Global compliance with Hepatitis B vaccine birth dose and factors related to timely schedule.

A review

1. Summary

A systematic review of published studies was conducted to identify experiences on birth introduction. So far, 54 studies have been analysed, most of them from the WHO Western Pacific Region. For the WHO Eastern Mediterranean and Western Pacific Region it was possible to obtain national data for most of the countries included in the region.

Coverage is high in China, the country which contribute to more than 30% of HBsAg carriers globally, but is lower in other high endemic countries from Western Pacific Region. Being born outside of a health facility and weakness of outreach vaccination service seems to be the most important factors related to underperformance of birth dose delivery.

In India, which is the second country with more chronic carriers in the world, health services weaknesses seems to be related to underperformance of birth dose delivery.

In developed countries, where the main objective is early detection of HBsAg + mothers and providing adequate management for the offspring, studies showed good coverage but still under 90% for most of them. Poverty and migration status seems to be major risk factors for a lower likelihood to get protected against perinatal transmission in those countries.

New ways to deliver hepatitis B vaccines to neonates being born at home should be envisaged if the goal of eliminating perinatal transmission of hepatitis B is to be achieved.

2. Introduction

Chronic infection by hepatitis B virus (HBV) is one of the leading risk for development of chronic liver diseases. Currently it is estimated that there are about 250 million of persons chronically infected with the virus around the globe (Schweitzer A, 2015). Most of the chronic carriers are concentrated in the Western Pacific Region with China alone contributing with more than 30% of them. (Schweitzer A, 2015) (Chen, 2010) (Wiesen E, 2016)

Vaccination is the single most important intervention against hepatitis B infection and, given that the higher risk of chronic liver diseases occurs when people get infected at birth, a birth dose is the most effective tool to decrease, on the long term, the amount of chronic carriers (WHO, 2010). This is especially important in China and other Asian countries, where perinatal transmission explains most cases of chronic carriage of HBV. (WHO, 2009)

Birth dose is defined by WHO as a dose of monovalent vaccine delivered within the first 24 hours after birth. It has been recommended to be added to the EPI schedule since 2009 at least. Many countries, especially in the Western Pacific area and the American and the Caribbean (LAC), have already incorporated birth dose as part of the routine EPI schedule (Hennessey K, 2013) (Allison R,

2016) (Ropero A, 2005). Still there are areas of high endemicity where few efforts have been done to introduce birth dose as in Africa region (AFRO) (Andersson M, 2015).

There have been few efforts on evaluate how countries have managed to introduce HBV vaccine birth dose and the magnitude of the coverage reached after introduction. Some efforts have been done at country level or at regional level but there is no published analysis on how HBV birth dose implementation has unfolded globally (Hennessey K, 2013) (Allison R, 2016) (Miyahara R, 2016). One of the potential benefits of assessing globally the experience of birth dose introduction is to strength the will in other countries that have not introduced it so far. Also, it would be important to identify which factors are impairing the adequate implementation of birth dose in order to recommend measure that may overcome barriers to reach a better coverage.

In order to address this issue, WHO has funded a systematic review of published studies assessing HBV birth dose coverage and factors favouring or impairing access of newborns to this intervention. The purpose of this is to provide SAGE with evidence for strengthening the recommendations to complete the introduction of birth dose around the world.

3. Primary Questions:

SAGE may consider the following questions:

1. How much has birth dose implementation advanced in the WHO regions?

2. Which factors have been identified as barriers for the good performance of birth dose introduction?

4. Methods

A search of literature was undertaken using the following Mesh terms:

Vaccination.

Mass vaccination.

Hepatitis B.

Hepatitis B virus.

Hepatitis B surface antigen.

The following non Mesh terms were also included in the search:

Hepatitis B vaccine birth dose.

Hepatitis B birth dose.

The data bases consulted included: Pubmed, Embase, Science Direct, and BIREME.

They were combined in different ways using the Boolean connector AND/OR and a list of titles of articles was elaborated and they were screened to select those which should be looked for abstract review. In a second step, abstracts were reviewed and a list of articles to be search for full text was prepared. After accessing the full text some other articles were excluded. The articles remaining on the list were read in full and data abstracted.

Inclusion criteria: We included articles depicting results from observational studies designed to assess the coverage of birth dose and/or factors related to birth dose compliance. Surveys or qualitative studies on parent´s or health workers´perceptions about hepatitis B vaccine birth dose were also included.

Articles complying with those criteria and written in English, Spanish, Portuguese, or French were included.

Exclusion criteria: articles with the following characteristics were excluded:

Articles evaluating seroprotection,

Articles on clinical efficacy (clinical trials) of the birth dose

Articles showing the efficacy of subsequent hepatitis B doses.

Articles which do not bear original results such as review articles or opinion/editorial articles. Some review articles were kept in the list to be consulted lately for obtaining more references or to be referenced in the discussion of results.

Articles reporting birth dose in the framework of experimental studies designed to increase the proportion of timely birth dose.

Articles written in languages other than those mentioned above.

Two persons conducted all phases of the literature search. They selected, independently, those articles that should be read in full and then selected together those which should be picked for data extraction.

An Excel data base was built to store the variables abstracted from the selected articles. The following variables were collected: first author last name, publication year, years when study was conducted, country where the study was conducted, type of study, whether barriers were evaluated, and list of barriers mentioned.

Proportion of birth dose coverage was presented by WHO region and country. A list of factors related to compliance with hepatitis B birth dose was also presented by WHO region and country.

5. Results

An initial list of 6,789 articles were generated by the combination of search terms. After reviewing titles they were reduced to 134 and finally 52 were included in the analysis. The region with more references was Western Pacific while AFRO had the lowest. Most studies have data on coverage only but some have reasons for no vaccination also.

