Hepatitis C in the News: Reading Between the Lines

January 30, 2017 By Lucinda K. Porter RN

Hepatitis C made The New York Times, "Are New Drugs for Hepatitis C Safe? A Report Raises Concerns." (Denise Grady, Jan 24, 2017) Perhaps you first read about it on Hep, "Report Raises Concerns About the Safety of Hepatitis C Treatments." You may have read Carleen McGuffey's response in her blog, "Misleading Hep-C Article." Today I add my own thoughts.

Let's begin with the original report from, "Perspectives from New Adverse Events Report" (January 2017) published by the Institute for Safe Medication Practices. (ISMP). The purpose of this report is to, "Examine the emerging risks of the new drugs for hepatitis C for triggering liver failure, a rare and catastrophic medical event that often ends in death or a liver transplant." They conclude:

> "While direct-acting antivirals to treat hepatitis C should be ranked as a major medical advance, the large number of cases of liver failure and death as well as antiviral failure show the need for further investigation of the serious adverse effects of this expensive new class of drugs. The activation of hepatitis B cases highlighted by the FDA could not have been detected in clinical testing for approval because such patients were excluded. In addition, some safety data before approval for ledipasvir-sofosbuvir was uninterpretable because of lack of a control group of any kind, and a new reliance on historical data to characterize benefit. Beyond the most severe liver failure cases were hundreds of additional cases where liver function was impaired rather than improved by treatment. Policies to approve new treatments quickly exact a price in serious injuries and deaths that might have been avoided with a more complete safety profile and better understanding of the most vulnerable patients."

Let's apply some clinical thinking to this report…

Who is the ISMP? According to their website, the ISMP is "a nonprofit organization devoted entirely to medication error prevention and safe medication use." Before this, I've never heard of them, and the same was true for the message board of hep C advocates I know.

Are their conclusions based on solid evidence? The short answer is no. First, this is a data review, which tends to be biased. Second, the data that they reviewed isn't a good representation of the picture. They reported, "Overall, 165 (31.5%) had died at the time of the report. While it was challenging to separate cases to which complications of hepatitis C might have contributed, 90%

of the cases were submitted by healthcare professionals, who would be likely to understand the natural progression of the disease." Those of us on the front lines know that doctors were "warehousing" their patients, waiting for the new drugs to come out. (Also read, Rick Nash's blog, "The HCV Warehouse and It's Locked Doors.") After the new hepatitis C drugs were aapproved, doctors treated their sickest patients first, many of whom were already close to death. This practice is still occurring, as mentioned in my blog last week.

Second, I question the validity of the statement, "90% of the cases were submitted by healthcare professionals, who would be likely to understand the natural progression of the disease," I know plenty of healthcare professionals who don't understand basic stuff about hepatitis C, such as testing their baby boomer patients. I hope that patients with advanced liver disease are in the hands of hepatologists, but I don't assume it.

Read the entire report. We tend to read media bytes and want a bottom line. If you read the conclusions, the ISMP states, "While direct-acting antivirals to treat hepatitis C should be ranked as a major medical advance, the large number of cases of liver failure and death as well as antiviral failure show the need for further investigation of the serious adverse effects of this expensive new class of drugs…" They don't say these drugs are bad. They say we need, "Policies to approve new treatments quickly exact a price in serious injuries and deaths that might have been avoided with a more complete safety profile and better understanding of the most vulnerable patients." Can't argue with that.

Put it in context. Let's assume that everything in the report is true. However, something is missing. We don't know the size of the base. They used the figure, "524 reported cases of liver failure and 165 deaths." That number is incredibly high if a thousand people were treated, but low if a million were treated. Would you take a drug if 165 out of a thousand people died versus 165 out of a million?

Also, we need to know how many people would have had adverse events had they not had hep C treatment. If a thousand would have had liver failure without treatment, then 524 cases is a better looking number.

Understand the risk. The New York Times wrote, "The number of adverse events appears relatively small, and the findings are not conclusive." This is true. Also, we need to remember that an adverse event is not a cause. It is an independent event that may or may not be related to a medication.

Please, please, please, don't let headlines like the one in The New York Times stop you from accessing life-saving hepatitis C treatment. Get your facts from experts, not from journalists.

© 2026 Smart + Strong All Rights Reserved.