Form II

Investigation form for anaphylaxis/severe complications following contraceptive usage

This has to be filled by MOH for any complication mentioned under section 5 of Form I, except anaphylaxis/suspected anaphylaxis and sent within 14 days of notification of the event to Director. Maternal and Child Health, with a copy to MO.MCH.

In case of anaphylaxis /suspected anaphylaxis following contraceptive usage, this has to be filled by a district level team headed by MO.MCH, and sent within 7 days of notification of the event to Director. Maternal and Child Health.

Section 1- General Information

1.1.Information of the patient	
Name	MOH division
Age (Years)	PHM area
Parity	Address & contact number

1.2.Information regarding the contraceptive commodity accused with the complication
OCP ☐ DMPA ☐ Implant ☐ IUD ☐ Condoms ☐
Brand (if relevant)..... Batch number(if relevant).....
Date of manufacture (if relevant) ..... Date of expiry (if relevant) .....

Date of receipt of the batch by the service provider	
Storage condition (if relevant);	
Drugs/commoditites exposed to extreme cold or warmth	Yes ☐ No ☐
Drugs/commodities exposed to extreme humidity	Yes ☐ No ☐
Drugs/commodities exposed to direct sunlight	Yes ☐ No ☐
Physical appearance of package (if relevant)	
Good ☐ Damaged ☐ Discoloured ☐ Other (Specify).....	

1.3.Information regarding other drugs and commodities used, if any, (for administration of the family planning method or for performing the procedure) Eg: syringes, anaesthetic drugs

Drug/commodity	Brand	Batch no	Date of manufacture	Date of expiry	Physical appearance	Storage condition of the product

Section 2 –Information on family planning service provision

2.1.Information regarding the service provider	
Government ☐ Private ☐ Non Governmental Organization ☐	Name of the Institution
Type of clinic ☐ Poly clinic ☐ Combined clinic ☐ Family planning only ☐ NR ☐	
Who provided the service? VOG ☐ MOH ☐ MO ☐ RMO / AMO ☐ PHNS/NS/NO ☐ PHI ☐ PHM ☐ Other (Specify)	
Information about other staff available at the clinic/theatre	
Designation of the officer	Work experience

2.2.Information about service provision: **General information.**
Number of participants/patients for the clinic/theatre list on the day of performance/administration of the method?
Number of clients for family planning services
Average time spent on performing the procedure (LRT/Vasectomy)/administering the method
Date and time the method administered/performed
Pre-assessment
Who performed the pre-assessment-
Blood pressure during the pre-assessment -
Any condition of category 2, 3 or 4 of WHO Medical EligibilityCriteria Wheel(adapted for Sri Lanka)

Record keeping
Batch number and brand of the commodity written in the client record Yes ☐ No ☐ NR ☐

2.3 Emergency Management	
Staff member (designation)	**Whether undergone Emergency Management Training**
	Yes ☐ No ☐ Year of training ☐☐☐☐
	Yes ☐ No ☐ Year of training ☐☐☐☐
	Yes ☐ No ☐ Year of training ☐☐☐☐
	Yes ☐ No ☐ Year of training ☐☐☐☐
All the required drugs and equipment available in the emergency tray Yes ☐ No ☐	

Section 3 - Clinical history

Symptoms and signs of the patient following the adverse event *(for events other than anaphylaxis/suspected anaphylaxis),* *(For anaphylaxis/suspected anaphylaxis fill the relevant part in* **Section 5** *)* *(Attach extra papers if needed)*
Date and time of onset of symptoms
First contact: VOG☐ MOH☐ MO ☐ RMO/AMO ☐ PHNS/NS/NO ☐ SPHM/PHM ☐ Other (Specify) ..... Date d d m m y y y y Time ☐☐:☐☐ am/pm

Name of the hospital	Date and time of admission	Ward number	BHT number

Contraceptive History	
For new acceptors	**For current users**
Date of acceptance	Date of previous dose
	Duration of use
	Brands used
Any previous methods used?	
Any history of adverse events for contraceptive methods?	

Past Medical History
Any known allergies(food, drugs, latex etc…)-
Any acute illness patient has had within 2 weeks prior to the event-
Any drugs patient had been on, within the preceding 2 weeks of the event-
Any chronic disease -
Any significant diseases in the past-

Past Surgical History

Investigations *(for events other than anaphylaxis/suspected anaphylaxis),* *(For anaphylaxis/suspected anaphylaxis fill the relevant part in Section 5)* *(Attach extra papers if needed)*
Management *(for events other than anaphylaxis/suspected anaphylaxis; specify the dose, strength, route and site of administration of each drug)* *(For anaphylaxis/suspected anaphylaxis fill the relevant part in Section 5)* *(Attach extra papers if needed)*
Diagnosis/Cause of death
Post mortum findings (if relevant)

Section 4- Clustering of events.

Similar events among other clients who attended the same clinic	Yes☐ No☐
Similar events among other clients using the same brand of the particular contraceptive	Yes☐ No☐
Similar events reported in the community(other than among the contraceptive users)	Yes☐ No☐

Signature & date..... Designation.....

Section 5 (*In case of an anaphylaxis and suspected anaphylaxis this section has to be filled by a district level team headed by the MO.MCH).*

5.1 Signs and symptoms					
System involved	**Sign or symptom**	**Date and time of appearance*** **	**System involved**	**Sign or symptom**	**Date and time of appearance**
Skin and Mucosa[1] (Specify the site)			Central Nervous System[4]		
Respiratory System[2]			Gastro-Intestinal System[5]		
Circulatory System[3]			Any other		

5.2. Management									
Name of the drug	Dose & Route	Site	Strength	Time	BP/Pulse		Place (hospital, field.etc)	Expiry date of adrenaline	Batch number of adrenaline
					Before	After			
Adrenaline 1st dose									
Adrenaline 2nd dose									
Any other drugs (Specify)									
Expiry date of adrenaline and batch number-									
Who has given adrenaline-									
Details of any other procedures related to patient management(eg: CPR)									

5.3. Investigations	
Blood for Mast cell tryptase 1st sample	Time
Blood for Mast cell tryptase 2nd sample	Time
Any other investigation :	Results

5.4. Diagnostic Criteria-			
Rapid onset of signs/symptoms		≥ 2systems involved	

Important signs/symptoms of each system are listed below:

1.Urticaria,erythema,pruritis,prickling sensation, bilateral red eye, unilateral red eye, itchy eyes , angio-oedema in tongue/throat/uvula/larynx/lip/face/limbs/others,

2.Sneezing,rhinorrhoea,sore throat, hoarse voice, stridor, sensation of throat closure, cough, tachypnoea, difficulty in swallowing, rhonchi, wheezing, in drawing /retractions, chest tightness, grunting, cyanosis, difficulty in breathing

3.Decreased central venous pressure, capillary refill time >3 sec, heart rate (specify the rate)

4.Loss of consciousness, distress

5.Diarrhoea,nausea,abdominal pain/cramps, vomiting

***** For diagnosis of anaphylaxis it is of special importance to identify the signs/symptoms which occur before administration of adrenalin. Thus please give special attention when specifying the time.**