There were studies aimed to evaluate birth dose coverage in general population and in high risk population. High risk population were defined as children born from mothers carrying HBsAg (HBSAg +). Most studies on high risk population were conducted in developed countries while most community based studies were carried out in the developing world especially in the region of Western Pacific.

5.1 Birth dose coverage in Western Pacific

Western Pacific region is the area with more information on the advances of the implementation of birth dose. Many countries, including China, have reached high coverage with birth dose. In China, there are probably areas with less than 95% of birth dose coverage, the official estimate, as suggested by data from several of the community based studies. Table 1

Table 1. Birth dose coverage from published studies from China

Author	Year published	Study setting	Population studied	Coverage	
Cui	2006	Community	General	76%	
Zhou	2009	Community	General	32%	
Cui	2010	Community	General	74%	
Hu	2012	Community	high risk	85%	
Cui	2013	Hospital	General	98%	
Cui	2013	Community	General	74%	
Hennessey	2013	Oficial data	General	95%	
Huang	2013	Hospital	high risk	96%	
Kang	2014	Hospital	high risk	98%	

*__Study setting__ means source where information on coverage was obtained from. Community generally refer to data obtained from community surveys, Hospital refers to data obtained from hospital records, and official data is generally obtained from routine EPI data collected at different levels of a particular country.

Several major countries in the Western Pacific region have high coverage with birth dose: Malaysia, Mongolia, and Korea. Others are struggling with very low levels of birth dose coverage: Laos, Cambodia, Philippines and Vietnam.

Table 2. Birth dose coverage from published studies among other large countries from WHO Western Pacific Region

Author	Year published	Country	Study setting	Population studied	Coverage	Observaciones
Hennessey	2013	Cambodia	Official data	General	68%	data from 2011
Mao	2013	Cambodia	Community	General	55%	
Keuatvongsa	2013	Laos	Hospital	General	74%	
Hennessey	2013	Laos PDR	Official data	General	20%	data from 2009
Hennessey	2013	Malaysia	Oficial data	General	95%	data from 2011
Hennessey	2013	Mongolia	Oficial data	General	96%	data from 2011
Sobel	2011	Philippines	Hospital	General	22%	
Hennessey	2013	Philippines	Official data	General	40%	data from 2011
Patel	2014	Philippines	Community	General	40%	
Patel	2014	Philippines	Hospital	General	86%	
Hennessey	2013	Rep. Korea	Oficial data	General	95%	data from 2010
Hennessey	2013	Vietnam	Official data	General	55%	data from 2011
Nguyen	2014	Vietnam	Community	General	30%	2007-2008
Nguyen	2014	Vietnam	Community	General	53%	2004-2006
Nguyen	2014	Vietnam	Community	General	22%	2000-2003

*__Study setting__ means source where information on coverage was obtained from. Community generally refer to data obtained from community surveys, Hospital refers to data obtained from hospital records, and official data is generally obtained from routine EPI data collected at different levels of a particular country.

Many small islands and territories (Brunei, Samoa, Cook, Polynesia, Hong Kong, Macao, Guam, Nauru, Niue, New Caledonia, Marianas Islands, Singapore, Palau, Tokelau, and Tonga) have reached a coverage of 90% or more, but there are others with coverage as lower as under 80% (Fiji, Kiribati, New Guinea, Solomon, and Vanuatu). Table 3.

Table 3. Birth dose coverage in small territories of Western Pacific Region

Author	Year published	Country	Study setting	Population studied	Coverage
Hennessey	2013	Am Samoa	Official data	General	100%
Hennessey	2013	Brunei	Official data	General	95%
Hennessey	2013	Cook Islands	Official data	General	97%
Patel	2016	Cook Islands	Community	General	95%
Wilson	2000	Fiji	Community	General	22%
Hennessey	2013	Fiji	Official data	General	61%
Hennessey	2013	French Polynesia	Official data	General	100%
Hennessey	2013	Guam	Official data	General	100%
Hennessey	2013	Hong Kong	Official data	General	95%
Wilson	2000	Kiribati	Community	General	35%
Hennessey	2013	Kiribati	Official data	General	66%
Hennessey	2013	Macao	Official data	General	100%
Hennessey	2013	Marshall Is	Official data	General	74%
Hennessey	2013	Micronesia	Official data	General	81%
Hennessey	2013	New Caledonia	Official data	General	99%

Hennessey	2013	N Mariana Is	Official data	General	100%
Hennessey	2013	Nauru	Official data	General	100%
Berlioz Arthaud	2003	New Caledonia	Community	General	8%
Hennessey	2013	New Guinea	Official data	General	31%
Wiesen	2016	New Guinea	Hospital	General	31%
Hennessey	2013	Niue	Official data	General	100%
Hennessey	2013	Palau	Official data	General	100%
Hennessey	2013	Samoa	Official data	General	100%
Hennessey	2013	Singapore	Official data	General	99%
Hennessey	2013	Solomon Is	Official data	General	75%
Hennessey	2013	Tokelau	Official data	General	100%
Patel	2016	Tokelau	Community	General	77%
Wilson	2000	Tonga	Community	General	90%
Danielsson	2009	Tonga	Hospital	General	92%
Hennessey	2013	Tonga	Official data	General	100%
Hennessey	2013	Tuvalu	Official data	General	98%
Wilson	2000	Vanuatu	Community	General	60%
Hennessey	2013	Vanuatu	Official data	General	73%
Hennessey	2013	Wallis Futuna	Official data	General	100%

*__Study setting__ means source where information on coverage was obtained from. Community generally refer to data obtained from community surveys, Hospital refers to data obtained from hospital records, and official data is generally obtained from routine EPI data collected at different levels of a particular country.

