Wilton Park

Summary report

HIV co-infection with viral hepatitis: implications for screening and treatment in Asia

Saturday 28 February – Monday 2 March 2015 | WP1393

Introduction

1. Millions of people with HIV/AIDS worldwide are living with serious co-infections, including chronic viral hepatitis B (HBV) and hepatitis C (HCV). An estimated 10 percent of people with HIV have chronic HBV infection, and as many as 30 percent are estimated to be chronically HCV-infected. These proportions are even higher in many Asian countries. In response, Wilton Park convened a high-level stakeholder meeting to address the challenges of Asia's HIV-viral hepatitis co-infection epidemic.

2. The three-day meeting was attended by more than 60 health experts from nearly 20 countries with a broad range of experience, including ministry of health officials, leading clinicians, researchers and economists, as well as representatives from patient and advocacy groups, global public health organizations and funding agencies.

Overview of Discussions

3. To set the stage experts presented an overview of global HIV and viral hepatitis co-infection. In subsequent sessions, participants engaged in deeper discussion about HIV-viral hepatitis co-infection in regions throughout Asia, taking into account unique country-specific issues. Representatives from China, India, Indonesia, Myanmar and Vietnam presented case studies on co-infection programming in their countries, highlighting lessons learned and offering examples of successes that could be replicated in other areas within the region. Another session focused on enhancing collaboration across government, patient advocacy groups and private industry to ensure high-level strategies are aligned and to mobilise policymakers and donors to address viral hepatitis. Participants provided perspectives based on their experiences working with their respective governments, funding mechanisms and patient populations.

4. The diversity of participants' backgrounds and insights contributed to informed and candid conversations about current challenges and significant opportunities in the response to Asia's co-infection epidemic. These discussions and debates centred on major scientific advances in diagnostics and therapeutics, pathways and barriers to access, funding and treatment policies and the need for better coordinated, systematic surveillance to inform new policy and treatment guidelines. On the second day of the meeting, participants identified four key focus areas meriting more in-depth discussion and divided into smaller working groups. These focal points were: (1) treatment and prevention of co-infection, (2) simplification of treatment delivery, (3) advocacy priorities and (4) health financing.

5. There was general agreement that a more coordinated and collaborative effort is needed to build on the momentum that the meeting generated, raise the visibility of HIV-viral hepatitis co-infection as a public health priority and intensify the response to the epidemic. While differing opinions emerged throughout the meeting, the expert group identified several areas where further action is needed to significantly reduce the burden of HIV-viral hepatitis co-infection in Asia. The specific recommendations that garnered the most widespread support are summarised below.

Major Themes

6. The burden of viral hepatitis in Asia is unique – it is a generalised disease that affects men, women and children of all ages and backgrounds, not only specific, at-risk populations. Participants noted that it is especially critical to address the heavy burden of viral hepatitis in China and India.

7. Addressing HIV-viral hepatitis co-infection first may provide useful programmatic lessons learned and open the door for programmes to address viral hepatitis mono-infection.

8. Many participants noted that several Asian countries are well positioned – politically, economically and in terms of health systems capacity – to initiate viral hepatitis programmes now and lead by example.

9. There is an urgent need for a cross-sectoral group – including academics, clinicians, governments, advocates and the private sector – to address the challenges and opportunities viral hepatitis presents globally. This will require members of each sector to collaborate with non-traditional partners.

General Recommendations

While there was not consensus on all actions needed, the recommendations below surfaced most frequently.

10. **Simplify the issue at the clinical level.** Currently, viral hepatitis is a physician-dominated field. HBV has ten strains or genotypes; HCV has six genotypes; specialists are required; diagnostics and monitoring are complicated; liver disease staging is not easy. The level of complication makes tackling viral hepatitis more daunting. There is a need to broaden the dialogue to include patients, advocates and other stakeholders and simplify how challenges and solutions are communicated.

11. **Develop accurate, easy to administer, affordable point-of-care diagnostics for HBV and HCV.** In the absence of broadly accessible and affordable fibroscans and genotype testing, the following alternatives should be prioritised:

    - An effective treatment option that eliminates the need for genotyping;
    - Utilising current investments in diagnostic capacity to expand the platform for viral hepatitis (PEPFAR, Global Fund);
    - A pipeline review of diagnostic development;
    - New hepatitis B and C diagnostics;
    - A strengthened or new product development partnership for hepatitis B and C diagnostics (for example FIND).

12. **Make HBV and HCV treatments affordable.** Numerous approaches can assist in this effort: voluntary generic licensing; tiered pricing; government and regional negotiation; patent pooling; global demand forecasting; volumes-based procurement; patent oppositions; compulsory licensing; market competition; local manufacturing; reduced tariffs on medicines; regulatory harmonisation; and streamlined approval processes (i.e., WHO pre-qualification and FDA tentative approval).

