NATIONAL IMMUNISATION PROGRAM (0-5 YEARS) – GUIDELINE, BRUNEI DARUSSALAM 2017

CHILD HEALTH SERVICES, COMMUNITY HEALTH SERVICES, MINISTRY OF HEALTH, BRUNEI DARUSSALAM

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(A) The Cold Chain

1. Temperature:

- The system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C.

2. Cold chain breach:

- Exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking).

3. Freezing:

- A situation where vaccines experience temperatures at or below 0°C. Vaccines may not appear frozen but may have been damaged at these temperatures.

4. Safe Vaccine Storage:

- Store vaccines in a purpose-built vaccine refrigerator in their original packaging.
- Nominate a staff member to be responsible for vaccine management, and a back-up staff member to take responsibility in their absence.
- Ensure all people involved in vaccine transport, storage and administration are trained in vaccine management to ensure the vaccines remain effective and potent.
- Perform vaccine storage self-audits at least 12 monthly.
- Perform temperature monitoring of vaccine refrigerators twice daily; before the refrigerator is used for the first time and the end of each day.
- Temperature must be maintained between +2^{o}C and +8^{o}C.
- Any refrigerator breakdowns must be recorded and repaired immediately.

5. Cold Chain Breach situation:

- Immediately isolate the vaccines and label ‘Do not use’ or ‘Quarantine’.
- Keep in the designated refrigerator for ‘Do not use’ or ‘Quarantine’ vaccines between +2°C and +8°C.
- Fill in the Breakdown Cold Chain Report Form and submit to the pharmacy quality control unit immediately.
- Await and follow instruction from pharmacy on further action to be taken on the quarantine vaccine accordingly.

- Need an official letter from quality control unit, pharmacy to state if the quarantined vaccines can be reused back in clinic. Upon this clearance instruction to reuse, two nurses are needed to cross verify which quarantined vaccines are to be reused back and the label of 'quarantine' on each vial is to be removed and at same time placed back with the rest of the vaccines that can be administered.
- If the quality control unit, pharmacy reported that these quarantine vaccines are NOT to be reused anymore, it has to be sent back to Pharmacy unit to be discarded.

6. Transporting Vaccines:

- Specially designed containers for transporting vaccines must be used if available.
- If not available, a cooler box filled with freezer blocks or ice packs can be used.

(B) CHILD HEALTH IMMUNISATION (0-5 YRS)

National Immunisation Program 0-5 years, Brunei Darussalam

Age at vaccination	Vaccine	Order of Dose
0 week (at birth)	*BCG	1st dose
0 week (at birth)	*Hepatitis B (pediatric formulation)	1st dose
2 months	DTaP, IPV, Hib, HepB	1st dose
4 months	DTaP, IPV, Hib, HepB	2nd dose
6 months	DTaP, IPV, Hib, HepB	3rd dose
12 months	MMR	1st dose
	Hib	Booster dose
1 year & 6 months	MMR	2nd dose
5 years old	DTaP, IPV	1st Booster dose

*administered in hospital postnatal ward within 24 hours after birth.

Influenza (Trivalent Inactivated):

It is incorporated as part of the Flu Pandemic program to give to those less than two years old at a one-off regimen only. It is not part of the National Immunisation Program.

It can be administered concurrently with other vaccines in the current NIP as long as it is given at a different site, using a different needle and syringe.

Recommended doses of influenza vaccine (Trivalent Inactivated)			
Age	Dose	*Number of doses (receiving vaccine as first year of vaccination)	Number of doses (subsequent years)
6 months to < 3 yrs	0.25ml	2	1
3 to < 9 yrs	0.5ml	2	1

*Two doses, at least 4 weeks apart, are recommended for children aged 6 months to < 3 years, who are receiving influenza vaccine for THE FIRST TIME. The remaining 0.25mls left over in the vial is to be discarded.

(C) CATCH UP OF IMMUNISATION (0-5 YEARS)

Please refer to **Appendix A** for the catch-up immunization table and FAQs.