5.1.1 Barriers for hepatitis B birth dose in Western Pacific Region

The most frequent factor associated to low birth dose coverage mentioned in the studies, both hospital-based and community-based, was being born at home. It was found in 4 studies conducted in different countries. It was followed by false contraindications for administering the birth dose, and by other aspects related to health workers training. Quality of outreach services was also found in three studies (community and hospital base), and lack of vaccine was mentioned in two hospital based studies.

One of the few low endemicity countries in the region, Australia, also conducted one study on factors related to delivery of a timely birth dose in high risks children. The only factor they found related to delays in birth dose was birth not being attended by a specialist, a factor that is a bit different from those in less developed, high endemic, countries of the region.

Table 4. Barriers for timely hepatitis B birth dose in Western Pacific Region Community based studies

Author	Year published	Country	Study setting	Population studied	Reasons 1	Reasons 2	Reasons 3	Reason 4	Reason 5
Mao	2013	Cambodia	Community	General	Maternal education	Birth at home			
Cui	2006	China	Community	General	Birth at home				
Zhou	2009	China	Community	General	Birth at home	Parent awareness on HBV	Ethnic minority	Parents concern on adverse effect	
Patel	2014	Philippines	Community	General	Birth at home				
Murakami	2008	Vietnam	Community	General	Vaccine storage	Pregnancy tracking performance	Conflicting guidelines at hospitals	Private maternity services	Low birth weight
Murakami	2014	Vietnam	Community	General	Media report on adverse effects				

Table 5. Barriers for timely hepatitis B birth dose in Western Pacific Region. Hospital based studies

Author	Year published	Country	Population studied	Reasons 1	Reasons 2	Reasons 3	Reason 4	Reason 5	Reason 6
Sahhar	2015	Australia	high risk	Care by obstetritian					
Kang	2014	China	high risk	Low birth weight	Prematurity				
Keuatvongsa	2013	Laos	General	Vaccine outage	False contraindications	Health workers training	Limited outreach services		
Wiesen	2016	New Guinea	General	Health workers training/ supervision	Quality of outreach services	HB vacc available in facility	Vaccination in weekends	Birth at home	Mother knowledge of HBV
Patel	2014	Philippines	General	Out of pocket Cost	False contraindications	HW training	Vaccine availability	Private providers	Birth at home
Sobel	2011	Philippines	General	Trained staff	Standing order for HB admon	Copy of HB vacc policy in health facility			

5.2 Birth dose coverage in AFRO Region

Four studies from AFRO region were found and only one of them was conducted using a community survey. Coverage with birth dose was high in Comoros and Mayotte, small islands, but almost inexistent in Gambia and Nigeria. Interestingly, a retrospective assessment of hospital records in Mayotte showed a high coverage for children born from HBsAg+ mothers. Around 60% of HBsAg+ mothers were also HBeAg+.

Table 6. Birth dose coverage found in studies from AFRO region

Author	Year published	Country	Study setting	Population studied	Coverage
Muszlak	2007	French Comoros	Hospital	General	94%
Sadoh	2008	Nigeria	Hospital	General	1%
Chakvetadze	2011	Mayotte	Hospital	high risk	83%
Miyahara	2016	Gambia	Community	General	1%

*__Study setting__ means source where information on coverage was obtained from. Community generally refer to data obtained from community surveys, Hospital refers to data obtained from hospital records, and official data is generally obtained from routine EPI data collected at different levels of a particular country.

5.2.1 Barriers for hepatitis B birth dose in AFRO Region

Social and demographic factors related to timely birth dose in The Gambia are described by Miyahara for The Gambia. Living in rural areas was the most important risk factor for no receiving a birth dose (OR=6,1 CI 3.2-11.8). (Miyahara R, 2016).

5.3 Birth dose coverage in AMRO Region

Most observations came from a low endemic country, United States of America. There are differences between studies done on high risk population or general populations. Timely birth dose tend to be higher in high risk populations than in general populations. Coverage is lower in community based studies. Zhao 2011 presented birth dose coverage obtained from national surveys and it is even lower though sit seems to have increased in the last years analysed.

Table 7. Birth dose coverage found in studies from AMRO region

Author	Year published	Country	Study setting	Population studied	Coverage	Observaciones
Luna	2009	Brazil	Community	General	40%	
Dayan	2007	Puerto Rico	Hospital	high risk	1%	
Thomas	2004	USA	Hospital	high risk	80%	
Bascom	2005	USA	Hospital	General	76%	
Zhao	2011	USA	Community	General	62%	2007
Zhao	2011	USA	Community	General	58%	2006
Zhao	2011	USA	Community	General	51%	2005
Zhao	2011	USA	Community	General	51%	2004
Zhao	2011	USA	Community	General	50%	2003
Zhao	2011	USA	Community	General	49%	2002
Zhao	2011	USA	Community	General	44%	2001
Zhao	2011	USA	Community	General	34%	2000
Zhao	2011	USA	Community	General	33%	1999
Zhao	2011	USA	Community	General	56%	1998
Sainato	2013	USA	Hospital	high risk	100%	
Myers	2015	USA	Hospital	General	92%	

5.3.1 Barriers for hepatitis B birth dose in Western Pacific Region

Most studies on barriers have been conducted among hospital users and describe mostly the obstacles for delivering a birth dose within the hospital. Several studies described how coverage of birth dose was pulled down by a normative on thimerosal. Cost of the vaccine or administrative issues with reimbursement of costs by insurers was also a deterrent of birth dose. Socio economic factors of neonate's family was also related to low probability of receiving a timely birth dose.

