DevelopmentofPharmacovigilanceElectivemoduleformedical students

According to the National Medical Commission, it is mandatory to conduct electives during MBBScurriculum.Electiveisthecoursewhichthestudentsoptontheir own.Pharmacovigilance refers to detection, assessment, understanding and prevention of adverse effects (WHO). There is dearthof literature regardingpharmacovigilanceelective programsin India. MBBSstudents need comprehensive training about pharmacovigilance during UG curriculum for its thorough understanding and clinical application. An effective pharmacovigilance module can help in developing Indian Medical Graduate (IMG) into a better clinician, professional and critical thinker.

Comment [BU1]: ?

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1. OBJECTIVES:

Attheendoftheelective,thelearnersshallbeable to:

a. TogetabetterunderstandingoftheconceptofPharmacovigilance.
b. Tohavetheknowledgeofunderstanding,prevention,managementandreportingof adversedrug reactions (ADR).
c. TohaveknowledgeaboutPharmacovigilanceprogramofIndia.
d. ToidentifyADR,fillintheADRform,performcausalityassessmentanduploadingin VIGIFLOW software.

2. LEARNINGOUTCOMES:

Attheendofthecourse,studentsareexpectedtohavegained:

a. Knowledge about understanding the concept of Pharmacovigilance, identifyand analyze various types of ADR.
b. SkillstoidentifytheADRinclinicalsettingsandreporttheADRtoAMC (Adverse drug monitoring center).
c. Skillstoanalyze&interprettheADRdataandperformcausalityassessmentto generate signal.
d. Communicationskillstocommunicate effectivelywithhealthcare professionals.
e. SkillstouploadthedataonVIGIFLOWsoftware.

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3. DURATIONOFCOURSEANDMINIMUMQUALIFICATIONFORADMISSION:

a. Durationofthecourseis2weeks.

b. CandidateshouldhaveclearedPart-1MBBS.

c. CandidateshouldoptforelectiveinPharmacovigilance.

Comment [BU2]: Alignment issue

4. INSTRUCTIONALDESIGN:

TheTeaching-Learningstrategiesincludemainlyleaner centeredwithcombinedmodeoflearning.It comprises, but not limited to the following:

a. Teachinglearningmethodology:

Themodalityofteachingwillbeintheformoflectures,self-directedlearning,demonstrations, tutorials, case discussions, hands on training etc.

S.No	Topicsto becovered	Teaching hoursallotted (hrs.)	Teaching-learning method
1	ADRtypes,identificationand classification	1	Interactivelecture

2	Regulatoryframework:nationaland international	1	Interactivelecture
3	Pharmacovigilance databases	1	Interactivelecture
4	Pharmacovigilancecommunication	1	Grouppresentation and discussion
5	Mockpharmacovigilance meeting	1	Grouppresentation and discussion
6	Pharmacovigilancelifecycle	1	seminar
7	Pharmacovigilanceand medical devices	1	Interactivelecture
8	Globalharmonizationin pharmacovigilance	1	Interactivelecture,
9	PvPI	1	Seminar
10	ADRCase presentation	1	Discussion

II:Practical

1	ADR case discussion. 'IndividualCaseSafetyReports' ('ICSRs')-assessmentandformationof a report	Groupdiscussionand analysis of case
2	ADRreportingformfilling,causality assessment, review & feedback. Importantcasefindings&its significance.	Hands-onexercise, demonstration
3	Dataanalysistools. IntroductiontovariousPVdatabases	Practicalsession
4	Signaldetectionprinciples. Signaldetectionandmanagement: finding and analysis of ICSRs	Simulation exercise and group discussion onstrategiesforsignal management.
5	Pharmacovigilanceandrisk management.	Group presentationsand discussions

6	ImportanceofcommunicationinPV. Communication of drug safety information.	Roleplay,peer evaluation and feedback
7	Medicationerrors	Demonstration
8	Hospitalvisit	

5. SYLLABUS

S.No	Topic
	THEORY
1.	WhatisPharmacovigilanceandwhatistheneed? Introduction:Definition&ImportanceofPharmacovigilance(PV),historical aspect, PV in India and world.

