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Ministry of Health

Introduction of Measles, Mumps, Rubella Vaccine (MMRV) into the National Immunization Programme and changes to the National Immunization Schedule

General Circular No. 02-123/2011

Provincial/Regional Directors of Health Services,
Directors of Teaching Hospitals/Specialized Campaigns,
MSS/DMOO of Provincial/Base Hospitals,
Heads of Decentralized Units,
Regional Epidemiologists, Medical Officers (MCH)
Medical Officers of Health.

1. Mumps pathogen and the disease

The mumps virus belongs to the family *Paramyxoviridae*. Humans are the only known natural host for mumps virus. The virus is spread via direct contact or by airborne droplets from the upper respiratory tract. It requires more intimate contact for transmission than the measles or varicella viruses. The incubation period averages 16–18 days with a range of two to four weeks. Typically, mumps begins with non-specific symptoms such as myalgia, headache, malaise and low-grade fever that within a day are followed by the characteristic unilateral or bilateral swelling of the parotid glands. Within one to three days, other salivary glands are visibly affected in approximately 10% of the cases. After about one week, fever and glandular swelling disappear, and unless complications occur, the illness resolves completely. In approximately 30% of the cases, infection passes with non-specific symptoms only or without symptoms at all. **There is no specific therapy for mumps infection.**

Until recently mumps has been a common infectious disease in all parts of the world, with annual incidences ranging from approximately 0.1% – 1%, in certain populations even reaching 6%. Mumps is generally a mild, self-limiting disease, although complications such as aseptic meningitis, encephalitis or orchitis may occur. Although deaths due to mumps are rare, the disease can impose a substantial economic burden on society due to the fact that, in unvaccinated communities, **almost every person may get infected** and run a relatively higher risk of complications.

2. Possible complications due to disease

Asymptomatic pleocytosis (>5 leucocytes/mm3) in the CSF is found in 50%–60% of mumps patients, whereas symptomatic aseptic meningitis is reported in up to 15% of the cases. Meningitis occurs more often in males than in females and adults are at a higher risk than children.

Mumps encephalitis without signs of meningitis is reported in 0.02%–0.3% of the cases. Although the case-fatality rate of mumps encephalitis is low (1.4%), permanent sequelae such as deafness occur in about 25% of the cases.

Acquired sensorineural deafness caused by mumps is one of the leading causes of deafness in childhood, affecting approximately 5 in 100 000 mumps patients.

Mumps orchitis occurs in 20%–50% of post pubertal males. Both testes are affected in approximately 20% of these cases, but mumps orchitis is rarely associated with permanently impaired fertility. However, a history of mumps orchitis seems to be a risk factor for testicular cancer. Symptomatic oophoritis and mastitis are relatively uncommon, and apparently without long-lasting consequences for the patients.

Acquisition of mumps during the first 12 weeks of pregnancy is associated with a high (25%) incidence of spontaneous abortions, although malformations following mumps virus infection during pregnancy have not been found. Pancreatitis is reported as a complication in approximately 4% of the cases, but the relationship of mumps disease to diabetes mellitus remains speculative.

3. Protective immune response following natural infection

Only one serotype of mumps virus exists. In general, natural infection confers lifelong protection against the virus, but recurrent mumps attacks have been reported. **It is not known whether boosting by circulating wild virus in the community is a prerequisite for lifelong immunity** against this disease. Studies in several different countries have demonstrated that the seroprevalence of antibodies to mumps virus often reaches approximately 90% in individuals 14–15 years of age.

4. Mumps disease burden in Sri Lanka

As described in section 1 to 3, mumps is a widespread self limiting disease with very low mortality but very high morbidity. Except available statistics on hospital morbidity hardly any data is available on mumps outpatient care seeking pattern and community level disease burden. Henceforth, the next best option to make an estimate of the mumps disease burden in Sri Lanka is to apply annual incidence rates reported from other countries to Sri Lankan population estimates and derive the best estimates for Sri Lanka. As described in section 4, reported annual incidence rates varied from 0.1 % to 1%. By application of least case scenario incidence rate of 0.1% to Sri Lankan estimated of 20 million, it derives 20,000 mumps cases per year. With an estimated average duration of disability of 14 days per mumps case will derive 280,000 days of disability .