Table 8. Barriers for hepatitis B birth dose in AMRO Region

Author	Year published	Country	Study setting	Population studied	Reasons 1	Reasons 2	Reasons 3	Reason 4	Reason 5
Bascom	2007	Puerto Rico	Hospital	General	Month of delivery	Birth weight			
Dayan	2001	USA	Hospital	high risk	Mother age	Hospital	Being less educated	Being single	
Aiken	2001	USA	Hospital	Managers	Reimbursement	Outreach inconvenience			
Thomas	2002	USA	Hospital	high risk	Thimerosal				
Cabana	2002	USA	Hospital	Managers	Thimerosal				
Clark	2004	USA	Hospital	Managers	Thimerosal				
Cooper	2005	USA	Hospital	HW	Tracking hospital immunizations	High cost	reimbursing	parents unwilling	Safety concerns
Zhao	2011	USA	Community	General	2 or + providers	Public/private provider	Mother Married status	Mother education	
Myers	2015	USA	Hospital	General	Marital status	Race			

5.4 Birth dose coverage in EURO Region

All coverage data from EURO came from high risk population and nearly all from hospital based studies. Most studies were conducted before 2010 and it should be noted that some of them do not show good performance of the screening and management of HBsAg + mothers.

Table 9. Birth dose coverage found in studies from EURO region

Author	Year published	Country	Study setting	Population studied	Coverage
Adamo	1998	Italy	Hospital	high risk	55%
Stroffolini	2003	Italy	Hospital	high risk	95%
Van Steerbengen	2002	Netherlands	Hospital	high risk	73%
Feiring	2016	Norway	Official data	high risk	90%
Rhiner	2007	Switzerland	Hospital	high risk	83%
Polat	2011	Turkey	Hospital	high risk	99%
Wallis	1999	UK	Hospital	high risk	88%
Sloan	2005	UK	Hospital	high risk	92%
Giraudon	2009	UK	Hospital	high risk	81%
Manikkavasagan	2009	UK	Hospital	high risk	95%

5.4.1 Barriers for hepatitis B birth dose in EURO Region

There were only studies from UK looking for factors associated to delays for birth dose. All were conducted among high risk populations at hospital levels. Difficulties in the screening process, migratory status and poverty seems to be the most important individual factors related to low likelihood of timely hepatitis B vaccine birth dose.

Table 10. Barriers for hepatitis B birth dose in EURO Region

Author	Year published	Country	Study setting	Population studied	Reasons 1	Reasons 2	Reasons 3
Sloan	2005	UK	Hospital	high risk	Year of birth	antenatal booking	Maternal serological status
Giraudon	2009	UK	Hospital	high risk	London sector of residence	Command of english	

5.5. Birth dose coverage in Eastern Mediterranean Region

Birth dose coverage in Eastern Mediterranean region is low in several major countries like Morocco,, Syria, Iraq, and Tunicia. Political turmoil is likely related to underperformance of the health services services including vaccination.

No specific study for barriers impairing hepatitis B birth dose delivery was found in this region.

Table 11. Birth dose coverage found in studies from Eastern Mediterranean region.

Author	Year published	Country	Study setting	Population studied	Coverage
Allison	2016	Djibouti	Community	General	94%
Allison	2016	Iran	Community	General	97%
Allison	2016	Iraq	Community	General	43%
Allison	2016	Kuwait	Community	General	96%
Allison	2016	Lebanon	Community	General	94%
Allison	2016	Lybia	Community	General	99%
Allison	2016	Morocco	Community	General	14%
Allison	2016	Oman	Community	General	99%
Allison	2016	Palestine	Community	General	97%
Allison	2016	Qatar	Community	General	92%
Allison	2016	Saudi Arabia	Community	General	98%
Allison	2016	Siria	Community	General	78%
Allison	2016	Tunicia	Community	General	80%
Allison	2016	United Arab Emirates	Community	General	91%
Allison	2016	Eastern Mediterranean	Community	General	24%

5.6 Birth dose coverage in South East Asia Region

Only India and Indonesia had data on birth dose coverage which seems to be low for both countries. Coverage for high risk population is higher in one study but still under 90%.

Table 12. Birth dose coverage found in studies from South East Asia region .

Author	Year published	Country	Study setting	Population studied	Coverage
Creati	2007	Indonesia	Community	General	23%
Alexander	2013	India	Hospital	high risk	85%
Lahariya	2013	India	Community	General	10%

5.6.1 Barriers for hepatitis B birth dose in South East Asia Region.

Policy and health services shortcomings seems to be important factor related to low birth dose coverage in India and Indonesia.

Table 13. Barriers for hepatitis B birth dose in South East Asia Region.

Author	Year publish	Country	Study setting	Population studied	Reasons 1	Reason 2	Reason 3	Reason 4	Reason 5
Alexander	2013	India	Hospital	high risk	Birth outside				
Lahariya	2013	India	Community	General	Fear of vaccine wastage	HW poor knowledge			
Creati	2007	Indonesia	Community	General	policy weakness	limited transport	poor communication	cold chain	HW training

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Barriers to implement the Hepatitis B vaccine birth dose.

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The World Health Organization (WHO) recommends that "all infants should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours" (*1*), even in countries where *Hepatitis B virus* (HBV) is of low endemicity.

As a leading cause of liver cancer and liver disease, HBV infection is an important threat to global health. Globally, over two billion people are estimated to be living with the virus, while around 360 million are chronically infected and at risk of developing life-threatening liver diseases. Many infections are acquired early in life; perinatally, or horizontally during early childhood, particularly in regions of high endemicity where these routes are the most common modes of HBV transmission (1). This has important implications for disease prevention and control as the likelihood of developing chronic infection is higher at younger ages: 90% if infected at birth; 25%–50% if infected between the ages of one to five years, and 5%–10% if infected over the age of five years (2, 3).

