Elimination of Hepatitis C Virus in Australia

Laying the Foundation

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KEYWORDS

- Hepatitis C, HCV • Elimination • People who inject drugs • Australia
- Direct acting antivirals, DAA, public health

KEY POINTS

- Australia has laid the foundation for hepatitis C virus elimination within the next decade.
- Key aspects of this foundation include high levels of screening and diagnosis, unrestricted access to direct-acting antiviral therapy, a diverse range of models of care, and high coverage of harm reduction strategies.
- Key features include government risk-sharing arrangement with the pharmaceutical companies, minimal out-of-pocket cost, no restrictions based on liver disease stage or drug/alcohol use, prescribing authorization for all registered medical practitioners; and retreatment is allowed.
- Although initial uptake of direct-acting antiviral therapy was high, more efforts are required to continue the momentum.
- An hepatitis C virus elimination monitoring and evaluation program is in progress to inform further strategies required to achieve hepatitis C virus elimination targets.

INTRODUCTION

The development of direct-acting antiviral (DAA) therapy for chronic hepatitis C virus (HCV) infection is one of the great advances in clinical medicine in recent decades. Involving simple (once daily oral dosing), tolerable, short duration (8–12 weeks), and highly efficacious (cure rates of >95%) regimens, DAA therapy has the potential to markedly increase HCV treatment uptake and turn around the escalating global disease burden associated with chronic HCV infection.[1] The transformative nature of DAA therapy underpinned the development of World Health Organization (WHO) goals to eliminate HCV as a public health threat, which include 80% of eligible patients treated, a 65% decrease in HCV-related mortality, and an 80% decrease in new HCV infections by 2030.[2]

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Major barriers to broadened DAA access have been low rates of HCV screening and diagnosis in most countries,[3] and restrictions driven largely by high drug pricing and related concerns of budget impact.[4,5] In contrast, Australia has had an active HCV screening program for more than 2 decades, with an estimated 81% of the HCV-infected population diagnosed,[6,7] and the development of an unrestricted DAA access program, launched in March 2016.[8] The development of the Australian Government-funded DAA access program is described, along with key features that strengthen the foundation for achieving the WHO HCV elimination targets.

KEY FEATURES OF RESPONSE TO HEPATITIS C VIRUS OVER THE LAST 2 DECADES

There are several key features that have driven the successful HCV response. Australia has a history of national HCV strategic development, with the First National Hepatitis C Strategy launched in 2000, is in a Fourth Strategy (2013–2017),[9] and is developing a Fifth Strategy. This strategic development has been underpinned by partnerships between government, clinical, academic, and civil society stakeholders. Government funding for national and state-based hepatitis and drug user community organizations has been pivotal to these partnerships, and has driven community-based education and advocacy. HCV education and training for primary care and addiction medicine physicians from the early 2000s has facilitated high levels of screening, and laid the foundation for the current major involvement of these groups in DAA prescribing.[8] The broad implementation of harm reduction strategies for people who inject drugs (PWID), from the early 1990s, maintained a low prevalence of human immunodeficiency virus (HIV) infection (around 1% among PWID),[10] prevented many HCV infections[11] (although the chronic HCV prevalence was 45% before the DAA scale-up),[12] and provided the public health interface to enable a highly marginalized population to have high levels of HCV screening (around 90%).[12,13] Finally, as with the HIV response in Australia, bipartisan support (from both major political parties) and political leadership have been crucial to the development of HCV public health strategies that are pragmatic, highly cost effective, and generally well-accepted by the broader community.

MAJOR MILESTONES IN THE DEVELOPMENT OF THE UNRESTRICTED DIRECT-ACTING ANTIVIRAL ACCESS PROGRAM

A pivotal meeting was convened in 2014 by Dr Sue Hill, Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent body that evaluates applications for government subsidization of therapeutic agents. Representatives from the government, clinical, academic, civil society groups, and the pharmaceutical industry were present. The hepatitis and drug user community-based organization representatives were particularly vocal in advocating “access to all,” rather than a liver disease stage-restricted access strategy that most high-income countries were pursuing.

In July 2014, the PBAC rejected the initial application for subsidization of sofosbuvir plus ribavirin (for genotypes 2 and 3) by Gilead, on cost-effectiveness grounds. In March 2015, the PBAC reevaluated sofosbuvir plus ribavirin (for genotypes 2 and 3), and further DAA regimens, including sofosbuvir/ledipasvir (for genotype 1), and sofosbuvir plus daclatasvir (for genotypes 1 and 3). The committee recommended access for all patients with chronic HCV infection aged 18 years or older. Importantly, the public minutes of the PBAC meeting stated that the cost effectiveness of these therapies should be at the $AUD 15,000 ($US 12,000) per incremental cost-effectiveness ratio level, rather than the generally accepted benchmark for therapeutic interventions of $AUD 40,000 to 50,000 ($US 32,000–40,000) per incremental cost-effectiveness ratio