According to the statistics available at the Medical Statistics Unit, 3,127 and 3,441 cases of live discharges of mumps cases has been reported from the Government hospitals during the years of 2008 and 2009 respectively with the completeness of 75 % of hospital reporting. Therefore after making allowance for 25 % of Government hospitals non-reporting and possible private sector hospitalizations taken into consideration, it is safe to conclude as an average of 4000 to 5000 mumps hospitalizations per year. Some of these hospitalizations are severe complications of mumps such as mumps encephalitis, meningitis, parotitis and orchitis which requires an average 7 days of hospitalizations giving rise to considerable number of hospital days. According to the data reported to the Epidemiology Unit, around 50% of cases are below 15 years, indicating the benefit of vaccination in early childhood.

5. Mumps vaccines

Live attenuated mumps virus vaccines have been developed in Japan, the former Soviet Union, Switzerland and the United States. Different strains of mumps virus are used for the development of the vaccines.

Mumps vaccines are available as monovalent, bivalent measles–mumps vaccine, and trivalent MMR vaccine. In most countries, immunization against mumps is delivered through MMR. According to the WHO, by December 2010, 2-dose MMR schedules has been implemented in 132 countries out of 193 member states in their national immunization programmes. The first dose is usually given to children aged 12–18 months, the second dose after a minimum interval of 1 month. Most children have received the second dose by the time of school entry (about 6 years of age).

The minimum amount of attenuated mumps virus that a single dose should contain is determined by the national regulatory authority of the country where the vaccine is produced. Depending on the manufacturer, hydrolysed gelatin or sorbitol, or both, are used as stabilizers for mumps vaccines. The freeze-dried vaccine could be kept frozen at –20° C or refrigerated between +2° C and +8° C until used. It should be protected from light both before and after reconstitution. Reconstituted vaccine must be kept in the cold chain and must be discarded at the end of the vaccination session or within 6 hours if not used (whichever comes fi rst). Mumps vaccines are injected subcutaneously.

In general, adverse reactions to mumps vaccination are rare and mild. The most common adverse reactions are parotitis and low-grade fever**.** However, moderate fever sometimes occurs and aseptic meningitis has been reported at widely different frequencies depending on the vaccine strain used. Vaccine-associated meningitis resolves spontaneously in less than one week without any sequelae.

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Pregnant women should not receive mumps vaccine, and pregnancy should be avoided for three months after vaccination (fetal damage has, however, not been documented). Allergy to vaccine components such as neomycin and gelatine is contraindicative.

6. Schedule of administration of MMR Vaccine and changes to the National Immunization schedule

1st Dose of MMR vaccine - on completion of one year

2nd dose of MMR vaccine - on completion of 3 Years

With introduction of MMR vaccine to the National Immunization schedule following important changes also will come into effect.

a. Change of age of administration of Live JE vaccine from current schedule of “on completion of 1 year” to “on completion of 9 months “

b. Change of age administration of 1st dose of Measles Vaccine from current schedule of “on completion of 9 months” to “on completion of 1 year” with the administration of the 1st dose of MMR

c. Administration of Measles Rubella (MR) Vaccine in current schedule at “on completion of 3 years” will be replaced by 2nd Dose of MMR vaccine in the new schedule

d. MMR vaccine could be offered to females in child bearing age (16 – 44 years) as a rubella containing vaccine instead of Rubella Vaccine.

The National Immunization schedule which comes to effect from 1st October 2011 and approved by the National Advisory Committee of Communicable Diseases on 3rd June 2011 is annexed for your information and display.

7. Dose of MMR vaccine

The recommended dosage is 0.5ml of reconstituted vaccine.

8. Route and site of administration

MMR vaccine should be administered subcutaneously to the outer mid thigh or mid deltoid region of the upper arm depending on the age of the child.