(D) IMMUNISATION PROCEDURE:

1. Pre-vaccination screening:

➢ Providers should:

- ensure that the child is well today
- ensure that they have the right person to be vaccinated
- check which vaccine(s) are indicated, including any previously missed vaccine doses
- consider whether alternative or additional vaccines should be given
- check if there are any contraindications or precautions to the vaccines that are to be given
- ensure that the patient to be vaccinated is the appropriate age for the vaccines to be given
- check that the correct time interval has passed since any previous vaccine(s)

➢ Pre-vaccination screening (example):

Condition of the child to be vaccinated	Action	Rationale
Unwell today: • Acute febrile illness • Acute systemic illness	Defer all vaccines until afebrile. Note: Children with minor illnesses and afebrile (without acute systemic symptoms/signs) should be vaccinated	• To avoid an adverse event in an already unwell child, and/or • to avoid symptoms to be mistakenly attributed to vaccination

2. Administration of vaccine

- For administration of any vaccine, all immunisation providers should be familiar with, and adhere to the following:

Occupational health and safety issues:

- The standard principles of infection prevention and control should always be followed during vaccination to prevent the transmission of infectious organisms. These principles include recommendations for routine hand hygiene, the use of personal protective equipment as appropriate, the handling and disposal of sharps, and routine cleaning of the work environment.

Equipment for vaccination includes:

- medical waste (sharps) container
- vaccine, plus diluent if reconstitution is required
- 3 mL syringe (unless vaccine is in pre-filled syringe)
- alcohol swab
- appropriate injecting needle
- clean cotton wool and tape to apply to injection site after vaccination
- gloves

Identifying the injection site:

- The choice of injection sites depends primarily on the age of the person to be vaccinated. The two anatomical sites recommended as routine injection sites are the anterolateral thigh and the deltoid muscle. Immunisation service providers should ensure that they are familiar with the landmarks used to identify any anatomical sites used for vaccination.

Ensure the '7R's of immunisation is practiced:

- a potent vaccine stored at the
  Right temperature
- given at the
  Right dose
- to be given at the
  Right age
- within the
  Right interval
- with a
  Right vaccine
- through a
  Right route
- by an authorised person with
  Right training

Skin cleaning:

- Alcohol and other disinfecting agents *must* be allowed to dry before vaccine injection (to prevent inactivation of live vaccines and to reduce the likelihood of irritation at the injection site).

3. Administering multiple vaccine injections at the same visit

- Ensure separate syringes and injection sites are used.
- The vaccines in the NIP can be co-administered as per in the NIP schedule or if found needed for catch-up purposes.
- MMR live vaccines can be given at the same time as other live attenuated vaccines or other inactivated vaccines.
- If MMR live vaccine is not given simultaneously with other live attenuated vaccine, there should be a 4-weeks gap between any two live attenuated vaccines.
- Need to document in both Bru-HIMS and the Yellow card/ MCH hand book, which site each vaccine is administered during multiple vaccine injections.

(E) CONTRAINDICATIONS

1. Contraindications to vaccination

There are only **two** absolute contraindications applicable to *all* vaccines:

- Anaphylaxis following a previous dose of the relevant vaccine
- Anaphylaxis following any component of the relevant vaccine.
- There are two further contraindications applicable to live vaccines:
  - Live vaccines (e.g. BCG, MMR, varicella) should not be administered to persons who are significantly immunocompromised:
    - HIV/AIDS-infected
    - Organ or bone marrow transplant recipients
    - Receiving radiotherapy / chemotherapy or received radiotherapy / chemotherapy within at least the last 6 months
    - * On high dose steroids, orally or rectally [Children receiving ≥2mg/kg/day for ≥ 1 week, or 1mg/kg/day for 1 month]
    - *Any immunodeficiency syndromes

      (* *To discuss with the doctor first)*
  - Live vaccines should not be administered during pregnancy.

Note:

<u>Influenza vaccine (inactivated Trivalent):</u>

It should not be given to those who have had:

- Confirmed anaphylactic reaction to a previous dose of vaccine
- Confirmed anaphylactic reaction to any component of the vaccine
- Confirmed anaphylactic hypersensitivity to egg products
- Confirmed cases of very severe allergy to egg

