New Hepatitis C Treatments and Viral Load Results: Clearing Up Confusion

March 23, 2015 By Lucinda K. Porter RN

New hepatitis C medications are changing lives, saving lives, and bringing hope. However, there is some confusion about viral load testing used during hepatitis C treatment. I am aware of this confusion because I am repeatedly asked two questions.

Question One:

"What does this test mean?" This question is accompanied with test results such as:

HCV Viral Load (Log IU/mL) <1.18 not="" detected="" o:p="">

Answer: This is the very best news.

Undetectable means that hepatitis C is gone, and presumably all gone. The confusion over this test is because viral load tests don't measure down to zero. Further, viral load tests vary. For instance, the Abbott RealTime HCV assay (assay is a fancy word for a test that determines and measure the ingredients of something) measures down to 12 IU/mL in a 0.5 mL sample of blood. This means that if you have 12 IU/ml of hepatitis C (HCV RNA) in your blood, the test will detect it and count it. If you have less than 12, the test might not see it, and if it does, it won't be able to count it. .

Each test has its own detection range, some lower than others. The main thing is this:

- "Not detected" = negative for hepatitis C
- "Detected" or an actual number of how much HCV RNA you have = positive for hepatitis C

If you are concerned that you may have some residual HCV swimming around in your body, hoping to set up shop in your liver, rest assured, as this is quite unlikely. Hep C replicates a trillion times a day, so "not detected" might as well be zero. It is extremely unlikely that a small amount of HCV will remain alive in your body without having replicated to much higher amounts. In fact, viral load tends to replicate at much higher numbers when treatment fails.

Question Two:

I am on treatment with Harvoni. My pre-treatment viral load was X million. My week 4 (or week 8 or week 12) viral load came back detectable. I am devastated. Should I be?

Answer: No.

In the old days, back when treatment was long and used interferon, there were clear milestones that helped us know what our chances were of permanently clearing hepatitis C. Ignore all of that. New research funded the NIH Clinical Center showed that low levels of HCV RNA at the end of treatment are not predictive of treatment response among patients with hepatitis C virus treated with interferon-free regimens. (*Clinical Infectious Diseases*, March 2, 2015) In fact, low levels of HCV RNA detected at the end of treatment, and even post-therapy, do not signify treatment failure.

Here is a bit more information. Sidharthan and colleagues enrolled 114 subjects with chronic HCV/genotype 1 and no prior treatment. Six patients with detectable viral load at the end of treatment achieved a sustained virologic response (SVR12). You can read more about it: *Utility of Hepatitis C Viral Load Monitoring on Directly Acting Antiviral Therapy* - S Sreetha Sidharthan, et al.

The bottom line is that a detectable viral load at the end of treatment DOES NOT mean that treatment failed when using Harvoni-based treatment.

Important:

- Don’t despair if you have detectable virus during or at the end of HCV treatment.
- Be sure your doctor doesn’t stop treatment just because you have detectable HCV RNA. The HCV guidelines recommend viral load testing after 4 weeks of therapy and at 12 weeks following treatment completion. If quantitative HCV viral load is detectable at week 4 of treatment, repeat viral load testing at treatment week 6. If viral load has **increased** by greater than 10-fold on repeat testing at week 6 (or thereafter), then discontinuation of HCV treatment is recommended. There are no other recommendations to stop or extend therapy based on viral load results.

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