9. Contraindications

There are only a few contraindications for administration of MMR vaccine. General contraindications to vaccination specified in the Immunization Handbook issued by the Epidemiology Unit in 2002 are applicable to the MMR as well.

However, it should be **postponed** in specific instances given below,

- Fever more than 38.5^0C
- Acute stage of any infectious disease
- Temporarily acquired severe immunodeficiency states due to recent immuno suppressive therapy such as systemic corticosteroids, chemotherapy , irradiation etc

It should be **avoided** in

- Children with proven or suspected severe hypersensitivity to Measles, MR, MMR vaccines or its components such as Neomycin and Gelatin.
- Congenital or acquired severe immunodeficiency states such as impaired immunological mechanisms, malignant conditions and Acquired Immune Deficiency Syndrome etc

10. Precautions:

It is advised to review child's medical history before administration of the MMR vaccine with a view to identifying children with compromised health status. Parents/ caregivers of such children should be communicated that there may be the possibility of coincidental worsening of the health status of the vaccinated child due to the compromised health status which could be erroneously attributed to the vaccination.

11. Storage:

MMR vaccine should be stored and transported in a temperature between 2 and 8 ^{0} C and should be protected from sun light and should preferably be kept in the upper shelf of the main compartment of the refrigerator with the dilluent in all places storing the vaccine including MOH offices.

If the vaccine is not used immediately after reconstitution, it should be stored at 2°C to 8°C not longer than 6 hours and away from light. After 6 hours or at the end of the season it should be discarded.

12. Injection safety:

At present only auto-disable (AD) syringes are used in the National Immunization Programme in the country. Therefore, administration of MMR vaccine will be carried out using AD syringes and used syringes should be discarded to safety boxes. AD syringes and safety boxes for the National Immunization Programme will be provided by the Medical Supplies Division in coordination with the Epidemiology Unit. RDHS, MOH and head of medical institutions are responsible for ensuring the availability and use of injection safety items at all immunization clinics in their respective areas.

Further it is emphasized that appropriate and safe disposal of sharps should be ensured in all aspects of the programme.

13. Vaccine accountability:

MMR vials are presented as 10 dose vials. Therefore, measures should be taken at immunization clinics whenever possible to open a vaccine vial when a group of five eligible children are identified. Each vial of vaccine is accountable and any significant wastage should be clearly documented, and reported to both Epidemiology Unit and RDHS.

14. Role of MOH in the introduction of MMR vaccine to the National Immunization Programme

- Training of MOH staff on introduction of MMR vaccine
- Creating public awareness regarding the MMR vaccine by organizing public education programmes
- Timely requisition of adequate vaccine stocks for the area, supervision of storage, transport of vaccines and maintenance of cold chain
- Timely requisition of adequate stocks for the area, identifying mechanisms for disposal of AD syringes and sharp waste for the area and monitoring the implementation and sustenance of the activity
- Screening and excluding children for whom offering the MMR vaccine is contra indicated
- Monitoring vaccines for immediate AEFI and initiating appropriate actions
- Monitoring and evaluation of immunization coverage and vaccine wastage of MMR vaccine quarterly, based on the Quarterly EPI Return for the area and taking corrective measures when required.
- Reporting of AEFI at MOH level monthly and speedy investigation of severe AEFI
- Monitoring and supervision of record keeping at clinic level and MOH level
- Monitoring timeliness of EPI returns sent from MOH office to RDHS/RE
- MOH is accountable for vaccine management responsibly.

15. Role of Public Health Nursing Sister/ Supervisory Public Health Midwife in the introduction of MMR vaccine to the National Immunization Programme.