2. False contraindications to vaccination:

- No one should be denied the benefits of vaccination by withholding vaccines for inappropriate reasons.
- The following conditions are ***not*** contraindications to any of the vaccines in the National Immunisation Program schedule. Persons with these conditions should be vaccinated with all recommended vaccines:
    - mild illness and afebrile
    - family history of any adverse events following immunisation
    - past history of convulsions
    - treatment with antibiotics
    - treatment with locally acting (inhaled or low-dose topical) steroids
    - replacement corticosteroids [for live vaccines refer to E(1)]
    - asthma, eczema, atopy, hay fever or 'snuffles'
    - previous infection with the same pathogen
    - prematurity (vaccination should not be postponed and can be given if the infant is medically stable)
    - history of neonatal jaundice
    - low weight in an otherwise healthy child
    - neurological conditions, including cerebral palsy and Down syndrome
    - contact with an infectious disease
    - child's mother is pregnant
    - child to be vaccinated is being breastfed
    - women to be vaccinated is breastfeeding
    - recent or imminent surgery
    - poorly documented vaccination history
    - autism and family history of autism

(F) ADVERSE EFFECTS FOLLOWING IMMUNISATIONS

For reporting of adverse effects from immunisations, refer to **Appendix B**.
To submit the AEFI form to the nearest pharmacy unit for the respective child health clinic.

Vaccines	Adverse Effects
Diphtheria	Swelling and redness at the injection site. Malaise, fever and headache may occur. A small painless nodule at the injection site may appear but resolves without sequelea. Anaphylaxis is rare.
Haemophilus Influenza Type B	Swelling and redness at the injection site (10% of cases). These effects usually disappear within 24 hours. The incidence of these effects decreases with subsequent doses.
Hepatitis B	Side effects are transient and mild and include soreness at the injection site, low grade fever, rash, nausea, dizziness, malaise, influenza- like symptoms, myalgia and arthralgia. Serious neurological reactions like Guillain-Barre Syndrome (GBS) and demyelinating diseases have been reported, however, a causal relationship with hepatitis B vaccine has not been established.
Measles, Mumps, Rubella	Malaise, fever, rash may occur after MMR vaccination, mostly about a week after immunisation and last for about 2-3 days. Febrile convulsions, encephalitis and parotid swelling are rarely reported.
Pertussis	Swelling and redness at the injection site, fever and inconsolable/persistent crying are common self- limiting reactions. Convulsions and encephalopathy following pertussis vaccine are rare.
Inactivated Polio	Pain, swelling or redness at the injection site are common and may occur more frequently following subsequent doses. A small painless nodule may form (this usually disappears with no consequences).
Tetanus	Pain at the injection site is common and can persist for days. Headache, lethargy, myalgia and fever are also common. Anaphylaxis and urticaria may occur although rarely.
Influenza	Pain, swelling or redness at injection site, low grade fever, myalgia, arthralgia, immediate reactions such as urticaria, bronchospasm, and anaphylaxis can occur, most likely due to hypersensitivity to residual egg protein.
Tuberculosis (BCG)	Severe injection site reactions, large ulcers and abscesses are common due to faulty injection techniques. Vertigo and dizziness are occasionally reported. Anaphylaxis is rare.

REFERENCES:

- Pocket handbook on immunisation, Department of Health Services, Ministry of Health, Brunei Darussalam, 2004.
- Updates to the 10th edition of the Australian Immunization Handbook *(last updated August 2016)*
- Guideline on Cold Chain Management, Department of Pharmaceutical Services, Ministry of Health, 2009
- Green Book, UK (Immunisation against infectious diseases) *(last updated February 2016)*
- Table 2: Recommended Routine Immunisation for Children *(updated March 2017)*, World Health Organisation
- Recommended Immunisation Schedule for Children and Adolescents Aged 18 Years or Younger, United States, 2017; Centers for Disease Control and Prevention

Thanks of acknowledgment to:

