Hep C Drug Development Pipeline is “Robust,” Says Report

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There is neither global nor national surveillance for HCV-related illness and death, Clayden and Harrington point out in the report’s introduction and executive summary, but more than 300,000 people die from HCV complications each year, and HCV mortality will continue to increase in the coming decade.

The prospects for dramatic—indeed in some cases revolutionary—changes in prevention and treatment for HCV in the next decade are amazingly good, the authors suggest. “Decades of high-quality research, increased investment, and growing and targeted community-based activism have set the scene for the possibility,” the authors say.

According to the report, several generations of new direct-acting antivirals (DAAs) are in the pipeline for HCV, holding out the promise that it may be possible to cure people with oral drugs in the future. Currently, 14 HCV protease inhibitors—not including the just-approved Victrelis (boceprevir) and Incivek (telaprevir)—6 NS5a inhibitors, 10 non-nucleoside polymerase inhibitors, 8 nucleoside or nucleotide polymerase inhibitors, 3 host-targeting agents, 4 novel interferons, 3 immunomodulators, a microRNA inhibitor and an extract of milk thistle are in development.

“If the promise of all-oral DAA cures is realized,” Clayden and Harrington write, “the potential to roll out HCV treatment globally would then become dramatically easier, and hundreds of millions of lives could be saved. But most people with hepatitis C will not be cured—or even treated. The drugs are simply too expensive. New HCV treatments must be accessible to those who need them.”

The report also warns that neither the health care system nor the provider community is ready to administer new and complex HCV regimens to an onslaught of newly diagnosed patients. Major adjustments will be needed to ensure that people with HCV—who often may need mental health care, addiction treatment, and HIV care and treatment—can be treated with dignity.

Tracy Swan of TAG who wrote the report’s section on HCV drug development recommends the immediate establishment of a standing, multidisciplinary federal HCV treatment-guidelines panel—modeled in part after the very successful DHHS HIV Therapy Guidelines panels for adults, adolescents, and children—to review new data as they emerge, and to promulgate a coherent and up-to-date standard of care for all individuals with HCV.

Swan is critical of the pharmaceutical industry's failure to provide early-access trials and programs for people at risk for progression to end-stage liver disease.

Preapproval access to new HCV drugs will save lives, and inform clinical practice in patients with urgent need. Swan is also dismayed that HCV drugs can come to market without information on how to safely and effectively use them during HIV treatment, with methadone, or in combination with other commonly used medications—or that coadministration may not be possible.

The 2011 Pipeline Report can now be accessed on the i-Base or TAG websites.

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