









Position Statement

Australian Health Organisations refute Cochrane Review Report and affirm efficacy of Direct Acting Antiviral (DAA) therapy for hepatitis C

Australia, June 2017

This joint Position Statement aims to strongly refute and reject the findings of the <u>Cochrane Review Report</u>¹ titled *Direct-acting antivirals for chronic hepatitis C*, published by the <u>Cochrane Hepato-Biliary Group on 6 June 2017</u>.

The Position Statement was prepared by the expert panel who published a <u>Consensus Statement for Australian</u> <u>recommendations for the management of hepatitis C for virus infection</u>² representing the Gastroenterological Society of Australia (Australian Liver Association), the Australasian Society for Infectious Diseases, the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, the Australasian Hepatology Association, Hepatitis Australia and the Royal Australian College of General Practitioners.

The organisations above developed this position statement to urge health practitioners and patients not to be swayed by this flawed report claiming new direct-acting antivirals (DAAs) for hepatitis C do not save lives.

Direct Acting Antiviral (DAA) therapy for hepatitis C is effective

Our position affirms the clinical benefits of DAAs, which offer sustained virological response (SVR). SVR is a marker for cure of hepatitis C.^{3, 4} Clearing the hepatitis C virus has been shown in natural history and prior treatment studies studies to substantially reduce the risk of liver cancer and liver failure, reducing mortality from cirrhosis and liver cancer.^{5,6,7,8} Curing hepatitis C can also improve quality of life, including physical, emotional, and social health; decrease concerns regarding transmission, and alleviate suffering associated with such a stigmatized illness.^{9,10,11}

In the Report, the clinical trials analysed by the <u>Cochrane Hepato-Biliary Group</u> were designed as short-term studies to demonstrate antiviral efficacy in terms of curing hepatitis C. They were never intended to assess long-term outcomes including morbidity and mortality. Lack of demonstration of these outcomes in these short term studies should not be taken as evidence for no benefit.

Following the listing on the PBS (Australian Pharmaceutical Benefits Scheme) in March 2016 of DAA therapy for all Australians living with hepatitis C (regardless of fibrosis stage or drug and alcohol use), Australia is now placed as one of the few countries globally to be able to achieve elimination of this virus from the population.

Treating the more than 200,000 people in Australia living with chronic hepatitis C is expected to significantly reduce the burden of liver disease in the future

In the first year of DAA listing over 33,000 Australians have commenced therapy with very high rates of treatment success. Continuing high rates of treatment uptake over the next decade will translate into major reductions in the burden of liver disease into the future.

Health professionals are encouraged to discuss DAA treatment with any patients living with hepatitis C. Likewise, patients should not be swayed by this flawed report and should not defer seeking treatment based on this study.











- 1. Cochrane Database of Systematic Reviews 2017, Issue 6. Art. No. CD012143. DOI: 10.1002/14651858.CD012143.pub
- 2. Hepatitis C Virus Infection Consensus Statement Working Group. Australian recommendations for the management of hepatitis C virus infection: a consensus statement (January 2017). Melbourne: Gastroenterological Society of Australia, 2017
- 3. Swain MG, Lai MY, Shiffman ML, et al. A sustained virologic response is durable in patients with chronic hepatitis C treated with peginterferon alfa-2a and ribavirin. Gastroenterology. 2010;139(5):1593-1601.
- 4. Manns MP, Pockros PJ, Norkrans G, et al. Long-term clearance of hepatitis C virus following interferon alpha-2b or peginterferon alpha-2b, alone or in combination with ribavirin. J Viral Hepat. 2013;20(8):524-529.
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- 6. Morgan RL, Baack B, Smith BD, Yartel A, Pitasi M, Falck-Ytter Y. Eradication of hepatitis C virus infection and the development of hepatocellular carcinoma: a meta-analysis of observational studies. Ann Intern Med. 2013;158(5 Pt 1):329-337.
- 7. van der Meer AJ, Veldt BJ, Feld JJ, et al. Association between sustained virological response and all-cause mortality among patients with chronic hepatitis C and advanced hepatic fibrosis. JAMA. 2012;308(24):2584-2593.
- 8. Veldt BJ, Heathcote EJ, Wedemeyer H, et al. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. Ann Intern Med. 2007;147(10):677-684
- 9. Boscarino JA, Lu M, Moorman AC, et al. Predictors of poor mental and physical health status among patients with chronic hepatitis C infection: the Chronic Hepatitis Cohort Study. Hepatology 2015; 61(3):802-11.
- 10. Neary MP, Cort S, Bayliss MS, Ware JE, Jr. Sustained virologic response is associated with improved health-related quality of life in relapsed chronic hepatitis C patients. Semin Liver Dis. 1999;19(Suppl 1):77-85.
- 11. Younossi ZM, Stepanova M, Henry L, et al. Effects of sofosbuvir-based treatment, with and without interferon, on outcome and productivity of patients with chronic hepatitis C. Clin Gastroenterol Hepatol. 2013; [Epub ahead of print].

About the Hepatitis C Virus Infection Consensus Statement Working Group

This position statement is a joint and collective statement representing:

- The Gastroenterological Society of Australia (Australian Liver Association)
- The <u>Australasian Society for Infectious Diseases</u>
- The Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
- The <u>Australasian Hepatology Association</u>
- <u>Hepatitis Australia</u>
- The Royal Australian College of General Practitioners