13. **Establish timely international and national clinical guidelines.** Agencies must keep pace with therapeutic and diagnostic innovations when developing screening, care and treatment guidelines.

14. **Create a base of reliable epidemiological data.** Research on hepatitis co-infection and mono-infection at global, national and regional levels is desperately needed. For HCV, this means more data on modes of transmission, and for HBV, more data on mother-to-child transmission.

15. **Strengthen global, regional and country advocacy.** Compared to HIV, current viral hepatitis advocacy is underdeveloped and underfunded. The advocacy community should be supported to focus efforts on HBV and HCV with a long-term target of elimination; launch and scale up treatment and prevention

programmes, including harm reduction initiatives; and engage health and finance ministries, as well as donor organisations, on funding issues.

16. **Increase awareness among patients, physicians and policymakers.** Particularly at the country-level, political support has been an essential component of the limited successful viral hepatitis programmes to date (e.g., Egypt). Participants stressed the need to place viral hepatitis on the political agenda, citing the media and internet-based patient awareness programmes, such as those in China, as effective tactics.

17. **Initiate local pilot projects.** Participants generally agreed that the community of clinicians, policymakers, advocates and private companies should launch local demonstration projects in co-infected populations to provide proofs of concept that are needed to stimulate governments, NGOs and international agencies to take on larger-scale projects.

18. **End stigma associated with at-risk populations, particularly people who inject drugs (PWID).** For example, while Indonesia has a viral hepatitis programme included in the country's universal health coverage plan, PWID and those who use alcohol are excluded from coverage.

19. **Address drug resistance.** Particularly for HBV treatments and in light of the potential impact resistance has on the HBV vaccine. HBV treatment options with high barriers to drug resistance are available which can treat both HIV and hepatitis B.[1]

20. **Advocate for funding at the global and national levels, for both mono- and co-infection.** In light of reduced donor contributions, the likelihood of a vertical programme (e.g., Global Fund or PEPFAR) for viral hepatitis is slim or limited to HIV co-infected populations. While many viral hepatitis programmes will be funded by national governments, this may only be a reality in middle-income countries. Several participants noted the importance of engaging with finance and defence ministries. Philanthropy and sovereign wealth funds can possibly play a role in expanding the global envelope for funding, and innovative financing mechanisms, such as social impact bonds and loans, will also be key to securing financing for viral hepatitis.

21. **Develop an investment case.** Stakeholders must clearly demonstrate the financial burden that viral hepatitis poses to society. WHO is working on the investment case for China, and the Coalition to Eradicate Viral Hepatitis in Asia Pacific (CEVHAP) is focused on defining the economic impact of HBV and HCV in the region.

22. **Link viral hepatitis efforts to broader public health efforts.** Given common modes of transmission and the link to cancer, stakeholders can incorporate viral hepatitis into non-communicable disease efforts.

23. **Identify viable paediatric treatment options.** Include children in clinical trials.

24. **Strengthen universal HBV immunization programmes.** Although there is no cure for HBV, an effective vaccine and effective treatment options are available. In high-burden countries, HBV vaccine coverage should be high, and low-cost birth dosage vaccines should be mandatory.[2]

25. **Develop country strategies and action plans.** Strategies should reflect the latest innovations and include awareness, prevention, care and treatment components. To effectively influence budget

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[1] Per new WHO guidelines, "nucleos(t)ide analogs (NAs) which have a high barrier to drug resistance (tenofovir or entecavir) are recommended in all adults, adolescents and children aged 12 years or older in whom antiviral therapy is indicated."

[2] The WHO issued the first hepatitis B guidelines, "Guidelines for the Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection," shortly after the Wilton Park meeting. The guidelines specifically recommended the following: "all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours, followed by two or three doses."

allocations and international support, strategies will require good epidemiology, economic analysis and strategic thinking by public health professionals.

26. **Keep prevention a priority.** Reducing the risk of infection in medical settings is fundamental – screening of blood and use of clean needles for injections/vaccinations should be required. Harm reduction approaches, including clean needle exchange and opioid substitution therapy, should also be adopted more widely to address infection among PWID populations.

Summary

27. This Wilton Park meeting highlighted the urgent need to address HIV co-infection with viral hepatitis in Asia and globally, and outlined the existing challenges and opportunities to overcome the epidemic. In the near term, demonstration projects that show what is feasible and cost-effective can help motivate and inform policymakers, donors and other stakeholders to build on burgeoning momentum and make co-infection a public health priority. In the long term, there is emerging agreement that eliminating viral hepatitis is a realistic goal given recent therapeutic breakthroughs and energised research and development efforts.

Robin Hart
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