decreases after first few injections)	41 – 46%
Irritability, anxiety, nervousness	33 – 47%
Insomnia	30 – 40%
Hair loss (more like thinning than total loss)	28 – 36%
Neutropenia (a type of low white blood cell count)	26 – 27%
Chills (usually decreases after first few injections)	25 – 48%
Nausea and vomiting	25 – 46%
Loss of appetite	24 – 32%
Injection-site reaction	23 – 75%
Depression	20 – 31%
Itching	19 – 47%
Rash	16 – 56%
Dizziness	14 – 21%

Side effect	Approximate chances of occurrence*
Pain around liver area	12%
Breathing difficulty	9 – 26%
Abdominal pain	8 – 13%
Viral infection	12%
Diarrhea	11 – 50%
Anemia	11 – 12%
Weight loss	10 – 29%
Dry skin	10 – 26% (probably higher)
Cough	10 – 23%
Concentration problems	10 – 17%
Chest pain	8%
Menstrual disorders	7%
Upper respiratory problems	6 – 12%
Increased sweating	6 – 11%
Upset stomach	6 – 9%
Memory impairment	6%
Fungal infection	6%
Blurred vision	5%
Constipation	5%
Dry mouth	4 – 12% (probably higher)
Malaise (“the blahs”)	4 – 5%
Thyroid problems	4 – 5%
Feeling “flush”	4%
Hemorrhoids	3 – 12%
Anorectal discomfort	3 – 11%
Anal itching	1 – 6%

Other side effects were reported in less than 1% of research subjects. A few were thoughts of suicide, suicide attempt, psychosis and autoimmune disorders.

Note: You can find the complete side effect profile of specific HCV medications at: www.hcvadvocate.org/hepatitis/factsheets.asp#FDAInserts

In addition, the Food and Drug Administration has added the following to the Medication Guide for each approved interferon product.

• *What is the most important information I should know about HCV therapy?*

- Some people, such as pregnant women or their partners, should not be treated with current HCV drugs. If you have a condition that is contraindicated (not advised) for treatment, be sure it is under control prior to starting the drugs.
- Body organ problems: any interferon may cause lung problems including: trouble breathing, pneumonia, inflammation of lung tissue, and new or worse high blood pressure in the lungs (pulmonary hypertension), which can be severe and lead to death. Cases of weakness, loss of coordination and numbness due to stroke have been reported in patients taking any interferon, including patients with few or no expected risk factors for stroke.
- Eye problems: Changes in vision such as decrease or loss of vision (blindness) may happen in some patients. You should have an eye exam before you take [brand name of interferon]. If you have eye problems or have had them in the past you may need eye exams while you are taking any interferon. Tell your medical provider or eye doctor right away if you have any changes in your vision while taking [drug name].
- Nerve problems: People who take any interferon with telbivudine (TYZEKA) can have nerve problems such as continuing numbness, tingling, or burning sensations in the arms or legs (peripheral neuropathy). Call your medical provider if you have any of these symptoms.
- HCV medications, particularly boceprevir (Victrelis) and telaprevir (Incivek) may interact with drugs or supplements you are taking. Be sure to tell your medical provider about everything you take before starting on HCV treatment.
- Report any history of HIV, colitis, hepatitis B, cancer, history of mental illness, substance abuse, or sleep problems.

APPENDIX E

*HCV Treatment Response Rates**

Genotype 1:

- Incivek (telaprevir), pegylated interferon plus ribavirin-Incivek (750 mg) is a pill that is taken every 7 to 9 hours, pegylated interferon is a weekly injection and ribavirin is a pill taken twice a day
 - Treatment Naïve: Up to 79% SVR**
 - Treatment Experienced (relapsers, partial responders, null responders): Up to 86% SVR