- Training of PHMM on MMRV
- Education of the public regarding the MMRV
- Monitoring and supervision of maintenance of cold chain and proper storage of vaccine stocks
- Supervision of organization of immunization clinics to facilitate administration of MMRV
- Supervision of disposal of used AD syringes and other injection materials

- Monitoring of immunization coverage, vaccine wastage, AEFI with regard to MMRV at Clinic/PHM level and MOH level
- Monitoring and supervision of record keeping at the clinic level and MOH level
- Accurate, timely compilation of MMR related EPI data

16. Role of Public Health Midwife in introduction of MMR vaccine to the National Immunization Programme.

- Education of the public on the MMRV
- Maintenance of cold chain during transport of vaccines and during clinic sessions
- Providing immunization and monitoring vaccines for immediate AEFI at the clinics level
- Enforcing vigilance and providing personal attention to prevent dropouts from immunization and to detect AEFI with regard to MMRV
- Safety assurance of the sharps waste disposal activity in the immunization clinics
- Maintenance of accurate records regarding MMRV: Birth and Immunization Register, Clinic Immunization Register, Clinic AEFI Register, Part A/B of CHDR, Clinic Summary, Quarterly MCH Clinic Return

17. Role of Regional Epidemiologist/ MO-MCH in introduction of MMRV vaccine to the National Immunization Programme.

- Conduction of district training programmes for MOH and hospital staff at district level and active participation, co-ordination and supervision of training programmes at MOH level
- Estimation of required stocks of MMRV for the district
- Close monitoring of requisition of MMRV , vaccine storage and maintenance of cold chain at Regional Drug Stores and at MOH level
- Close supervision of vaccine and AD syringes supply in the region
- Overall supervision of mechanisms developed in the region for disposal of AD syringes and sharp waste
- Close monitoring and supervision of immunization coverage and vaccine wastage quarterly and reporting of AEFI monthly with regard to MMRV

18. Role of Heads of Health Institutions in introduction of MMRV vaccine to the National Immunization Programme.

- Timely acquisition of adequate vaccine stocks and AD syringes for the immunization clinic
- Close monitoring of vaccine storage and maintenance of cold chain at institutional level
- Close supervision of vaccine and AD syringe supply to the clinics
- Overall monitoring of immunization coverage, vaccine wastage and AEFI with regard to MMR vaccination at hospital level
- Overall monitoring and supervision of record keeping at hospital level
- Officer in charge of the EPI clinics is responsible and accountable for vaccine management. Each vial of vaccine is accountable and any significant wastage should be clearly documented, reported to both the Epidemiology Unit and the RDHS.

19. Role of Officer In-Charge/ Regional Medical Supply Division (RMSD) in the introduction of MMRV into the National Immunization Programme.

- Timely requisition of adequate vaccine stocks and AD syringes for the district
- Timely distribution of vaccines and AD syringe to MOH and medical institutions
- Maintenance of cold chain for vaccine during storage at RMSD and transport
- Preparation of the correct monthly stock return for the district
- OIC RMSD is totally responsible and accountable for vaccine management at the RMSD. Each vial of vaccine is accountable and any significant wastage should be clearly documented, and reported to both the Epidemiology Unit and the RDHS. OIC RMSD will be held responsible for any losses due to unacceptable reasons.

20. Training of Health Staff

Replacing currently used Measles and MR vaccines in the National Immunization Programme with MMR vaccine and change in the schedule of administration of LJEV, requires training and education of field health staff to provide the knowledge and skills to sustain a successful programme.

Following have been identified as important issues that should be clearly and completely addressed during all training sessions.

- Mumps disease, and role of MMRV in prevention and control of Mumps
- Rationale for change of immunization schedule
- MMR vaccine (contrindications, vaccine administration, storage etc)
- Use of injection safety items (AD syringes, safety boxes)
- Vaccine logistics (vaccine wastage, accountability, maintaining adequate stocks)
- Record keeping: (maintenance of records and registers, completeness, accuracy and timeliness of returns)
- Vaccine safety: (adverse events following Immunization)

At the national level, Regional Epidemiologists/ MOO(MCH) will be given an orientation and they will be the trainers for their respective health staff. They will be responsible for training MOOH and hospital staff who conducts EPI clinics in their respective districts/ medical institutions.