Since perinatal or early postnatal transmission is an important cause of chronic infections globally, the first dose of hepatitis B vaccine should be given as soon as possible (<24 hours) after birth even in low-endemicity countries. (1)

Ensuring that all infants receive a dose of hepatitis B vaccine within 24 hours of birth requires implementation of specific programmatic measures. Increasing the number of infants born in facilities or attended by trained health staff would improve birth dose coverage. Ensuring that there is coordination between immunization services and maternal health services is important so that vaccine is available at the place of delivery or immediately after birth. Expanding vaccine management systems and innovative outreach to provide vaccine for home births (4) will ensure that hepatitis vaccine is available in settings where births take place. Efforts to develop new heat-stable and freeze-stable hepatitis B vaccine will aid these attempts. In addition, health promotion efforts aimed at parents and training aimed at

providers are needed to increase awareness about the importance of administering hepatitis B vaccine within 24 hours of birth.(5).

Methods

We contacted the African Regional Office and the South-East Regional Office to enquiry about the countries recommendations on the introduction of the Hepatitis B vaccine birth dose. We asked the regional offices to provide the answers in consultation with the countries to the following questions:

1. Have the NITAG's recommended the introduction of the hepatitis b vaccine birth dose

2. What are the main barriers to the introduction of the birth dose?

3. What are the recommendations to overcome these barriers?

Results

African Regional Office

Table 1: Schedules currently used in AFRO

Type of vaccine	birth	1p	2p	3p	booster	Number of countries
DTaPHibHepIPV		6 w	10 w	14 w	18 months	1
DTwPhibHepB		2 m	3 m	4 m		2
DTwPhibHepB		2 m	4 m	6 m		1
DTwPhibHepB		2 m	4 m	6 m	18 months	1
DTwPhibHepB		3 m	4 m	5 m		1
DTwPhibHepB		6 w	10 w	14 w		37
DTwPhibHepB		8 w	12 w	16 w		2
Hep B_Pediatrics		6 w	10 w	14 w		1
Hep B_Pediatrics	0					2
Hep B		1st contact	+1m	+2 m		1
Hep B		6w	10w	14w		2
Hep B	0	1m	5m			1
Hep B	0					6

Source: http://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/

According to the information provided by the AFRO region, 10 of 47 countries have introduced the hepatitis b birth dose in their immunization schedule.

Among the nine countries that provided HepB-BD in their vaccination schedule in 2015, coverage was <80% in three (Angola at 19%, Mauritania at 51% and Nigeria at 43%), between 80-95% in four (Botswana and Namibia at 87%, Cap Vert at 93% and Sao Tome at 91%), and >95% in two (Algeria and The Gambia).

In Sierra Leone, the EPI Technical Committee (TCC) has recommended the introduction of Hepatitis b birth dose for 2018. Niger is planning to introduce the birth dose in 2019.

In Mauritius the hepatitis b birth dose is given to babies whose mothers are HBV infected.

Of the remaining 37 countries, 36 confirmed that they have not introduced the hepatitis b birth dose and no information was provided on the other one. However, this country have reported no coverage of the hepatitis b birth dose to the WHO and UNICEF Estimates of National Immunization Coverage as of July 2015; therefore we consider it as not having introduced the birth dose.

Among the 37 countries that have not yet introduced the birth dose, 10 had an established NITAG and three had recommended the birth dose introduction into the national schedules. One country, Cameroon is pending approval of the 2017 budget to purchase the birth dose.

Figure 1:

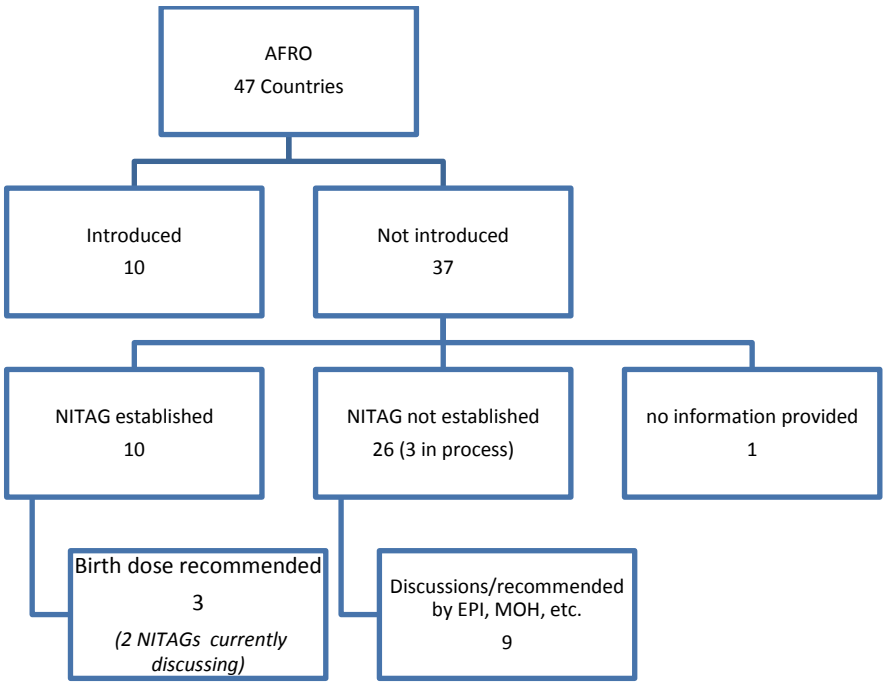

Table 2: Barriers to introduce the birth dose in the AFRO region

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Bénin	Sujet encore à l'étude par le CNCV Benin.	Contrainte de temps, le groupe allait se réunir par rapport à la question sur l'hépatite quand il lui a été demandé de donner son avis sur l'introduction du RR vu que la soumission GAVI est très imminente	Le groupe analysera la question juste après l'étude du RR à mi-août 2016.
Burkina Faso	L'Hépatite B à la naissance n'est pas encore à jour dans le calendrier vaccinal au Burkina-Faso.	La question n'a pas encore été discutée. Cette question sera soumise au CCIA pour décision.	Après approbation du CCIA nous prendrons des mesures idoines pour son introduction après une étude de faisabilité.
Burundi	le GCTV pas encore fonctionnel. La proposition a été introduit au cabinet du Ministre.	Le cabient du Ministre de la santé n'a pas encore répondu à la question du PEV.	Poursuivre le plaidoyer pour acceler la réponse du cabinet.

