Leaping Ahead with Hepatitis C Treatment Data

February 29, 2016 By Lucinda K. Porter RN

Leap Day is an important day in my house. On February 29, 1980, I asked my now-husband to marry me. My husband is an introvert, and I was not going to leave the timing of that question to him.

Hang in here with me, because there is a connection between my marriage proposal and hepatitis C, albeit a stretch. If you and your medical team made hep C treatment decisions based solely on the drug manufacturers' FDA-approved package information, your options would be limited. Instead, I suggest leaping ahead to the newly revised HCV Guidelines. More formally known as Recommendations for Testing, Managing, and Treating Hepatitis C, this document is provided by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), in collaboration with the International Antiviral Society–USA (IAS–USA).

The HCV Guidelines are a summary of the evidence. I am not going to summarize their summary, but here are a couple of observations.

- The HCV Guidelines may recommend a treatment based on research even if there isn't an FDA indication for it. For instance, the HCV Guidelines recommended Harvoni for genotypes 4, 5, and 6 long before the manufacturer requested that the label be expanded to include these genotypes. The same is true for Daklinza, which was originally labeled to treat genotype 3 patients, but the HCV Guidelines also recommended for genotype 1.
- The revised HCV Guidelines have dropped from their table the treatment recommendations for 8 weeks of Harvoni (ledipasvir/sofosbuvir) for those with viral loads of less than 6 million. The recommendation isn't gone completely; it is discussed in the supporting evidence:

> "ION-3 excluded patients with cirrhosis and investigated shortening therapy from 12 weeks to 8 weeks (with or without RBV). (Kowdley, 2014) SVR12 rate was 93% to 95% across all arms, with no difference in SVR in the intention-to-treat analysis. However, relapse rates were higher in the 8-week arms (20 of 431) regardless of RBV use compared with the 12-week arm (3 of 216). Post-hoc analyses of the 2 RBV-free arms assessed

> baseline predictors of relapse and identified lower relapse rates in patients receiving 8 weeks of ledipasvir/sofosbuvir who had baseline HCV RNA levels below 6 million IU/mL (2%; 2 of 123), and was the same for patients with similar baseline HCV RNA levels who received 12 weeks (2%; 2 of 131). This analysis was not controlled and thus substantially limits the generalizability of this approach to clinical practice. Preliminary real world (non-randomized) cohort data shows conflicting results on the comparable effectiveness of 8 and 12 weeks. Shortening treatment to less than 12 weeks for patients without cirrhosis should be done with caution and performed at the discretion of the practitioner."

What does this mean for you?

Work with your medical provider, and be informed. Your medical provider may not be up on the latest, so if you are, it may help. A good way to look at information, is to begin with the HEP website. The HCV treatment table is a simplified version of the HCV Guidelines. It's like looking at the back-of-the-envelope. From there you can look at the HCV Guidelines, and then read the explanation for their recommendations. This strategy will help you leap ahead. (Sorry, I couldn't resist.)

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