



NTUHDRC
臺灣大學健康資料研究中心

「台灣C肝治療面面觀」 公聽會

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Hepatitis C: global ambition, national realities



For the US CDC report see <http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>

For WHO HCV guidelines see <http://www.who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/>

For WHO model list of essential medicines see <http://www.who.int/medicines/publications/essentialmedicines/en/>

For WHO draft strategy see http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf

Last week, new surveillance data released by the US Centers for Disease Control and Prevention (CDC), report that US hepatitis C virus (HCV)-associated deaths reached a record high—19 659 in 2014. Around 3.5 million people are currently living with HCV in the USA. The cost of direct-acting antivirals (DAAs), the curative drug class of choice in new WHO guidelines, is prohibitive, with some US insurers covering only severe cases. WHO has added most new DAAs to its model list of essential medicines. With an estimated 130–150 million people worldwide infected with HCV, the global treatment gap is urgent and reminiscent of the early AIDS crisis, with most countries lacking access to curative medicines.

One such example is China. Around 8 million people are estimated to be infected with HCV, which is double the US burden. HCV-related liver cancer deaths rose by 283% from 1990 to 2013. Around 100 000 Chinese HCV patients are on suboptimum interferon-based regimens annually because DAAs are not available. High costs for middle-income countries notwithstanding,

DAAs are not yet registered nationally because the Chinese food and drug regulatory agency requires that all foreign medicines first undergo local clinical trials, a registration process that can take up to 5–8 years. Although HCV drugs qualify for (as yet undefined) accelerated registration, the situation is unacceptable for the 2.5 million Chinese HCV patients currently in need of treatment. According to WHO China, it is cheaper to treat than not to treat. Interferon-based regimens are estimated to be more than fourfold the cost of a standardised package using DAAs at an access price similar to Egypt. Solutions to consider would be a clinical trial waiver (granted for HIV antiretrovirals) or compulsory licensing for generic production.

The WHO global strategy on hepatitis will be deliberated at the World Health Assembly later this month. The goal to eliminate hepatitis as a major public health threat by 2030 is only achievable through planning urgent and affordable access to essential medicines—in all countries. ■ *The Lancet*

全球議題 各國難題

Towards the Elimination of Hepatitis B and C by 2030

The draft WHO Global Hepatitis Strategy, 2016–2021
and global elimination targets



World Health
Organization



Limited Access to New Hepatitis C Virus Treatment Under State Medicaid Programs

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The burden of fatal liver disease is increasing in the estimated 3.2 million adults chronically infected with hepatitis C virus (HCV) in the United States (1-3). Sofosbuvir (Sovaldi, Gilead Sciences), which was approved by the U.S. Food and Drug Administration in December 2013, is a new oral HCV treatment that,

safety compared with older, interferon-based treatments; thus, nonspecialist physicians, rather than a limited number of specialists, may be able to manage treatment for most HCV-infected persons (that is, non-relapsing patients without serious comorbid conditions). However, 30 states require that sofosbuvir be prescribed by a specialist in consultation with a specialist

“Treatment of patients with HCV infection is **cost-effective from a societal point of view**, but the combination of the high cost of treatment and insufficient Medicaid **budgets** precludes programs from providing widespread access to treatment”

世界各地的經濟評估結果，大多是「對社會來說具成本效益，但財務無法負擔」



“Budget-conscious payers are struggling—the estimated cost to treat **20,000** people in **England**, for example, is **£1 billion**. In fact, the high cost has created unprecedented concern from national agencies and has prompted exceptional collaboration between European nations. Led by France’s health minister, **14 European countries** are banding together for the first time to **share pricing negotiation information previously considered confidential.**”

衛生體系面臨新時代的考驗

“Therapeutic Spotlight: Hepatitis C-How Countries Are Adapting to the Post-Interferon Era”: <http://www.xcenda.com/Insights-Library/HTA-Quarterly-Archive-Insights-to-Bridge-Science-and-Policy/HTA-Quarterly-Summer-2015/Therapeutic-Spotlight-Hepatitis-C-How-Countries-Are-Adapting-to-the-Post-Interferon-Era/>



醫療科技評估觀點看決策問題



1. 要回答什麼問題?

誰在問問題?

要解決什麼問題?

有什麼解決的方法?



2. 盡量了解各種解決方案的 健康效益

優缺點在哪裡？

比(以前)好了多少？

差了多少？



3. 跟現有的方案做比較

多花的錢是否**值得**?
(成本效果、成本效益)



4. 方案可行性

財務支出預測是如何?
付得起嗎?



5. 其他層面的影響

公平性

公共衛生意義

其他民眾福祉

醫療科技進步

...

Do the right things!