- Head of Paediatrics Department, RIPAS Hospital, Brunei Darussalam

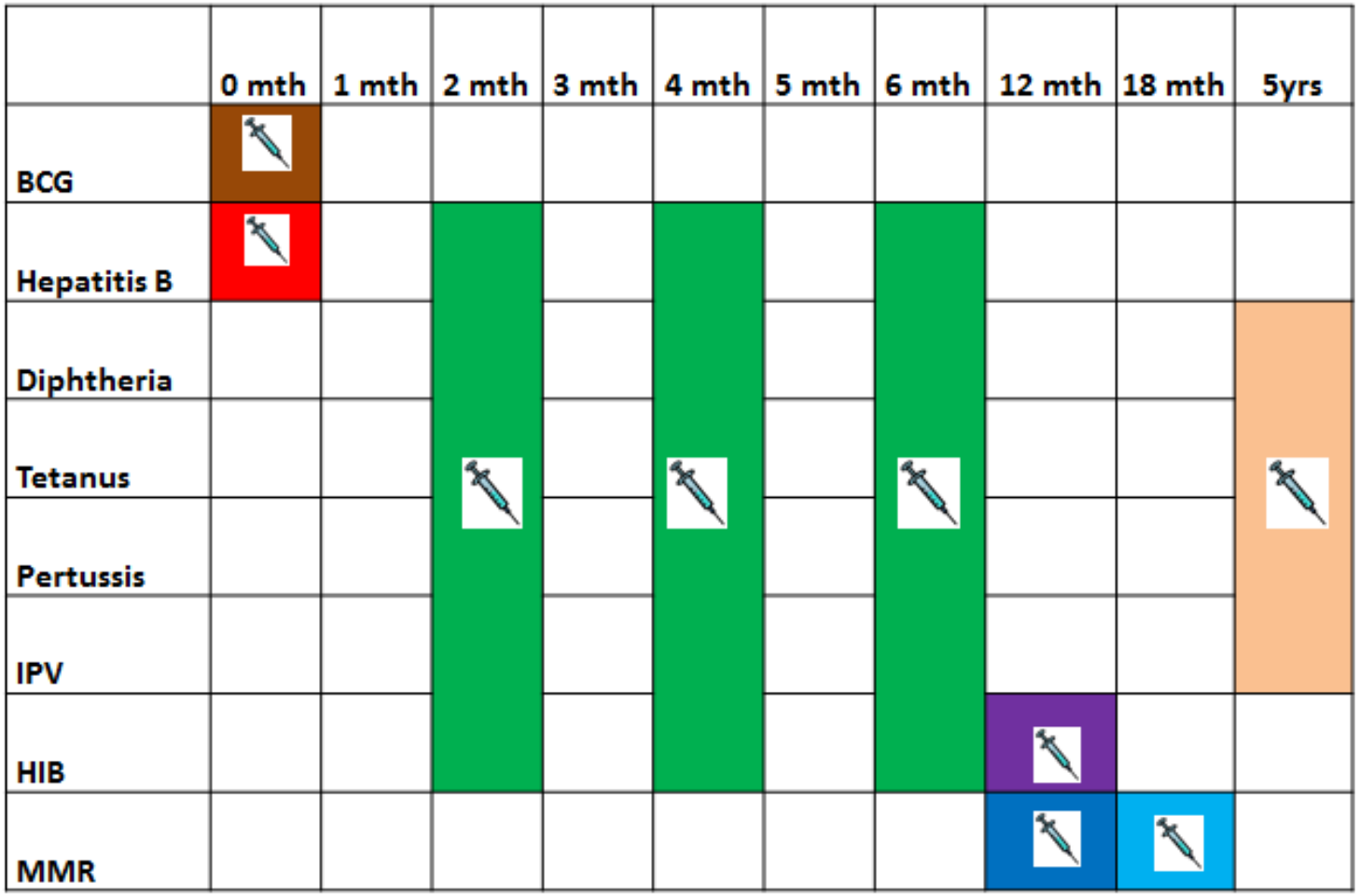
Appendix A

Catch up on

National Childhood Immunisation Program 0-5 years

(revised in June 2017)

National Childhood Immunisation Program



FAQ 1: Catch up Scenarios for InfanrixHexa and Hib booster

Age in Month	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Case 1	HB		6in1		6in1		6in1						Hib								
Case 2	HB		6in1		6in1		6in1						Hib								
Case 3	HB			6in1	6in1		6in1						Hib								
Case 4	HB				6in1	6in1	6in1						Hib								
Case 5	HB					6in1	6in1	6in1						Hib							
Case 6	HB						6in1	6in1	6in1						Hib						
Case 7	HB							6in1	6in1	6in1						Hib					
Case 8	HB								6in1	6in1	6in1						Hib				
Case 9	HB									6in1	6in1	6in1						Hib			
Case 10	HB										6in1	6in1	6in1						Hib		
Case 11	HB											6in1	6in1	6in1						Hib	
*Case 12	HB												6in1		6in1	4in1 HB					
* Case 13	HB																6in1	4in1 HB	4in1 HB		

HB	Hepatitis B
6in1	DTaP- IPV Hib HepB (Infanrix Hexa)
4in1	DTaP-IPV (Infanrix)
Hib	Haemophilus Influenzae Type B (Hiberix)

*case 12+13 are for those who **START** vaccination late at >12 months old

Notes: FAQ 1

Hepatitis B: (Hepatitis B junior 10mcg):

- Minimum interval is 4 weeks gap for catch up.
- The third dose not to be given at less than 24 weeks old (6months).

