Providing ready access to new hepatitis C treatments.

Hepatitis Australia National Advocacy Priority 2.1 – January 2014

Key Messages

- In 2012, 232,000 Australians were living with chronic hepatitis C.
- Viral hepatitis is the leading cause of liver transplants and a key contributing factor to the sharp increase in deaths due to primary liver cancer[1]
- It is well documented that the number of people receiving treatment for hepatitis C needs to increase significantly to reduce hepatitis C related morbidity and mortality.
- There are numerous international clinical trials underway for innovative, more tolerable and more effective hepatitis C treatments which are taken for a shorter duration.
- For many people, treatment of their hepatitis C infection can result in a cure.

But…

- Treatment rates among people living with hepatitis C have been declining since 2009 with only an estimated 2,360 (1%) receiving treatment in 2012.
- Australian's have experienced delays in access to new treatments.
- The financial and human burden of hepatitis C in Australia continues to grow.

The Issue

Hepatitis C is a blood borne virus. National surveillance data estimates there were 232,000 people[2] in Australia living with chronic hepatitis C in 2012. Despite treatment resulting in a cure for most people, treatment rates have declined significantly from a peak of 3,397 in 2009 to only 2,360 in 2012[2]. The Third National Hepatitis C Strategy[3] clearly states the need to increase the number of people accessing treatment for hepatitis C.

The rapid development of new highly effective interferon-free treatments for hepatitis C will significantly change the landscape of hepatitis C treatment in Australia. Gaining rapid access to newly developed and proven treatments, some of which are already approved in the USA will be vital to minimise the longer-term human and economic burden of hepatitis C in Australia.

Until recently, the standard therapy for hepatitis C in Australia was a combination of pegylated interferon and ribavirin given over 24 or 48 weeks according to genotype. In April 2013 the Australia Government approved the listing of two new drugs, boceprevir and telaprevir on the Pharmaceutical Benefits Scheme (PBS). These drugs are added to standard therapy to form triple therapy for treating hepatitis C, genotype 1. This increases the effectiveness of treatment as well as reducing the duration of treatment for some people, but it has increased side effects. The treatment for hepatitis C genotypes 2 & 3 remains unchanged in Australia at this point in time.

The considerable side effect profile of current treatment regimens is mostly attributed to the use of interferon administered as weekly injections, which act as a barrier to treatment uptake. This is about to change as a number of pharmaceutical companies have drug trials underway which focus on developing direct-acting, interferon free drug therapy, which will be much better tolerated with few side-effects. Hepatitis C treatment will move through ground-breaking changes in the next 2-5 years which has potential to support a substantial increase in treatment uptake resulting in cures for the vast majority of people (>90%) regardless of their genotype. The development of these new treatments has been described as one of the most significant advances in medical science in recent decades.

<u>Access to new treatments</u>

Australians had to wait over a year longer than citizens of some other developed countries to access boceprevir and telaprevir. When considering which drugs are approved for subsidised access through the PBS it is important to have rigorous checks and balances such as those of the Pharmaceutical Benefits Advisory Committee (PBAC). However, these processes should not result in lengthy delays in patient access to new innovative medicines that offer significantly improved cure

rates; a reduction in the health costs associated with advanced liver disease; and a reversal of the upward trend in hepatitis C related deaths which already exceed those for HIV each year.

In May 2013, the US Food and Drug Administration (USFDA) granted sofosbuvir (an oral nucleotide analog polymerase inhibitor) 'breakthrough therapy' designation.

> *"Breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions"*[4]

By 6th December 2013, the USFDA approved sofosbuvir (Gilead - Sovaldi), which taken in combination with ribavirin represents the first ever all oral, interferon-free hepatitis C treatment. In the US it has been granted a broad indication for use without interferon to treat people with genotype 2 & 3, in addition it may be given to genotype 1 patients who are interferon ineligible and patients with liver cancer who are waiting for liver transplants.

Australian governments have already acknowledged the need to increase treatment rates to reduce the longer-term burden on the health system and enhance prevention efforts.

> *"An increase of treatment uptake to 6000 per year would be highly cost-effective in terms of cost per quality adjusted life year gained, with increases to 8000 and 12 000 providing even further improvements"* Third National Hepatitis C Strategy 2010-2013

In light of this, the Australian Government must now instigate similar processes to ensure ready access to new treatments for hepatitis C by committing to fast-tracking new hepatitis C treatments through government approval processes.

Future impacts

With such a significant change in the treatment of hepatitis C now beginning, it is important to consider the flow on health system impacts associated with assessment for and delivery of treatment, support services and treatment follow-up. With almost 230,000 people living with chronic hepatitis C this will be particularly important to ensure ready access to treatment for hepatitis C.

This will require substantial collaborative work to inform, prepare and resource the health and community care system including; treatment awareness programs providing pathways to care; specific models of care tailored for population groups; development of clinical protocols; provision of multidisciplinary health professional training and links to community based services for complementary information and support.

The Solution

To reverse a growing burden of advanced liver disease and rising death toll from hepatitis C in Australia, new breakthrough hepatitis C treatments must be made available to Australians living with hepatitis C without delay. Hepatitis Australia believes the Australian Government should:

1. Drive improvements in access to treatment by introducing measurable targets for hepatitis C treatment together with appropriate monitoring and robust accountability systems;
2. Commit to fast-tracking PBS approval and supporting health system changes to facilitate access to new hepatitis C treatment for everyone with chronic infection; and
3. Fund the development of best practice, multi-disciplinary and holistic care pathways that are inclusive of new forms of treatment and responsive to the needs of people with hepatitis C.

References:

[1] Australian Institute of Health and Welfare. 2012, *Cancer survival and prevalence in Australia: period estimates from 1982 to 2010. Canberra.* http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=10737422721

[2] The Kirby Institute. *HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2013*. University of New South Wales, Sydney.

[3] Australian Government, Dept. of Health and Ageing, 2010, *Third National Hepatitis C Strategy 2010-2013*, http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp-national-strategies-2010-hcv/$File/hcv.pdf

[4] United States Food and Drug Administration http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm341027.htm