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சுவசிரிபாய
SUWASIRIPAYA

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சுகாதார பராமரிப்பு வைத்திய சேவைகள் அமைச்சு
Ministry of Health
385, දුම්බර බුද්ධරක්ඛිත විහාරාංශ වීදිය, කොළඹ 10.
385, Rev. Baddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.

30 JAN 2

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දිනය 29.12.201
திகதி)

All Provincial Directors of Health Services,

Regional Directors of Health Services,

Heads of Institutions,

Revised Notification and Investigation System for Adverse Events Following Contraceptive Usage, Contraceptive Failures and Suspected Quality Failures of Contraceptive Commodities.

The goal of National Family Planning Programme is to enable all couples in Sri Lanka to have a desired number of children with optimal spacing whilst preventing unintended pregnancies, by providing safe and effective family planning services.

However, around 70 complications including few life threatening complications, and around 500 suspected contraceptive failures are reported to the National Family Planning Programme each year. Quality is a concern in relation to any medical device. Considering all these, it has been identified the importance of having a notification and investigation system on above in order to maintain and improve the quality of the National Family Planning Programme.

The existing formats have been revised and finalized by the Family Health Bureau in consultation with international and local technical experts to notify and investigate adverse events following contraceptive usage including contraceptive failures.

Following formats are introduced under this system,

1. Form I- Notification form for adverse events (other than anaphylaxis) following administration of contraceptives.
2. Form II- Investigation form for anaphylaxis/severe complications following contraceptive usage
3. Form III- Investigation form for contraceptive failures.
4. Notification form for anaphylaxis following administration of contraceptives
5. Drug sample for quality testing (Complaint/ Surveillance) form

The draft formats and the procedure for notification and investigation are annexed herewith.

Anaphylaxis Event Record (AER) which is already in use has been changed as 'Notification form for anaphylaxis following administration of contraceptives' to notify anaphylaxis and suspected anaphylaxis events. 'Drug sample for quality testing (Complaint/ Surveillance)' form will continue to be used to investigate suspected quality failures of contraceptive commodities.

It is recommended to form district level committees of 3-5 members, led by MO.MCH which can be quickly mobilized to investigate anaphylaxis/ suspected anaphylaxis events.

Head of the Institution is responsible for and should ensure the efficient functioning of above mentioned notification and investigation system.

All Provincial Directors of Health Services, Regional Directors of Health Services and Heads of Institutions are kindly requested to bring to the notice of the relevant staff the contents of this letter.

Thank you.

.....

Dr.P.G.Mahipala,

Director General of Health Services.

Cc:

1. Deputy Director General (Public Health Services II)
2. Deputy Director General (Medical Services II)
3. Director/Maternal and Child Health
4. Director/Private Health Sector Development
5. Director/National Institute of Health Sciences
6. Chief Medical Officer of Health, Colombo Municipal Council
7. Medical Superintendents/District Medical Officers/Medical Officers in Charge- Base Hospitals/Divisional Hospitals
8. President/Sri Lanka College of Obstetricians and Gynecologists.
9. Medical Officers/Maternal and Child Health
10. Medical Officers of Health

FORM I

Complication other than anaphylaxis	
Contraceptive failure	
Poor quality	

Notification form for adverse events (other than anaphylaxis) following administration of contraceptives.