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Cameroon	Yes	Purchase of the vaccine that is registered in the country in 2017 budget pending waiting validation by the National Assembly in December 2016. Operating costs for this introduction.	The country is seeking financial and technical support from other partners other than Gavi
Central African Republic	GCTV not yet established in the country.	Not planned because of the Menafrivac introduction.	Provided for next cMYP.
Chad	NITAG not yet established	Question of the introduction of the birth dose not yet studied at the instance level (EPI and ICC)	Advocacy at the ICC, and forecast its introduction into next cMYP 2018-2022
Comoros	NITAG not yet established	New vaccine introduction is decided through the ICC but the Hep B Birth Dose has not been discussed for now. However it should not be a problem for us to introduce it if necessary.	
Congo (the)	Le GCTV n'est pas encore mise en place, mais il y' a une initiative de la société des gastro-enteologues du Congo qui en fait une priorité. Le PEV aurait déjà passé la commande pour quelques doses du vaccin contre l'hépatite B pour les enfants à la naissance	Les barrières pour son introduction effective restenet liées à la mise en place du GCTV et à la sensiblisation des autorités	Accélerer la mise en place du NITAG et le rendre fonctionnel afin B10 puisse aider au plaidoyer à des autorités; Mener un plaidoyer à l'endroit des hautes autorités
Cote d'Ivoire	Oui. Le CNEIV-CI a recommandé l'introduction d'une dose supplémentaire du vaccin contre l'Hépatite B à la naissance en 2015.	Les barrières étaient financières (non encore pris en compte dans le budget alloué au PEV) et logistique parce que cela nécessitera un flacon additionnel à stocker.	Prendre en compte cette dose supplémentaire dans le budget du PEV et augmenter la capacité de stockage par la construction de chambres froides au niveau central et régional.
Democratic Republic of Congo	GCTV pas encore fonctionnel. Nous attendons l'Arrêté du Ministre de la Santé Publique	Manque d'études qui prouvent la trsnmission périnatale	- Appuyer une étude à travers les Cliniques Universitaires - Plaidoyer pour accélérer la mise en place du NITAG

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Equatorial Guinea	GCTV pas encore établir crée dans le pays	Manque d'études qui prouvent la trasnmission périnatale	- Appuyer une étude à travers les Cliniques Universitaires - Plaidoyer pour accélérer la mise en place du NITAG
Eritrea	NITAG has not yet looked into the burden of mother to child transmission of Hepatitis B and the significance of introducing Hep B birth dose. The EPI programme manager has discussed with the director of communicable disease control program regarding the high prevalence of Hep B among blood donors and pregnant women attending ANC and agreed in principle the need to introduce Hep B birth dose. This may require further discussion and advocacy at the higher level to commit and prepare for the introduction of hep B vaccine at birth.	Concern of storage capacity and need of Government decision to finance the vaccine.	1. Advocate with the higher officials on the burden of MTCT of Hep B and the need to introduce Hep B birth dose in Eritrea. 2. To look for partners who will support the financing of the vaccine and introducing it to the routine program. 3. Procurement of additional cold chain equipment to accommodate the addition of Heb B birth dose vaccine
Ethiopia	The NITAG is newly established and not yet conducted a follow up meeting. However; introduction of birth dose of Hep B in the national RI is planned in the cMYP for 2018; though the cMYP document is pending for endorsement by higher officials.	a. Shortage of recent evidence on sero-prevalence of HepBsAg among pregnant women in local context; and also on disease prevalence	a. Disease prevalence and sero-prevalence studies need to be conducted/reviewed
		b. Though delivery by skilled birth attendant nationally is increasing (71%, HMIS 11 month report of 2008 EFY), early post-natal visit by HEWs is minimal and challenges implementation to administer the first dose of the vaccine within <24 hours.	b. Diversify funding opportunities
		c. Funding source other than government is also a challenge to sustain resources. No GAVI support.	c. Bring the agenda to the NITAG's attention

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Gabon	Le NITAG non opérationnel.	Barrière essentiellement financière.	Proposer l'introduction de la dose d'hépatite B à la naissance pour être prise en compte dans le budget de 2017.
Ghana	Plan to introduce HepB birth dose has been part of cMYP. It is part of the national Viral Hepatitis control plan.	We have just not taken up the initiative to develop the introduction process. We have postponed every year due to other activities.	It is just that the EPI team will activate the plan to develop the process. We have discussed very often and always push it forward.
Guinée	Le GCTV (NITAG) n'est pas formellement établi encore pour discuter de cette introduction. L'Hépatite B à la naissance n'est pas encore dans le calendrier vaccinal en Guinée.	• Absence de NITAG • Les politiques nationales ne permettent pas la dose de vaccin anti-hépatite B administrée à la naissance par conséquent, ne fait pas partie du calendrier vaccinal • Le vaccin n'est pas disponible dans les établissements sanitaires/ salle d'accouchement en raison de contraintes de la chaîne du froid	• L'introduction de ce vaccin dans le calendrier peut être discutée par le CCIA • Nécessité de mise en place de la CTC dans les salles d'accouchement suivie de la formation du personnel accoucheur.
Guinée Bissau	Despite the NITAG has not been created in the country, the EPI technical committee is considering to introduce Hep B birth dose.	There are no known particular barriers to the introduction of Hep B at birth, we could point out that this vaccine has not been included in the cMYP.	Include the Hep B birth dose in the cMYP
Kenya	No. KENITAG has not discussed on this subject matter	a. Has not been flagged for discussion, b. Lack evidence to support introduction	a. To commence engagement with national authorities b. Sharing of evidence from other countries on burden of Hep B c. Consider commencing assessments to determine burden among pregnant women.
Lesotho	NITAG is not yet established in the country	Confirmation of disease burden for heb B would be required as this is one of the criteria for introduction of new vaccine	
Liberia	NO	1. No NITAG yet despite repeated encouragement from WHO	1. Establish NITAG as soon as possible

