Building a Community of Practice to Assist Introduction of HepB Birth Dose in African Countries –Meeting 1-March 17th- Questions and Answers

Question: Can we get the documented experiences from those countries which introduced the HepB birth dose?

Answer: This is very important and will be the topic of the next birth dose meeting in this series in April.

Question: Which is the perspective on HBV CTC or Out-of-Cold-Chain vaccines being endorsed by WHO?

Answer: We agree – CTC (controlled temperature chain) would help with access. WHO has been working to have manufacturers submit for pre-qualification of their product for CTC. We have not been successful as yet.

Question: Please can you throw some light on loss of hepatitis B immunity among those who receive childhood doses when they reach their teenage years thus predisposing them to acute infections?

Answer: Studies have shown that there is a sustained immune response in teenagers who were vaccinated with HepB vaccine as infants and young children. A booster dose is not recommended.

Question: Is there any criteria for countries to introduce HBV dose vaccine such as HBsAg prevalence in pregnant women or the general population? Is it effective to introduce HBV vaccine when the prevalence of HBsAg in pregnant women nationally is below 3%?

Answer: For elimination, the HepB birth dose is recommended by WHO for all countries, regardless of prevalence.

Question: What strategies can be used to advocate for the implementation of the HBV birth dose in a country?

Answer: Multiple stakeholders in public health, clinical medicine and the community have roles for successful implementation of HepB birth dose implementation. The World Hepatitis Alliance, represented by Dr. Danjuma Adda, will be presenting tomorrow on advocacy and community mobilization activities related to HepB birth dose and PMTCT. This will be a good start to this conversation.

Question: We hear from many families in Africa that are asked to pay for the birth dose and cannot afford it. Does anyone know the status of GAVI re-implementing their program to provide free birth dose to countries? Is that still happening?

Answer: In Africa, universal HepB birth dose vaccination is most successful when parents do not have to pay for vaccination. Gavi is presenting tomorrow on an update to their plans. There will be time for discussion after their remarks.

Comments: Thank you for re-echoing this issue of out-of-pocket cost by mothers. In fact, I have witnessed this especially by mothers who are chronic hepatitis B carriers. One mechanism would be advocacy through NITAGS - this will be discussed further in Session 3 that is planned for the spring.

Question: How can we learn more about the methods used to collect the birth dose coverage of these countries. Is it self-reported? External audit?

Answer: The data that both Dr. Desai and Dr. Kabore shared was from the Joint Reporting Form (JRF) - https://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/ Birth dose data are collected and reported by the immunization programme. However, data is not disaggregated by hospital but by district.

Question: What is the level of population acceptability of this vaccine where it is already instituted in Africa?

Answer: There is good acceptability of the birth dose vaccination as showed by the coverage of doses in countries delivering the vaccine routinely.

Question: I would like to understand the data on prevalence of Hepatitis on children below 5 years is based on studies conducted in those countries or what were the data sources?

Answer: These data often come from health models which are limited by the lack of good primary data. Hepatitis surveillance and serosurvey data are needed for precise estimates. Some African countries have these data and others are seeking capacity to collect these data.

Comments: It is very important to link the HBV birth dose to the triple elimination in our advocacies and discussions. Elimination goals help bring key stakeholders to the table, especially in countries with high HIV prevalence. Integration is cost effective and hepatitis services can move hand in hand with the existing structures.

Question: There is resistance for the introduction of birth dose in some African countries due to lack of scientific evidence. What can we do to ensure that the NITAG appreciates the birth dose?

Answer: CGHE will develop a tool kit to inform the NITAG process.

Question: I may have missed it but did you mention the use of Uniject to facilitate the use of vaccine outside of cold chain and access? Is this being explored? I'm aware of its use with other vaccines but not HepB.

Answer: Uniject has been used for HBV vaccination in Indonesia and less frequently elsewhere. Cost is an issue. Uniject HBV has been used successfully by midwives in Indonesia and Vietnam. The use of Uniject was impactful in increasing coverage in areas that lacked cold chain or for home births in Asia. However, the cost is much higher than regular monovalent vaccine. Countries might not be able to fund this on their own. Papua New Guinea was the latest example where despite its success, they were not able to scale up due to high cost.

Question: What does HepB 0 mean?

Answer: The birth dose of HepB vaccine.

Question: Has there been any research (modelling?) done that looks at how leveraging anti-viral therapy in pregnant women (in addition to the regular HBV vaccination series for infants) would affect HBV-related outcomes in infants? It seems like most of the research and modelling work evaluates the HBV PMTCT interventions layered on top of each other (ex: HepB BD + HBIG + Anti-viral therapy during pregnancy), and curious about whether there's a research gap here? There are countries in the SSA region who have not introduced Hep B BD (yet) that do have strong HIV PMTCT programs and might be able to introduce HBV testing and anti-viral prophylaxis upon the backbone of their HIV PMTCT programs.

