

Simplify, simplify

Overhauling hepatitis B testing and treatment would lower costs and improve outcomes, say Margaret Hellard and Jessica Howell.

Hepatitis B is a major global killer: almost 300 million people worldwide are living with chronic hepatitis B infections, and more than 800,000 people die every year from hepatitis-B-related liver failure and liver cancer¹. The impact of this viral disease is greatest in low-resource settings.

Safe, effective and affordable hepatitis B treatments are available that suppress the virus, protecting the liver from continuing damage and reducing transmission risk. Globally, however, less than 10% of people with the disease are diagnosed and less than 8% receive treatment². Clearly, our current approach to hepatitis B diagnosis and management is not up to the task. New strategies are urgently needed.

On the basis of current guidelines set by international organizations, which in turn inform national prescribing policies, not all people infected with the hepatitis B virus (HBV) are eligible for treatment. Finding those who qualify requires several blood tests to check for liver inflammation, hepatitis B immunological responses and HBV levels in blood. Further tests are needed to assess liver scarring (fibrosis). Many of these tests are unaffordable or simply unavailable in low- and middle-income countries. An HBV level test, for instance, requires trained workers and expensive machines, and can cost as much as US\$100 in sub-Saharan Africa. Hepatitis B can become a chronic disease, requiring lifelong regular monitoring to ensure treatment is started at the right time to prevent complications. This complexity requires specialist management. But in low-resource settings, there are not enough experienced health workers to manage everyone with the condition.

So, the first task is to reduce the frequency and complexity of the tests required for hepatitis B monitoring. This change would remove some of the barriers people face in accessing care in two ways: first, by reducing the need for multiple visits to health services, and second, by allowing non-specialist health workers to manage hepatitis B. This could be achieved by substituting expensive laboratory tests with cheaper, rapid point-of-care tests that provide same-day results.

This simplified approach to hepatitis B testing entails a trade-off. The lower-cost technologies that make more widespread use possible also deliver less-accurate results than the gold-standard laboratory tests. However, this small loss of accuracy is outweighed by the benefits of increasing the number of people who can be tested and diagnosed.

An even simpler approach would be to offer treatment to everyone with hepatitis B, as already happens with two other viral diseases: HIV and hepatitis C. A 'treat-all' system of care would prevent someone missing out on the therapies

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they need. This strategy also requires less frequent monitoring, because the risk of hepatitis flare-ups is reduced.

Past concerns that influenced the decision to advise against a treat-all approach to hepatitis B are outdated. Hepatitis B treatments are off-patent, so they are now affordable. And fears that hepatitis B would become resistant to treatment if medications were unnecessarily prescribed have so far proved to be unfounded; no viral resistance to the hepatitis B drug tenofovir has been documented despite decades of use. There is thought to be only a small risk of the virus developing resistance to the other most commonly used medication, entecavir.

It is true that treating every person who has a diagnosed infection would mean some people with only mild liver disease would receive a treatment that they might not need – and, although it is generally safe, some of them might still experience side effects. They might also be at risk of a hepatitis flare-up if they ever stopped the medication. Despite that potential downside, we think that the time might be right to change our approach and treat all diagnosed people.

This strategy offers other health benefits as well. For example, there is emerging scientific evidence that a high level of virus is linked to the risk of developing liver cancer. These findings suggest that suppressing virus levels early on might be an effective strategy to reduce cases of this cancer³ (see page S64). Reducing virus levels in individuals also has the benefit of lowering the risk of transmission to unvaccinated people – including from pregnant people to their babies, a common source of chronic infections⁴ (see page S50).

Finally, a growing body of evidence shows that a treat-all approach for hepatitis B is more cost-effective than current practice⁵. The medications are less costly than the tests required to determine treatment eligibility. And removing those expensive tests would allow people to be treated by non-specialist health-care workers in community settings, instead of by specialists in hospitals.

The current approach to managing hepatitis B is not working. Testing and treatment guidelines are impractical for many low-resource countries, leaving most people with hepatitis B without lifesaving treatment. Simplified approaches to the disease that consider its prevalence and the socio-economic context are crucial if we are to achieve hepatitis B elimination globally. However, it is essential that people living with this disease are at the centre of any decision to change hepatitis B care, because until there is a cure, a treat-all approach means every infected person would have to take medication for life. For some, this might be a significant barrier; they would be confronted with their hepatitis B every day when taking a tablet, whereas previously it could be ignored for months on end. It is therefore imperative that we develop an optimal approach to testing and treatment that enshrines dignity, informed choice and equity in access to care.

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The authors declare competing interests; see go.nature.com/36cslup.