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
		2. RI suffered during the Ebola outbreak and recovery effort still ongoing including introduction of new vaccines that had their introduction postponed during the EVD outbreak	2. Continue to strengthen RI activities through outreach, PIRI and RI improvement activities
		3. Proportion of births that take place in HFs is about 56% (44% are outside Health facilities and this is not likely to change soon)	
Madagascar	Madagascar does not have NITAG. The introduction of Hepatitis B will be discussed in a special meeting with participation of paediatrician. Then the decision will be will be presented to ICC members for endorsement.	The main challenge is the availability of funds to introduce Hep B birth dose and sustainability. The country is struggling to pays co financing.	To include Hep B birth dose in GAVI supported vaccines.
Malawi	No	No barriers identified	Is it to be taken as a new vaccine or underused? Will Gavi support be available if a country is interested to introduce the vaccine?
Mali	La question de l'introduction du vaccin anit hepatite n est pas élucidée pour le moment au Mali , bien que un plaidoyer avait eu lieu au Ministere de la santé à cet effet mais la question sera discutée lors d'une reunion du CCIA et le recommandations pourraient etre prises en compte lors de l' élaboration du nouveau PPAC 2017- 2021	Le problème majeur est lié au fait qu'il faut vacciner à l'accouchement. Une evaluation doit etre faite avant l'introduction afin de cerner les contours et aussi faire le plaidoyer auprès des autorités pour la pirse en chage des doses sur le budget d'Etat	

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Mauritius	No	In Mauritius Hep B Birth Dose is given only to babies whose mothers are positive. On the other hand Hep B vaccine is part of the EPI and administered at 6 weeks, 10 weeks and at 9 months. (prior to introduction of PCV it was 14 weeks)	Absence of National policy allowing Hep B birth dose administration. On the other hand, an enabling factors is that almost 100% of births occur in public and private health institutions and deliveries are attended by trained / qualified health personnel.
Mozambique	Yes.	Financial constraints.	Initial support as with other GAVI vaccines, while advocating for price reduction to allow countries to takeover, gradually.
Niger	L'introduction de la dose a la naissance est prévue en 2019 dans le PPAC 2016-2020 qui a été validé lors d'un CCIA en décembre 2015. Le NITAG n'est pas fonctionnel pour recommander une telle introduction.	Comme c'est une dose qui ne sera pas supportée par GAVI, le pays devra prévoir l'achat dans le budget de l'Etat	Faire un plaidoyer dans le pays pour que l'Etat inscrire cet achat dans le budget achat des vaccins en 2019
Rwanda	Rwanda does not have NITAG, however the introduction of hepatitis B was approved by Ministry of health officials and it will be presented to ICC members for endorsement.	The main challenge is the availability of funds to introduce Hep B birth dose and sustainability.	To include Hep B birth dose in GAVI supported vaccines.

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Seychelles	The country as not yet introduced the Hep B birth dose. Hep B is currently being administered as pentavalent (DPT-HBV-Hib) at 3, 4, 5 months of age.	The country has simply not yet considered introduction of the birth dose possibly due to the fact that it is not a priority for the country. There are no major barriers to introduction of the vaccine; the country will consider this after the introduction of PCV in 2017. BCG is currently being successfully administered at birth at the maternity ward and thus Hep B birth dose could easily be administered during the same session. Additional funding for the procurement of the vaccine will probably be the only issue.	Some advocacy will be needed.
Sierra Leone	Sierra Leone is in the process of establishing a functional NITAG. The EPI Technical coordination Committee (TCC) has recommended the introduction of Hep B Birth dose in 2018	We are still at the planning stage, and have not identified major barriers. But some challenges we anticipate may include reaching all new born children with the vaccine within 24 hours of birth. This requires personnel, cold chain and other resources that must be planned for and quantified. There is a significant percentage of women who deliver at home in the communities and reaching all of them with a birth dose has to be worked out carefully.	Recommendations include: 1. Adequate planning and quantifying the resources required. 2. Developing an introduction plan 3. Adequate briefing of the MOHS authorities on plan and implications 4. Putting in place the required cold chain for the vaccine 5. Identifying human resources to deliver the vaccine in the facilities and communities 6. Adequate training and sensitisation on the vaccine and timing of vaccination soon after birth within 24 hours 7. Monitoring the uptake of the vaccine and putting in place measures to increase coverage.

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
South Africa	Discussions have started within our National Advisory Group on Immunisation (NAGI) with supporting documents from various SA academics (attached). A sub-committee prepared a detailed report on the Hep B epidemiology in SA etc. and presented to the NAGI on 30 March 2016. The NAGI supports the introduction of the birth dose of Hep B in the SA, taking into consideration other EPI priorities. The NAGI has not yet communicated their recommendation to the MOH.	The current emphasis in SA has been programmatic strengthening to ensure that the additional antigens do not cause strain to the existing program. Many vacant national posts are therefore being filled.	These are human resource issues that the DOH is currently addressing.
South Sudan			
Swaziland	Currently NITAG has not been fully established. However, there is a committee working on Hepatitis B including Hep B birth dose introduction.	Currently the Government is procuring 100% of her routine vaccine and has not prioritized the introduction of Hepatitis B birth dose.	Advocacy to high level authorities for the introduction of Hep B birth dose.
Tanzania	There is no NITAG in Tanzania.	There has been no discussion on this.	Tanzania is in the process of establishing a NITAG and will present the issue of introducing HepB Birth Dose to this body.
Togo	Le GTCV a été créé par arrêté ministériel. Mais les membre ne sont pas encore formé. Le Nouveau PPAC prévoit l'introduction l'hépatite B à la naissance Le CCIA a été informé	• Le GTCV ne s'est pas encore prononcé sur le sujet • Le plan d'introduction n'est pas encore élaboré • Financement de l'achat des vaccins pas encore déterminé	• Former les membre du GTCV • Appuyer l'élaboration du plan d'introduction du vaccin contre l'Hépatite B à la naissance • Plaidoyer pour que l'Etat prenne en charge l'achat des vaccins