Diphtheria+Tetanus+Pertussis: (3primary +1 booster)

- Mininum interval DTP containing vaccines are 4 weeks gap.

Haemophilus Influenzae type B priming dose: (3primary)

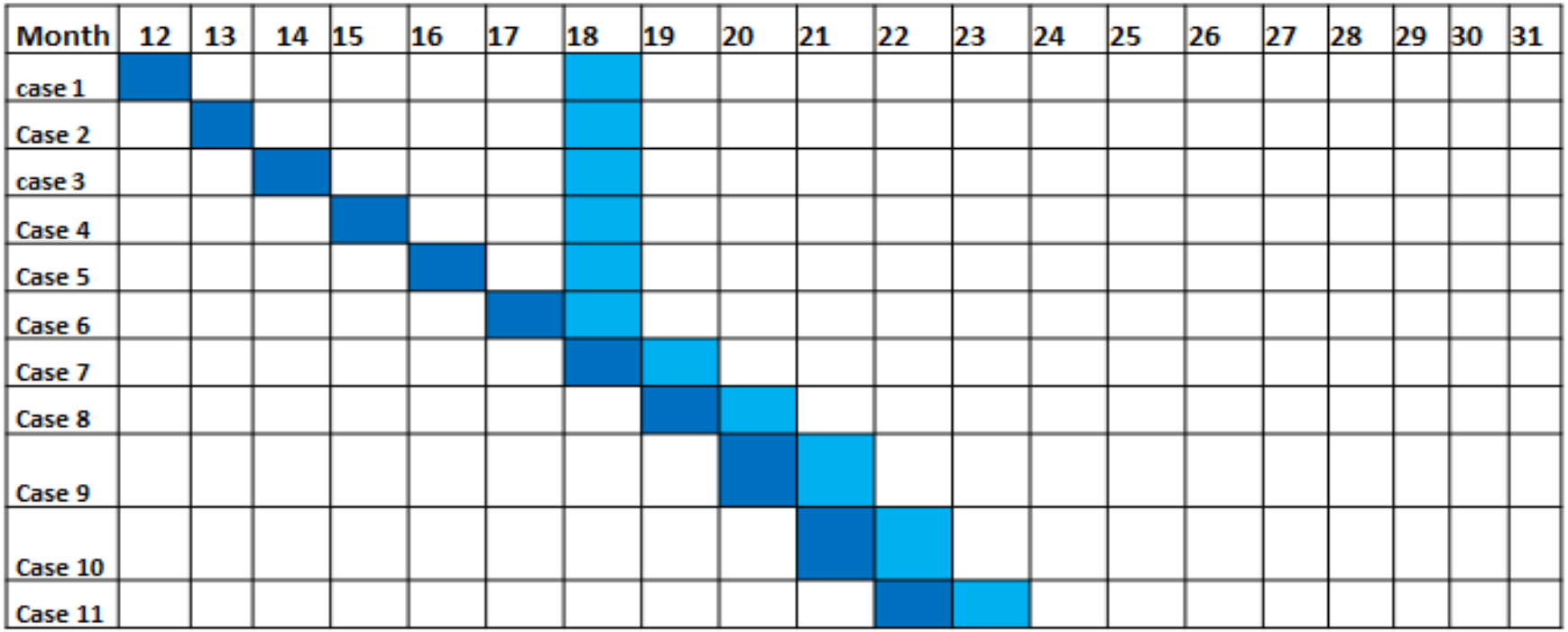
- Minimum interval between primary first three Hib doses is one month.
- Hib is not needed for healthy children above 5 years old.

Haemophilus Influenzae type B booster dose:

- Catch up of Hib booster for all those less than 5 years old of age.
- Minimum interval between 3rd dose Hib and Hib booster is 6 months.
- If ***FIRST*** dose of Hib is given between ages 12 to < 16 months old, only 2 Hib doses is needed. There should be a 2 month gap between the 1st and 2nd dose of Hib (Case 12).
- If ***FIRST*** dose of Hib is given at ≥ 16 months old, only 1 dose of Hib is needed (Case 13).

InfanrixHexa (6in1) can be given at the same time with MMR, Pneumococcal, Fluarix.