Treatment duration based on response-guided therapy: 24 or 48 weeks

- Victrelis (boceprevir), pegylated interferon plus ribavirin—Victrelis (800 mg) is a pill that is taken every 7 to 9 hours, pegylated interferon is a weekly injection and ribavirin is a pill taken twice a day
 - Treatment Naïve: Up to 66% SVR
 - Treatment experienced (including relapsers, partial responder—null responders were not included) : up to 66%

Treatment duration based on response guided therapy: 24, 36 or 48 weeks (included 4-week lead-in of pegylated interferon plus ribavirin)

Genotypes 2 – 6:

- Pegasys plus Copegus (Genentech (Member of the Roche Group))
 - Genotype 2 – 6: 70% SVR (48 weeks /1000-1200 mg ribavirin)
 - Genotype 2 & 3: 82% SVR (24 weeks/800 mg ribavirin)
- PEG-Intron plus Rebetol (Merck (includes Schering-Plough subsidiary))
 - Genotype 2 - 6: 75% SVR (48 weeks/800 mg ribavirin)

*Note: These are averages for all HCV patients. Response rates vary for certain groups of people. All figures taken from the manufacturers' package inserts

** SVR means sustained viral response. This means that HCV remains undetectable for at least six months after treatment is completed.

APPENDIX F

Factors that Influence HCV Treatment Response

- Metabolic Syndrome – a group of metabolic risk factors that include abdominal obesity, high triglycerides, low HDL cholesterol and high LDL cholesterol, high blood pressure, insulin resistance or glucose intolerance, prothrombotic state, and proinflammatory state. People with metabolic syndrome are less likely to respond to treatment
- Viral load – Patients with a high viral load are less likely to have a sustained response to treatment
- Age – The older the patient, the less likelihood of a sustained response to treatment
- Condition of the liver (histology) – The less liver damage, the more likely to have a sustained response
- IL28 – TT and TC genotypes are less likely to achieve a SVR compared to CC genotypes.
- Race – African Americans are less likely than Caucasians to have a sustained response to treatment. More research is needed for other ethnic groups
- Weight – Patients who are at a healthy weight are more likely to have a sustained response to treatment
- Steatosis – This is a fatty liver condition and those who have little or no steatosis are more likely to have a sustained response to treatment
- Co-infection – Patients with HIV or HBV are less likely to have a sustained response to treatment
- Excess iron - Patients with excess iron are less likely to have a sustained response to treatment
- Gender – Women are slightly more likely than men to have a sustained response to treatment
- Alcohol use – The use of alcohol has been associated with a lower response rate
- Adherence – Patients who take the maximum prescribed dose of medication and only rarely miss a dose are more likely to have a sustained response to treatment

The factors on this list over which you may have control are adherence, weight, steatosis, age and alcohol use. Treatment or no treatment, patients are strongly encouraged to avoid alcohol use. If this is a problem for you, seek help. If you are overweight, losing weight may improve your chances of having a favorable treatment outcome. If this is a problem for you, seek help. Exercising, losing weight, and

eating a low-fat diet may help you reduce or avoid steatosis. Although you cannot change your age, remember that you will never be younger than you are at this moment. In ten years, you will be ten years older. This is a good argument for starting treatment sooner rather than later.

APPENDIX G

Motivations and Potential Benefits of HCV Treatment

- May remove or “clear” the HCV virus from the body, temporarily and possibly permanently
- May improve liver tissue and health
- May lessen or eliminate HCV symptoms, such as fatigue and body aches
- May slow HCV progression
- May help to avoid the need for a liver transplant
- May help to avoid liver cancer
- May improve quality of life
- May reduce or eliminate the feeling of “being infectious”
- May help to put the period of HCV in your life behind you
- May make sense to try to eliminate HCV before conceiving a baby
- May give a feeling of satisfaction for “having tried one’s best”
- May create the feeling of being “proactive”
- Having treatment now rather than later, may improve overall chances
- It can be inspiring to consider that many people have been treated and many have cleared HCV
- Some trust their medical providers enough to seek and pay for their opinions – enough to follow their advice
- It is possible to just try it and stop if it seems to be too much

Visit the HCV Advocate website’s Living with Hepatitis C Web page for personal stories about people with hepatitis C.