Country/**Pays**	1. Has the NITAG recommended the introduction of Hep B Birth Dose? **Est-ce que le Nitag (GCTV) a recommandé l'introduction de la dose d'Hepatite B à la naissance?**	2. What are the barriers to the introduction of Hep B Birth Dose? **Quelles sont les barrières à l'introduction de l'Hépatite B à la naissance?**	3. What are your recommendations/action points to overcome these barriers? **Quelles sont vos recommandations/Actions pour surmonter ces barrières?**
Uganda	NITAG has been requested by MOH to provide a vaccine prioritization list for the next five years and HepB birth dose is one of the vaccines requested by MOH.	None at the moment, government will undertake it once they receive an official evidence based decision from NITAG	Not Applicable
Zambia	NITAG is yet to be established in Zambia- Tentatively after November following training	This is not planned for in the EPI cMYP and the program does not have any Burden of disease data. It is hoped that future new vaccine introductions will be tabled before the NITAG	The Ministry of Health has appointed a national focal point person for hepatitis prevention, control and treatment. The development of strategic plan for viral hepatitis prevention, control and treatment is still on-going. The key strategies have also been considered for inclusion in the on-going development of the 2017-2020 National Health Strategic Plan. Inclusion of Hep B Birth Dose is yet to be discussed. The Ministry plans to convene a stakeholders meeting for consensus development and roadmap.
Zimbabwe	Zim-NITAG has not yet recommended the introduction of Hepatitis B birth dose	Zim-NITAG was recently revived. The question of Hepatitis B birth dose is the first one on the Zim-NITAG agenda and is currently being used as a practical exercise for NITAG function	WCO is pushing forward the Hepatitis B birth dose on the agenda of the next meeting scheduled for 5/08/2016. We have assisted shape the question and have recommended NITAG to look at the question with high priority.

The most common barriers in the AFRO region to introduce the birth dose are:

- Funding for birth dose programmes
- The percentage of births that take place outside health facilities.
- Insufficient disease burden data
- Vaccine storage and access to cold chain
- Central policies and guidelines

The number of life births estimated for the AFRO region in 2015 was 35 380 279[1]. The number of life births in the countries that have no yet introduced the birth dose was 26 966 573 in 2015[1].

Data from WHO (http://www.who.int/maternal_child_adolescent/epidemiology/profiles/maternal/en/) shows that the proportion of life births taking place in homes ranges from 8% in the Congo to 89% in Ethiopia.

Data available for 33 countries were the birth dose has not been introduced shows that the proportion of life births in homes is 42.87% (95CI 42.85-42.89).

Data from the World Bank[2] shows that the range of births attended by skilled health staff in AFRO is 15.5% in Ethiopia to 99.2% in Mauritius. Data available for 36 countries show that 55% of life births are attended by skilled health staff.

[1] Un Population Division's World Population Prospects the 2015 revision
[2] http://data.worldbank.org/indicator/SH.STA.BRTC.ZS

South East Asia Regional Office

The WHO South East Asia Region has 11 Member States: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

Table 2: Schedules currently used in SEAR

Type of vaccine	birth	1p	2p	3p	booster	Number of countries
DTwPHep		2 m	4m	6m		1
DTwPhibHepB		2m	3m	4m	18m	1
DTwPhibHepB		2m	4m	6m		3
DTwPhibHepB		6w	10w	14w		6
Hep B	0					4
Hep B	0-7 days					1
Hep B	0	1 m				1

Source: http://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/

Currently 7 of 11 countries in the SEAR have the hepatitis B birth dose in their national schedule; one country introduced it in February 2016.

Among the six countries that provided HepB-BD in their vaccination schedule in 2015, coverage was <80% in two (Bhutan at 78% and India at 44%3), between 80-95% in one (Indonesia), and >95% in three (DPRK, Maldives, and Thailand).

Bangladesh, Myanmar, Sri Lanka, and Nepal do not provide a HepB-BD, though both Myanmar and Nepal may reconsider full or partial introduction of the birth dose as part of their national control strategies.

Indonesia is using Uniject outside of cold chain and Timor Leste will do so for home deliveries or in places far from health centers.

- HepB-BD was discussed at June 2016 ITAG meeting; with recommendation for regional control goal and as such NITAGs (as present at the meeting) are expected to continue the discussions.

[3] In India only 47% of births occur in health facilities and 52% are attended by skilled health personnel.

The barriers for introduction are

- costs (as no there is no Gavi support),
- insufficient disease burden data and
- aspects of OCC and/or future CTC.

The action points to overcome these barriers are

- advocacy for government budget allocation,
- sero prevalence surveys,
- country pilot studies on OCC and
- capacity building for NITAGs and NRAs

Barriers to achieving high coverage include

- Home deliveries without skilled birth attendance
- Lack of awareness and/or training among health staff at birthing facilities
    - Incomplete integration in newborn care package
    - False contraindications
    - Fear of adverse events following immunization (AEFI)
    - Weak coordination between MCH and EPI
- Vaccine supply
    - Presentation and availability
    - Access
    - Management like open vial policy
- Cold chain equipment and management
- Incomplete participation of private sector

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