FAQ 2: Catch up Scenarios for MMR



MMR1	Measles Mumps Rubella 1
MMR2	Measles Mumps Rubella 2

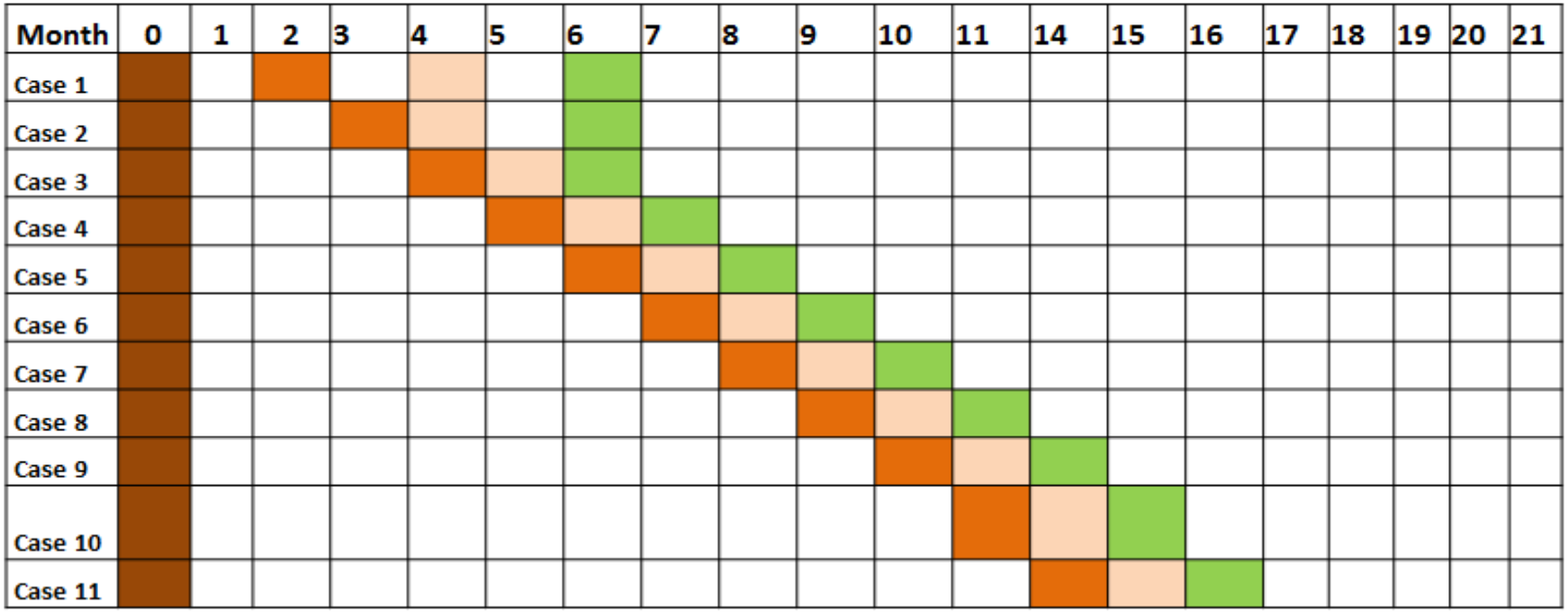
Notes for FAQ2

MMR:

- Minimum gap between doses is 4 weeks.
- MMR2 to be given at 18 months old or 4 weeks after MMR1 whichever is later.

For children who had 1st dose of Measles at < 11 months old, to re-vaccinate MMR at age 12 months old. The MMR booster dose is to be given at 18 months old as per schedule or 4 weeks later from the previous MMR dose, whichever is later.

FAQ 3: Catchup Scenarios for single vial Hepatitis B



	Birth Dose
HB1	Hepatitis B1
HB2	Hepatitis B2
HB3	Hepatitis B3

Notes for FAQ 3

Hepatitis B (Hepatitis B junior 10mcg):

- Minimum interval is 4 weeks gap for catch up.
- The third dose is not to be given at less than 24 weeks old (6months).

Appendix B

AEFI reporting form

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For office use only:
BRN _____
Initial report _____
Follow-up report ____

National Adverse Drug Reaction Monitoring Centre
Ministry of Health, Brunei Darussalam

SUSPECTED ADVERSE DRUG REACTION REPORT FORM

Please report **all** suspected adverse drug reactions including those for vaccines, self-medication, traditional medicines and health supplements. Do not hesitate to report if some details are not known. **MANDATORY FIELDS** are marked with *. **Identities of reporter and patient** will be kept confidential.

