ASSOCIATED HOSPITAL
GOVERNMENT MEDICAL COLLEGE KATHUA

ADVERSE DRUG REACTION POLICY

	GOVT. MEDICAL COLLEGE, KATHUA JAMMU AND KASHMIR	**Doc. No.**	**04**
		Issue Date	**15-06-2020**
		Revision Date	**15-12-2020**
		Revision No.	
		Next Review	**15-06-2020**
		Total Pages	**06**

Document Approval

Manual Name	**ADVERSE DRUG REACTION POLICY**	
Prepared By	• **Dr. Yangchen Dolma (I/C Medical Superintendent and HOD Community Medicine)** • **Aditya Bhanotra (Record Clerk)**	Signature
Reviewed By	**Dr. Yangchen Dolma (I/C HOD Community Medicine)**	Signature
Approved By	**Dr. Suleman Choudhary (Principal, GMC Kathua)**	Signature

List of contributors

S.no	Name	Designation
1	Dr.Yangchen Dolma	Assistant Professor
2	Aditya Bhanotra	Record Clerk

ADVERSE DRUG REACTION POLICY

ADVERSE DRUG REACTION POLICY

POLICY:

The policy is pertaining to adverse drug reaction reporting and Follow-up

PURPOSE:

To describe the procedure and reporting a adverse drug reaction for multi disciplinary review to all follow-up and prevent future medication errors

DEFINITION:

Adverse Drug Reaction (ADR) - any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

ABBREVIATION:

ADR: Adverse Drug Reaction.

SCOPE:

All Patient care areas.

RESPONSIBILITY:

Faculty, Consultants, Medical Officers, Staff nurses, FMPHWs and Pharmacists.

PROCESS DETAILS:

- Always suspect an ADR in the unwell patient taking any medication.
- The first step in management is to withhold or withdraw the suspected drug.
- Further treatment should be decided on an individual basis.
- Always tell the patient of a suspected ADR so that they are able to take precautions in the future.

REPORTING OF ADR

Adverse drug reactions are reported immediately to the doctors on duty by the nurses. Patient is also informed of the ADR. In case adverse reaction is not controlled within 10 to 15 minutes, treating Medical Officer refer the patient for further management. Adverse drug reaction forms are completed with 24 hours. A copy of adverse drug reaction form is also to be kept in patient's file.

COMPILING AND ANALYSIS OF ADVERSE DRUG EVENTS

Adverse drug events due to IV infusions of fluids are recorded with details of the batch No., expiry date, manufacturing date of I/V fluids, IV sets. The infusions is discontinued, immediately, bottle and I/V transfusion set are sealed and sent to the laboratory for cultures and incompatibility if any. After getting the report from the lab the event is analyzed, the pharmacy is instructed to stop issuing the concerned lot with same batch no. and distributor / manufacturer is intimated. Corrective and preventive actions are taken on the basis of analysis of data. Drugs Committee shall analyze ADR and take necessary preventive actions for reducing the risk of ADRs.

ACTIVITY AND RESPONSIBILITY:

S. No.	Procedural Steps	Responsibility
1.	After administration of the medicine, patient shall be monitored	Ward nurse / Treating medical officer
2.	If a patient suffers from ADR immediate Treatment must be prompted	Medical officer
3.	Adverse drug Reaction are reported immediately to the duty Medical officer	Nurse
4.	If patient condition cannot be controlled by Duty Medical officer, he/she has to refer the patient.	Duty Medical Officer
5.	Adverse event reporting form is filled up within 24hrs of ADR	Nurse/ Duty Medical officer
6.	A copy of Adverse event reporting form is also to be kept in patient's file.	Nurse
7.	Drugs Committee shall analyze ADR and take necessary preventive actions for reducing the risk of ADRs.	