MOOH will be responsible for training their own staff and this activity should be assisted and monitored by RE and MO/MCH of the district.

This guideline on introduction of MMR vaccineinto the National Immunization Programme may be used as the training material. It is the responsibility of REE and MOO (MCH) to share this with all MOOH and hospital staff during the district level training.

21. Records and returns

With the replacement Measles and MR vaccine with the MMRV in the National Immunization Programme, it is very important and vital to monitor the coverage of MMR immunization and AEFI very closely. This could be done using the same returns and records use in the EPI programme. It is very important to collect, enter, consolidate and forward accurate and quality data on time.

Registers and returns used

- Child Health Development Record (CHDR)
- Clinic Immunization Register
- Clinic Summary
- Clinic AEFI Register
- Birth and Immunization Register
- Quarterly MCH clinic Return
- Quarterly EPI Return
- Monthly Surveillance Report on AEFI (AEFI Form 2)
- Notification Form on AEFI (AEFI Form 1)
- Adverse Events Following Immunization (AEFI)case investigation form (AEFI Form 3)
- Monthly stock return of vaccines
- Vaccine Movement Register
- Clinic Vaccine Movement Register

Child Health Development Record

In the new version of the CHDR, Year, month and the date of MMR immunization along with the batch number should be recorded in the corresponding row given for the MMR 1 and MMR 2 vaccinations.

In the older versions of the CHDR, Mark the date of administration and batch number MMR 1 dose in the row earmarked for Live JE vaccine and MMR 2 in the row earmarked for MR vaccine after making the necessary alterations in the column of "Type of Vaccine". In the same manner Live JE vaccine should be marked in the row earmarked for Measles Vaccine at 9 months. It is mandatory to fill the same information in both A and B parts of the CHDR.

Clinic Immunization Register – H1216

All immunizations performed in the clinic should be entered in this register. MMR vaccinations performed should be entered under the MR vaccine column until revised registers are provided.

Clinic Summary – H 518

Entries in the clinic immunization register should be added up correctly at the end of each session and totals should be recorded in the clinic summary. Total number of children who have been immunized with MMR vaccine should be entered in the columns meant to enter data on MR immunization until revised forms are provided. This column should be marked as MMR.

Clinic AEFI Register

A clinic AEFI Register should be maintained at each immunization clinic to record all adverse events reported following immunization. The date of immunization of the relevant vaccine, name of the child, the type of the adverse event and the name of the vaccine including batch number should be entered in the AEFI register.

Birth and Immunization Register EPI/03/79 9 (Revised 2011)

Date of MMR 1 immunization should be recorded on "**column G "and** date of MMR 2 immunization should be recorded in the **"column K"** of the 2011 revised version of the Birth and

Immunization Register. In the previous versions MMR 1 could be recorded on column for measles immunization and MMR 2 on column for MR immunization.

Quarterly MCH Clinic Return- RH – MIS 527

At the end of the every month, entries in the clinic summary should be added up (totalled). Immunizations performed during the whole month should be recorded in this return monthly. This return should be sent by each PHM to the MOH office at the end of each quarter before the 5th of the following month. It is important to note that the spaces in this return are horizontally aligned in contrast to the vertically aligned columns in the clinic registers. .

Total number of children who have been immunized with MMR vaccine should be entered in the rows meant to enter data for MR until revised formats are provided.

Notification Form for Adverse Effect Following Immunization

All adverse events following immunizations which are observed by public health staff should be entered in the Immunization Clinic AEFI Register and transfer this information to MOH Office AEFI Register on the day of the MOH office monthly conference. It is very important to adhere to the case definition of the adverse events before entering and reporting in order to improve the quality of AEFI surveillance.

All AEFI presented to the hospital should be entered in the "AEFI form 1" and should be forwarded monthly to the MOH in the area. Any form of AEFI which is not included in the "AEFI Form 1" could be entered under the "other" category.