1. Reporting Source				
Institution		Telephone no:		
Designation of the reporting officer				
2. Information of the product/procedure				
Name of the product /procedure (OCP/DMPA/Implants/Condoms/LRT/Vasectomy)				
Brand (If relevant)		Batch Number (If relevant)		
3. Information regarding the patient (If relevant)				
Name		RDHS area		
Age (in years)		MOH division		
Telephone number		PHM area		
Address				
Date of administration of the method		Date of appearance of symptoms		
4. Information regarding the service provider				
Government ☐	Private ☐	Non-Governmental Organization ☐		
Name of the Institution/clinic				
5. Tick the event.				
OCP	**IUCD**	**Condom**	**DMPA**	**Implants**
Allergy ☐ Thromboembilism ☐ DVT ☐	Allergy ☐ Internal organ damage ☐ Perforation of uterus ☐ Expulsion ☐ Infection ☐ Vasovagal attacks ☐	Allergy ☐	Allergy ☐ Abscess ☐ Minor local reaction/ local infection ☐ Severe local reaction ☐	Allergy ☐ Local infection ☐ Abscess ☐ Local reaction ☐ Thromboembolism ☐ Difficult removal or missing rods ☐ DVT ☐ Expulsion ☐
Other event: (e.g Contraceptive failures, quality failures, any clustering of events, any event occurring in unusual numbers, any hospitalization, any event of public concern and any event the informant thinks necessary to inform) (Please describe):				
6. Outcome of the patient				

....

Signature & Designation of the Officer **Date**

Director/MCH - Family Health Bureau, No 231,De Saram Place,Colombo10
Tel;0112696677,0112681309, Fax 0112690790
Director/ MT & S - No 120,Norris Canal Road ,Colombo 10, Tel 0112698896/7, Fax 0112689704
Director/NDQAL - No 120,Norris Canal Road ,Colombo 10, Tel 0112687744, Fax 0112687742

Notification and investigation of an adverse event

	Event	Method and form	Time duration	Responsible officer to inform the event	To whom to inform
1.	Anaphylaxis	1) Over the phone	Within 6 hours	Any physician administering the method	D.MCH/FHB MO.MCH MOH
		2) Notification form for anaphylaxis following administration of contraceptives.	Within 24 hours		
		3) Form II	Within 7 days	MO.MCH	D.MCH/FHB
2.	1.Any serious reaction other than anaphylaxis 2.Clustering of events	1) Form I	Within 3 days	Any physician administering the method	D.MCH/FHB MO.MCH MOH
		2) Form II (Section 4)	Within 7 days	MOH	D.MCH/FHB MO.MCH
3.	Any minor reaction mentioned under sec. 5 of form I	1) Form I	Within 14 days of notification	Any physician administering the method	D.MCH/FHB MO.MCH MOH
		2) Form II	Before the 5th of following month	MOH	D.MCH/FHB MO.MCH
4.	Suspected quality failure	1) Over the phone	Within 6 hours	Any physician administering the method	D.MCH/FHB D.MT&S D.NDQAL MO.MCH MOH
		2) Form I	Within 3 days		
		3) Drug sample for quality testing(complaint/surveillance) form	Within 7 days		
5.	Contraceptive failure	1) Form I	Within 14 days	Any physician administering the method	D.MCH/ FHB MO.MCH MOH
		2) Form III	Before the 5th of following month	MOH	MO.MCH (To be reviewed at MCH review)

***Diagnostic criteria of anaphylaxis –**

Rapid onset of signs and symptoms of two or more of the following systems:
1.Skin and mucosa (including eyes and angio-edema of any site) 2. Respiratory system
3. Circulatory system 4.CNS 5.GIT

***Lab confirmation of anaphylaxis -Collect two blood samples (2 cc). First sample at ½ hour to 3 hours and second sample at 24 hours from the onset of the event. Centrifuge to separate the serum, and store in deep freezer until handed over to MRI. Send to MRI within 48 hours of collection**

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/commodities 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 ☐	

ection 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.**

6.1. Reasons for poor compliance as perceived by the client *(if relevant)*
7. Describe any issues related to the product /method that may have contributed to the failure (e.g. Substandard product, poor storage condition ie. whether exposed to extreme cold or warmth, extreme humidity, direct sunlight etc.)
8.Describe issues related to service provision that may have contributed to the failure (e.g. Wrong timing of initiation of the method, service provider issues, clinic over crowding, staff training etc.)
9. Field visits by PHM
Number of field visits done for this client during first 3 months of administration/insertion .....
Number of field visits done for this client after first 3 months of administration/insertion .....