Answer: There is a need for primary data on this. CDAF has been doing this kind of modelling. There are results in the Polaris Observatory. There will be a modeling presentation to kick off tomorrow from Imperial College (Dr. Shevanthi Nayagam).

Question: What is the range of percentage of HBeAg positivity in pregnant women in the African region?

Answer: The data we have now are based on small studies. We need large studies in various countries/areas of Africa to come up with good estimates. Based on a survey in Sierra Leone, the HBeAg prevalence was around 10% with very high HBV DNA viral load in these mothers.

Comment: In South Africa, we have seen increased HBeAg positivity in HIV positive pregnant women with much higher HBV viral loads. We need to reduce cost of HBV DNA monitoring - most primary health can do HIV viral load and have the infrastructure but cost is a limiting factor.

Comment: HIV viral load monitoring can be adapted to monitor HBV viral load. Access to monitoring HBV viral load may be more accessible than monitoring of HBeAg in the African Region. In a study in the Congo, 11% of women had a high viral load.

Question: When does the birth dose become cost-effective?

Answer: We have only looked at the birth dose followed by a complete HepB vaccine series. I'm not sure why we need to look at cost-effectiveness when universal birth dose is a WHO recommendation and the birth dose also protects against early horizontal transmission. There are ethical concerns with dropping birth dose and only focusing on screening and direct vaccination–based interventions only to infants born to HBeAg-positive mothers. With gaps in maternal HBV testing, this approach can result in infants born to HBV infected mothers who are HBeAg- as well as those who are HBeAg+.

Question: How was civil society involved in these activities and how can we get them involved?

Answer: Civil society is important and we hope that we can get them involved in more prevention activities. There is more work to be done on engaging civil society.

Question: Do you think we should start with a birth dose in birthing facilities and then move to home deliveries? How should we approach the scale-up?

Answer: In most of Asia, high birth dose coverage has been achieved by high rates of institutional births which also improves infant survival rates and it is less costly to implement a birth dose in institutions. Maybe the same needs to be done in the African Region.

Question: Home births are highest in the African Region. You mentioned micro-needle products for the birth dose. Are there any updates around this strategy?

Answer: The experiments on this are still ongoing and the mice experiments were promising. Hopefully, there will be results soon.

Question: There has been a lot in the chat about testing for HBV viral load. Is cost still an issue and has the scale up of COVID-19 testing brought more testing capacity to the region?

Answer: The integration with the HIV maternal testing programme could be used to test for HBV viral load. Cost is definitely an issue. If we scale-up, the volume will help lower the cost. Another issue is movement of the sample to the testing facility. Technology needs to be evaluated and updated. We should integrate with the HIV testing programme.

Answer: Cost is an issue and we had to use donated test kits to do the testing for our study and there were logistical issues. A lot of the women were lost to follow-up because of the time lag in getting the test results.

Answer: I don't think there should be a one size fits all approach. In some areas, testing may be feasible, but in villages, this may not be realistic. We have evaluated the reliability of the rapid diagnostic test and found that they were not as reliable as other laboratory tests. We need to improve the sensitivity of rapid diagnostic tests.

Comment: Agree- while we might have the same platforms for HIV, but the costs of specific test assays are too high. We need to advocate for better pricing of HBV VL and definitely to scale up POC diagnostics for other markers!

Comment: In regards to the costs of HBV DNA VL, the global pricing agreements for HIV and HCV viral load testing (referenced in CHAI's HCV Market Intel Report 2020) also apply to HBV and global ceiling pricing is trending toward highly-inclusive agreements, supporting more pricing visibility. As the panelist have flagged though, this global pricing has not always translated into lower pricing in countries (due to lower volume / fragmented procurement, marks-up, low visibility on the pricing components etc.). I agree that removing barriers to integrated testing across diseases can have multiple advantages for all programs, including helping lower pricing (for example: centralized, pooled acquisition integrated across diseases can streamline diagnostic procurement and leverage larger testing volumes to enables competitive contract negotiation). Report on HCV with reference to VL testing prices: https://www.globalhep.org/sites/default/files/content/resource/files/2020-05/Hepatitis-C-Market-Report_Issue-1_Web.pdf

Question: As shown in the study in DRC, there is lost to follow up in 11%? That is adding a challenge to targeted birth dose.

Answer: Yes, many women were lost-to-follow-up between enrollment and delivery, thus making the targeted approach more difficult and a universal approach more effective.