2.	BasicaspectsofADRs AdverseDrugreaction(ADR):WHOdefinitionofADR,identification& different types of ADR.
3.	ADRsofsomedrugs Regulatorybodies:India(PvPI),Global(UMC),Responsibilities,legal obligations.
4.	'IndividualCaseSafetyReports'('ICSRs') DetectionofSignal&itsmanagement:understandingsignaldetection, management of the signal, techniques of minimizing risks.
5.	Collection of data and its analysis Differentmethodsofcollectingdata Analysis techniques and tools
6.	Pharmacovigilanceinherbalandalternativemedicine Herb drug interaction and adverse events Importanceofmonitoringherbalandalternativemedicine

7.	Pharmacovigilance in Clinical trials Monitoringdrugsafetyinclinicaltrials Challenges and considerations
8.	Pharmacovigilance in special population Pediatric and geriatric considerations Pregnancy and lactation safety reporting MonitoringADRinpatientwithcomorbidities
9.	Benefit-RiskAssessment UnderstandingbenefitriskassessmentinPV Factors influencing benefit risk assessment Principles of risk assessment
10.	Ethics in PharmacovigilancePatientconfident ialityandreporting Reporting ADR
11.	Recent trends in pharmacovigilance RoleofBigdata,artificialintelligence

12.	SourcesofInformation
PRACTICAL	
S.No	**Topic**
1	CasestudyofADRanalysis.
2	ADRReporting&documentation.
3	PVdatabase&dataanalysistools,dataentryinVIGIFLOW.
4	Causalityassessment,assessmentofseverityofADR.
5	SimulationonSignaldetection.

6	CommunicationinPV.
7	Benefit/riskassessment

6. ASSIGNMENTS

- Onceaweektheoryassignment
- Onceaweekpracticalassignment

7. ASSESSMENT

Formativeassessment

Twiceaweek

Summativeassessment

- StudentLogbookhavingrecordofdailyactivitiestobemaintainedandsignedbythesupervisor with a "meets expectations" (M) grade after completion of electives.
- e-portfoliotobecreated

i) Documentationofcases

ii) Documentationofpowerpointpresentationdone

- 75%attendance&submissionoflogbook&e-portfolioiscompulsorytotakePart2Summative exams.

8ATTENDANCE:80 % attendance is mandatory in Theory and practical respectively.considering theory andpractical separately. The candidate shall complete the prescribed course satisfactorily to be eligible toappear for the final assessment and award of certificate.

9. PRE/POSTTEST:

To knowthelevel ofunderstanding priorto the courseand knowledgeacquired bythe participants during the course, a qualitative test will be conducted.

10. ASSESSMENTANDEVALUATION:

Quizzes**:**Shortquizzescoveringthekeyconceptsandlearningoutcomescanbeusedtoassessthe understanding and retention of material.

Writtenassignments:Writtenassignmentsthatrequirestudentstoapplytheconcepts.

GroupProjects**:**Projectsthatrequirestudentstoworktogethertoanalyzeandinterpret.

Examinations**:**Examsthatconsistofmultiple-choicequestions,shortanswers,longanswerquestions can be used to evaluate the understanding of the material.

11. **CRITERIA FOR AWARD OF GRADES AND CERTIFICATE:** A candidate shall be declaredPass and eligible for award of grade in certificate course if he/she secures at least 50% marks in both internal assessment and final assessment. A candidate qualifying certificate course will be awarded 10 credits for the said course.

12. GRADINGOFPERFORMANCE:LetterGradesandGradePointAllocations:

Acandidateshallbeawarded finalgradeattheendof thecoursebased ontheperformance. Thegrades and their

corresponding grade points are as follows:

MarksObtained (Percentage)	Grade	GradePoint	Performance
90.00–100	O	10	Outstanding
80.00–80.99	A	9	Excellent
70.00–70.99	B	8	Good
60.00–60.99	C	7	Fair
50.00–50.99	D	6	Average
Lessthan50	F	0	Fail

13. RECOMMENDEDREADINGANDRESOURCES:

a. Textbook of Pharmacovigilance concept and practice by GuruprasadMohanta,PrabalKumarManna.PharmaMedPress, latest edition.
b. TextbookofPharmacovigilancebySKGuptaand Shushma Srivastava, Jaypee Publications, latest edition.
c. FundamentalsofPharmacovigilancebySumitVermaandYogesh Gulati, Paras Medical Publications, latest edition.
d. E-Resources–Availableat: https://www.who-umc.org/media/165164/3-working-with-data-entry .pdf

e. E-Resources–Vigiflowuserguide.Availableat: https://www.adr.who-umc.org/userguide.pdf