10. Recommendations

....

Signature and Designation of the Officer **Date** **Contact number**

Notification form for anaphylaxis following administration of contraceptives.

(To be completed by any physician administering the method and should be sent within 24 hours of the onset of the event to D.MCH,MO.MCH,MOH)

If you suspect an anaphylaxis (see definition of anaphylaxis at the end of page 2) related to a contraceptive, please complete this form. Do not put off reporting because some details are not known. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the anaphylactic reaction.

Name:	Address:		Tel.no:
Date of birth: Age:	BHT number:	MOH Area	RDHS Area:

Past allergic history: Has patient had previous allergic reactions? ☐ Yes ☐ No

If 'Yes', Allergen is a ☐Drug ☐Vaccine (specify) ☐ Food ☐ Other Specify details,

Skin & Mucous	☐ Urticaria ☐ Erythema ☐ Pruritus ☐ Prickle sensation				Specify the site of skin reaction:	
	Eye	☐ Red bilateral		☐ Red unilateral	☐ Itchy	
	Angioedema	☐ Tongue	☐ Throat	☐ Uvula ☐ Larynx	☐ Lip ☐ Face	☐ Limbs ☐ Other
Respiratory system	☐ Sneezing ☐ Rhinorrhea ☐ Sore throat	☐ Hoarse voice ☐ Stridor	☐ Sensation of throat closure ☐ Cough	☐ Tachypnea ☐ Difficulty in swallowing	☐ Wheezing ☐ In drawing / retractions ☐ Chest tightness	☐ Grunting ☐ Cyanosis ☐ Difficulty in Breathing
Circulatory System	☐ Measured hypotension (specify BP)		☐ Decreased central venous pulse		☐ Capillary refill time >3secs	☐ Tachycardia (specify rate)
CNS	☐ Loss of consciousness		☐ Distress	☐ Other(specify):		
GIT	☐ Diarrhea	☐ Nausea		☐ Abdominal pain/cramp		☐ Vomiting
Diagnostic Criteria for anaphylaxis	☐ **Rapid onset of occurrence of above sign & symptoms**			☐ **Two or more systems are affected**		

Date & Time of contraceptive administration: Date(dd/mm/yy) Time : am/pm

Drug : Oral ☐ Parenteral ☐		☐1st dose ☐2nd dose ☐3rd dose ☐4th dose ☐Other
Generic name :	Trade name :	Dose (specify units, mg, ml, mg/kg) and regimen
Batch/Lot number :		Expiry date :

