Comment

From the big three to the big four

The increasing global burden of viral hepatitis was recognised by the World Health Assembly with the passing of two resolutions, the first in 2010,1 followed by a second in 2014.2 These resolutions identified viral hepatitis as a global health issue needing an “integrated and cost-effective approach” to its prevention, control, and management. At a global level, viral hepatitis is responsible for 1.44 million deaths every year (compared with 1.46 million deaths from HIV/AIDS, 1.20 million from tuberculosis, and 1.17 million from malaria). In Asia, the situation is different, with deaths from viral hepatitis outnumbering those from HIV, malaria, and tuberculosis combined.1 The data show a comparable burden of viral hepatitis with the big three infectious diseases—HIV, malaria, and tuberculosis—identified by the UN Millennium Development Goals (MDGs) for eradication.

A successful global response to viral hepatitis relies on a successful response to the epidemic in Asia, where 76% of the global population with viral hepatitis lives1 and where successful response to the epidemic in Asia, where 76% of the global population with viral hepatitis lives, and where 74% of the global deaths related to these infections occur.3 Financial investment in responding to viral hepatitis is minimal at a global level with no mention of chronic viral hepatitis in the MDGs. In the USA, although hepatitis C is at least five times more prevalent than HIV, little funding has been directed to improving prevention, care, or research (table).3 The World Health Assembly resolutions provided the rationale for the establishment of the Global Hepatitis Program within WHO, and the development of the Prevention and control of viral hepatitis infection: framework for global action in 2012. This framework was to provide national governments a structure to develop effective strategies and plans according to their specific hepatitis burden and challenges.

Despite the limitations, remarkable advances have occurred over the past decade in the Asia-Pacific region. The hepatitis B vaccination programme in China has effectively decreased the prevalence of chronic hepatitis in the MDGs. In the USA, although hepatitis C is at least five times more prevalent than HIV, little funding has been directed to improving prevention, care, or research (table).3 The World Health Assembly resolutions provided the rationale for the establishment of the Global Hepatitis Program within WHO, and the development of the Prevention and control of viral hepatitis infection: framework for global action in 2012. This framework was to provide national governments a structure to develop effective strategies and plans according to their specific hepatitis burden and challenges.

The needs assessment of people with viral hepatitis—China, funded by the Coalition to Eradicate Viral Hepatitis in Asia Pacific, done by La Trobe University, and to be released in summer 2015, found that people were diagnosed through educational or employment institutions, by a teacher or human resources staff with little information provided to

<table>
<thead>
<tr>
<th></th>
<th>HIV (US$)</th>
<th>Hepatitis B ($)</th>
<th>Hepatitis C ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>728 000 000</td>
<td>9 000 000</td>
<td>9 000 000</td>
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<tr>
<td>Care</td>
<td>2 270 000 000</td>
<td>70 000 000</td>
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<tr>
<td>Research</td>
<td>2 900 000 000</td>
<td>42 000 000</td>
<td>106 000 000</td>
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</tbody>
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Table: Funding for HIV, hepatitis B, and hepatitis C in the USA in 2010

We declare no competing interests.


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After rapid advancement of several promising Ebola virus disease vaccine candidates into phase 1 clinical trials, large randomised controlled trials (RCTs) that aim to show that an investigational vaccine prevents the clinical occurrence of Ebola virus disease have been initiated. The recent decline in Ebola virus disease incidence in affected regions is very welcome news from a humanitarian and public health perspective, but it might hamper direct assessment of vaccine effectiveness based on clinical Ebola virus disease endpoints. Moreover, candidate vaccines not being investigated in these trials will need to be assessed for efficacy. Therefore, although RCTs with disease endpoints are acknowledged as the most robust study design for showing vaccine efficacy, other approaches should be considered.

Approaches to demonstration of Ebola virus vaccine efficacy

Although an Ebola virus disease vaccine would be mainly used in west Africa and thus be subject to approval by the relevant national regulatory authorities, regulatory approval of a vaccine in North America or Europe has the potential to support regional approval. Manufacturers might also benefit if their vaccines are licensed in several countries before widespread distribution and use. Irrespective of jurisdiction, vaccines are licensed on the basis of data derived from adequate clinical trials showing that the products are safe and effective. Although all approaches to vaccine licensure require that quality and safety are shown, licensure will not necessarily require demonstration of efficacy in a clinical trial using a clinical endpoint. In the USA, products for serious or life-threatening