Monthly Surveillance Report on AEFI (AEFI Form 2)

All AEFI reported from the MOH area following immunizations should be summarized by the MOH in the Monthly AEFI return. Copies of this return should be sent to the RE and the Epidemiology Unit. It is very important to adhere to the case definition when reporting AEFI. Total number of AEFI should be entered under the MMR column opposite the relevant row. Special attention should be paid to obtain information on Adverse Events Following MMR vaccination from the mothers and the the guardians during home visits, before immunizing the next vaccine and to record them accurately. Special attention should be paid by the RE to obtain AEFI notified to the hospitals without any delay.

Monthly stock return of vaccine

The number of MMR doses required for the institutions for the month should be intended under the column "MR" in the monthly stock return of vaccine and it should be re named as "MMR" until revised forms are provided.

Clinic Vaccine Movement Register and Vaccine Movement Register

Clinic vaccine movement register should be maintained in each immunization clinic session held in the MOH area. Vaccine Movement Register should be maintained at the MOH office to be used when ever vaccine is transported out of the MOH office for any immunization clinic. The number of doses of vaccine used at the clinic and the number of immunization performed at the clinic should be entered for each clinic session for both registers. These registers are vital in compiling vaccine wastage.

Quarterly EPI Return (EPID/EPI/2/98)

Entries in all Quarterly MCH clinic returns received at the MOH office and data on immunizations performed in schools, estates, government hospitals, private institutions and by GPPs should be summarized on this return. The number of MMR 1 and MMR 2 immunizations performed for the particular quarter should be entered under the heading MMR 1 and MMR 2 vaccinations.

22. Monitoring and Evaluation

Close monitoring and evaluation of the introduction of MMRV into the national immunization programme from its initiation is important for sustenance of the programme. Presently used EPI indicators: i.e. vaccine coverage, vaccine wastage and rate of AEFI will be used for this purpose.

Monitoring of MMR immunization coverage, vaccine wastage and adverse events reported following MMR immunization should be done at MOH level by MOH and PHNS and at district level by RE and MO/MCH. Epidemiology Unit will be responsible for monitoring at the national level as for other EPI antigens.

Compared to the Measles and MR vaccines, MMR vaccine is a costly vaccine and it is important to monitor the wastage and to implement strategies to minimize it at all levels. In a given immunization session, two birth cohorts are to be immunized with MMRV, vaccine wastage should be less than the Measles and MR vaccine wastage.

Assessment of causes for vaccine wastage at each Immunization clinic level is important as these vary widely between different settings. Strategies for reducing wastage could then be designed accordingly.

Possible causes for high vaccine wastage

- Breakdown of cold chain or inadequacy of cold chain maintenance system
- Poor monitoring of proper vaccine movement between MOH office and immunization clinics
- Less number of vaccinees per clinic session

Strategies that could be designed

- Careful planning in vaccine indentation and distribution
- Strict maintenance of cold chain
- Careful planning of immunization clinic locations
- Careful planning for ensuring at least a group of five children are brought to open a 5 dose vial.
- Monitoring of proper vaccine movement at MOH level
- Maintenance of accurate records to minimize inadequacies of vaccine stocks at MOH level
- Improvement of safe vaccine storage

Minimizing Vaccine Wastage at Outreach Immunization Clinics

- MOH should identify an officer at each individual outreach immunization clinic to be responsible for proper vaccine movement at individual clinic level
- Vaccine Movement Register should be rigidly maintained to monitor the flow of vaccines in each outreach immunization clinic
- Only correct amounts of vaccine stocks should be sent to the outreach clinics based on the expected and estimated number of children to be vaccinated

23. Monitoring of Immunization Safety

MMR vaccine is safe. Possible minor adverse events that could occur following immunization of this vaccine has been listed above. All adverse events associated with MMR vaccine reported by mothers and public should be reported by field health workers using the Monthly AEFI Return. All field health officers should specifically inquire about AEFI following the previous immunization from mothers at the next immunization session.

Please bring the contents of this circular to the notice of all officers concerned in your Province/ District/ Institution/ Unit.

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Dr. U. A. Mendis
Director General of Health Services