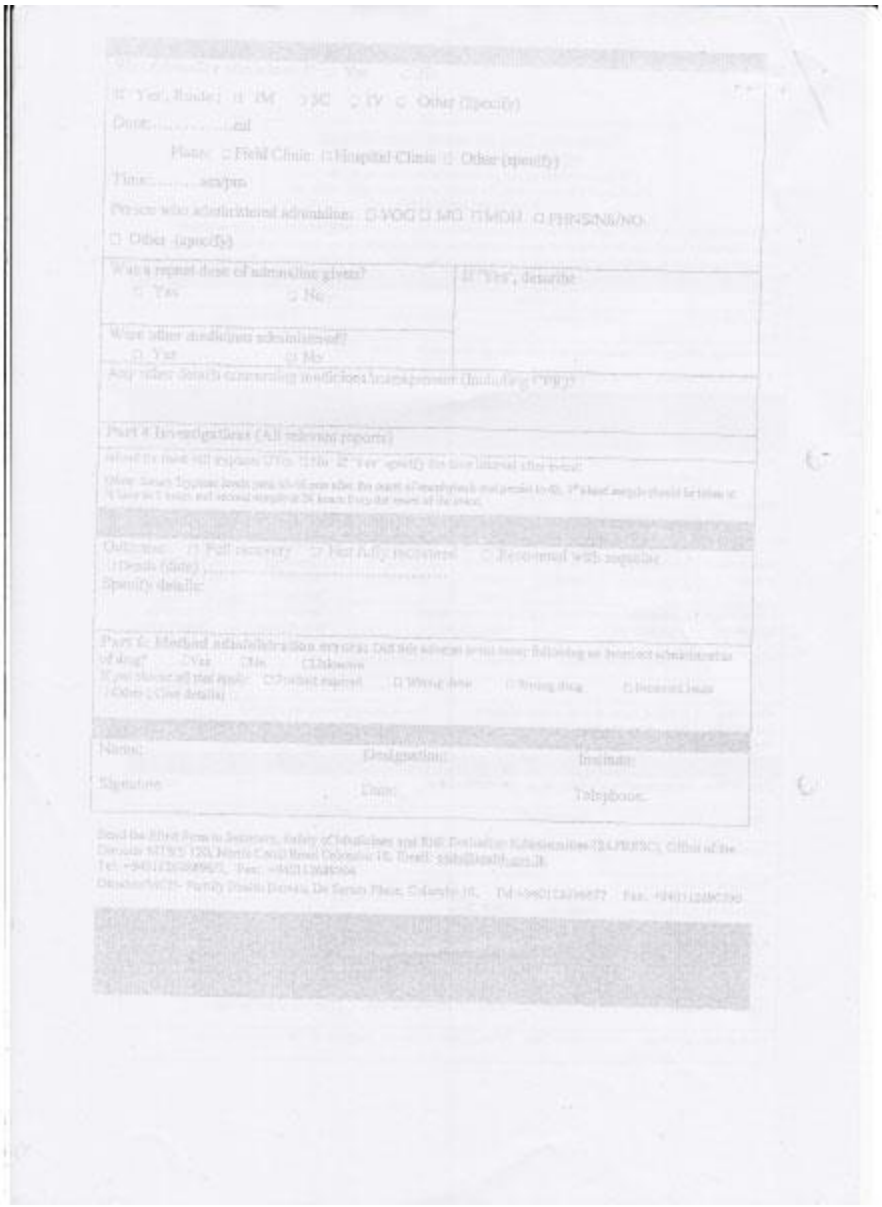
If parenteral contraceptive : ☐ Single dose ☐ Multi dose

Route of administration: ☐ Oral ☐ IM ☐ SC ☐ Other(specify)

Site of Administration: ☐ Deltoid ☐ Thigh ☐ Buttock ☐ Other (specify)

Person who administered: ☐VOG ☐MO ☐ MOH ☐ PHNS/NS/ NO ☐ PHM ☐ Other (specify)

Place of administration: ☐ Hospital Clinic ☐ Field Clinic ☐ Private Hospital ☐ GP ☐ Other(specify)



ANNEXURE X

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Director
National Drug Quality Assurance Laboratory
120 Norris Canal Road
Colombo 10

DRUG SAMPLE FOR QUALITY TESTING (COMPLAINT / SURVEILLANCE)

LABEL

1. Name of the product.
   (a) Generic name .....
   (b) Brand name (if any) .....
2. Dosage form .....
3. Specifications (state whether B.P., U.S.P., N.F., etc.):.....
4. Strength/s of the product (i.e., active ingredients):.....
5. Composition of the drug product (i.e. Each enteric coated tablet contains ... / or each ... etc):.....
   .....
6. Batch numbe. / Lot number :.....
7. Date of manufacture (if any) :.....
8. Date of expiry :.....
9. Manufacturer's name and full address. :.....
10. Description of the original container/pack :.....
    (if different from the submitted pack)
11. Quantity submitted Defective (YES/NO) Quantity: .....
    Unopened Packs (YES/NO) Quantity: .....
12. Stock available at the institution of the drug product of the same batch
    .....
13. Storage requirements stated on the label :.....
14. Storage condition at the source :.....
15. Nature of the problem /complaint with all relevant details
    .....
16. Any other remarks:.....

Name, Address and designation of the Officer making the request.

Head of the Institute / Decentralised Unit