(1) PATIENT DETAILS *

Patient name:_____ Date of birth:_____ Weight, if known (kg): _____

Gender: ☐ Male ☐ Female Medical record no. / BruHims no. / Identity card no. :_____

Nationality: _____ Ethnic group: ☐ Malay ☐ Chinese ☐ Other (please specify) :_____

(2) ADVERSE DRUG REACTION (ADR) DETAILS *

Description of ADR(s):_____

_____

_____

Date ADR(s) started: _____ Date ADR (s) stopped: _____ Do you consider the ADR(s) to be serious? ☐ Yes ☐ No

If **yes**, please indicate why the ADR is considered to be serious (please tick all that apply):

☐ Patient died due to reaction ☐ Life threatening ☐ Involved or prolonged in-patient hospitalisation
☐ Congenital abnormality ☐ Involved persistent or significant disability or incapacity
☐ Medically significant; please give details: _____

- Description of treatment of reaction : _____
- Outcome of reaction: ☐ Recovered ☐ Recovering ☐ Recovered with sequelae (any permanent complications or injuries)
  ☐ Not recovered ☐ Fatal (Date of Death): _____ ☐ Unknown

(3) SUSPECTED DRUG(S)/ VACCINE(S) * *(Additional pages may be attached)*

Product name, active ingredient & strength	Dosage form	Dosage regimen (dosage, frequency & route)	Product details: Batch No. (if known)	Date started	Date stopped	Prescribed for
1.						
2.						
3.						

(4) OTHER DRUG(S) (INCLUDING SELF-MEDICATION, TRADITIONAL MEDICINES & HEALTH SUPPLEMENTS CONSUMED AT THE SAME TIME AND/ OR IN THE LAST 3 MONTHS BEFORE THE ADR) *(Additional pages may be attached)*

Product name, active ingredient & strength	Dosage form	Dosage regimen (dosage, frequency & route)	Product details: Batch No. (if known)	Date started	Date stopped	Prescribed for
1.						
2.						

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3.						
4.						
5.						

5) OTHER RELEVANT INFORMATION *(Additional pages may be attached)*

Relevant Medical History (Include Allergies, Pregnancy Status, Smoking, Renal/ Hepatic Dysfunction etc) *(For congenital abnormalities, please state all other drugs taken during pregnancy and the last menstrual period)*	Relevant Investigations (Rechallenge If Performed/ Laboratory Data)

(6) REPORTER DETAILS *

Name: _____ Signature: _____

Profession: _____ Institution Address : _____

Date: _____ Tel No: _____ Email: _____

Thank you for taking the time to complete this form.

FOLD HERE FIRST

GUIDANCE ON ADR REPORTING

WHAT TO REPORT?

An adverse drug reaction is a response to a drug that is noxious (harmful) and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

The Ministry of Health encourages the reporting of **all** suspected adverse reactions to drugs and medicinal substances (including self-medication, traditional medicines or health supplements). In particular, please report:

- All suspected reactions to established products and new medicines regardless of their nature and severity.
- All serious adverse reactions which include reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, birth defects, persistent or significant disability or incapacity and if medically significant.
- All suspected drug interactions.

HOW TO REPORT?

The Suspected Adverse Drug Reaction Report form can be obtained from the National Adverse Drug Reaction Monitoring Centre and the nearest government pharmacy facility (hospital/ health centre). This form should be filled as completely as possible and returned to the address below or to the nearest government pharmacy facility (hospital/ health centre).

SUBMISSION OF FOLLOW-UP REPORTS

Any follow-up information for an ADR that has already been reported can be sent to us in another form or *via* any other modes of reporting. Please state that it is a follow-up report, indicating the date and reference number of the initial report.

FOLD HERE SECOND

To:

National Adverse Drug Reaction Monitoring Centre,
c/o Drug and Poison Information Section,
Department of Pharmaceutical Services, Ministry of Health,
Simpang 433, Kg Madaras
Brunei Darussalam BB3910
Tel: 2393298 ext 201, 206, 207
Fax: 2393096
Email: nadrmc.dps@moh.gov.bn

ADR Report Form Version 1.2016