APPENDIX H

Concerns, Fears and Potential Risks of HCV Treatment

(Note: Some of the fears and risks listed here are unlikely to occur. Ask your medical provider for the facts.)

- Fear of side effects
- Concerns that side effects will interfere with work or relationships
- May not remove or “clear” the HCV virus from the body
- Concern over potential loss of income
- Reduced quality of life during treatment
- May not improve liver tissue and health along with fear of worsening health
- May not reduce HCV symptoms, along with fear of increasing problems
- Concern about cost of HCV treatment
- May not slow HCV progression
- Concerns about physical appearance
- Not enough trust in medical providers or their ability to give adequate time and care
- If patient is older, treatment would delay plans to start a family, possibly risking future fertility

APPENDIX I

*Decision-Making Visualization Exercise***

If you are more of an intuitive decision-maker, you may prefer this imaginative exercise. You may want to have a friend lead you through the visualization, or you may just want to read through the exercise and imagine on your own.

Find a quiet, calming place to close your eyes and relax as you imagine...

You are walking along a path...it could be in the woods, on a beach, in a valley... whichever is your favorite place in nature. As you walk along feel the air around you...notice the smells...be conscious of the sounds...take note of any plants or vegetation around and what the path feels like under your feet...

Ahead you notice the path divides in two different directions. You take the first pathway that represents the first option you are considering. As you go down that path, experience that option. Try it on fully. How does it make you feel in your body...your heart...your mind? Notice everything inside you and outside you and what is happening...

Walk back to the fork in the path and try the other pathway that leads to your second option. Experience that option fully. How does it feel to experience this option?

Walk back again to the fork in the path. You suddenly see a third path that you had not been able to see before. You take the path and experience a solution you had not thought of before. What is it? What does it feel like?

Return back to the fork and then back down to where you originally started. You feel clear about something from these experiences. You take a deep breath, open your eyes, and come back to the present to write about your observations.

Write down your responses to the following questions:

- What is your reaction to this exercise?
- What feelings, thoughts or experiences did you have?
- What did you realize about yourself and your plan that you did not realize before?
- How have you or your goals changed because of this experience?
- What goals would you like to set for yourself now?
- If you are not ready to set a goal for yourself, what additional information do you need?
- What are any barriers that are preventing you from setting a goal?
- What can you do about these barriers?

**From the University of California, Berkeley

RESOURCES

HCSP GUIDES

The following HCSP Guides are available at www.hcvadvocate.org in pdf format and may be downloaded and printed.

- *A Guide to Hepatitis and Disability*
- *A Guide to Hepatitis C: Treatment Side Effect Management*
- *A Guide to Understanding and Managing Fatigue*
- *A Guide to Understanding Clinical Trials and Medical Research in Hepatitis C*
- *A Guide to Understanding Hepatitis C*
- *A Guide to Understanding Hepatitis C Basics*
- *Aging and Hepatitis C: An HCSP Guide*
- *Easy C - A Guide to Understanding Hepatitis*
- *Final Steps with HCV: An HCSP Guide on Death and Dying*
- *First Steps with HCV for the Newly Diagnosed*
- *Hepatitis C Support Group Manual*
- *Management of Hepatitis C by the Primary Care Provider: Monitoring Guidelines*
- *Women and Hepatitis C: An HCSP Guide*

ADDITIONAL

- HCSP Find a Physician Locator
http://linux.hcvadvocate.org/cgi-bin/doctor_lookup1.cgi
- HCSP Support Group Locator
http://linux.hcvadvocate.org/cgi-bin/sg_lookup1.cgi
- Ottawa Hospital Research Institute
<http://www.ohri.ca/DecisionAid> This website offers several excellent tools that can help with decision-making.

A GUIDE TO:
HEPATITIS C
MAKING TREATMENT
DECISIONS

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The information in this guide is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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