

## Development of Pharmacovigilance Elective module for medical students

According to the National Medical Commission, it is mandatory to conduct electives during MBBS curriculum. Elective is the course which the students opt on their own. Pharmacovigilance refers to detection, assessment, understanding and prevention of adverse effects (WHO). There is dearth of literature regarding pharmacovigilance elective programs in India. MBBS students 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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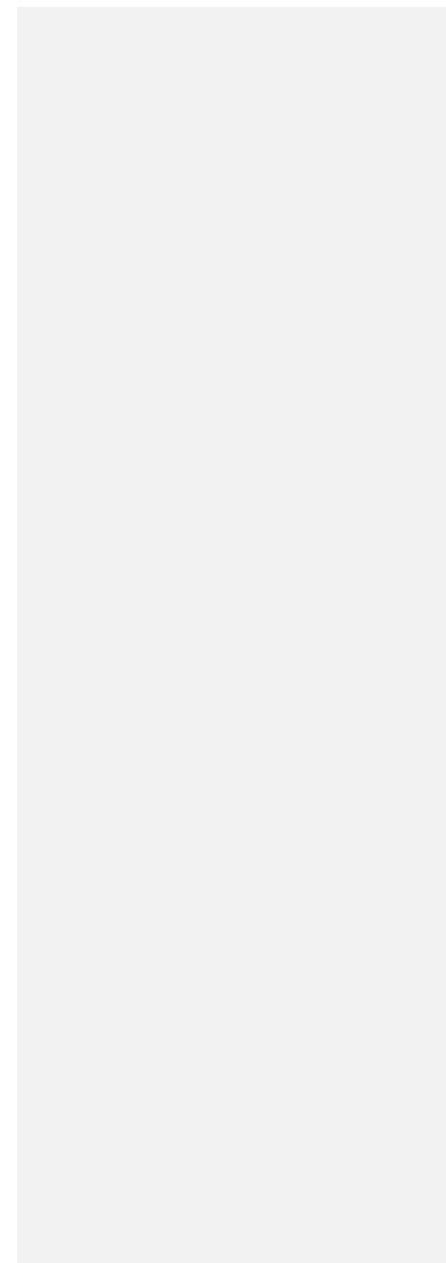
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## 1. OBJECTIVES:

At the end of the elective, the learners shall be able to:

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- a. To get a better understanding of the concept of Pharmacovigilance.
- b. To have the knowledge of understanding, prevention, management and reporting of adverse drug reactions (ADR).
- c. To have knowledge about Pharmacovigilance program of India.
- d. To identify ADR, fill in the ADR form, perform causality assessment and uploading in VIGIFLOW software.

## 2. LEARNING OUTCOMES:

At the end of the course, students are expected to have gained:

- a. Knowledge about understanding the concept of Pharmacovigilance, identify and analyze various types of ADR.
- b. Skill to identify the ADR in clinical settings and report the ADR to AMC (Adverse drug monitoring center).
- c. Skill to analyze & interpret the ADR data and perform causality assessment to generate signal.
- d. Communication skill to communicate effectively with healthcare professionals.
- e. Skill to upload the data on VIGIFLOW software.

### 3. DURATION OF COURSE AND MINIMUM QUALIFICATION FOR ADMISSION:

- a. Duration of the course is 2 weeks.
- b. Candidates should have cleared Part-1 MBBS.
- c. Candidates should opt for elective in Pharmacovigilance.

Comment [BU2]: Alignment issue

### 4. INSTRUCTIONAL DESIGN:

The Teaching-Learning strategies include mainly learner centered with combined mode of learning. It comprises, but not limited to the following:

#### a. Teaching learning methodology:

The modality of teaching will be in the form of lectures, self-directed learning, demonstrations, tutorials, case discussions, hands on training etc.

S.No	Topics to be covered	Teaching hours allotted (hrs.)	Teaching-learning method
1	ADR types, identification and classification	1	Interactive lecture

2	Regulatory framework: national and international	1	Interactive lecture
3	Pharmacovigilance databases	1	Interactive lecture
4	Pharmacovigilance communication	1	Group presentation and discussion
5	Mock pharmacovigilance meeting	1	Group presentation and discussion
6	Pharmacovigilance lifecycle	1	seminar
7	Pharmacovigilance and medical devices	1	Interactive lecture
8	Global harmonization in pharmacovigilance	1	Interactive lecture,
9	PvPI	1	Seminar
10	ADR Case presentation	1	Discussion

## II: Practical

1	ADR case discussion. 'Individual Case Safety Reports' (ICSRs)-assessment and formation of a report	Group discussion and analysis of case
2	ADR reporting form filling, causality assessment, review & feedback. Important case findings & its significance.	Hands-on exercise, demonstration
3	Data analysis tools. Introduction to various PV databases	Practical session
4	Signal detection principles. Signal detection and management: finding and analysis of ICSRs	Simulation exercise and group discussion on strategies for signal management.
5	Pharmacovigilance and risk management.	Group presentations and discussions



6	Importance of communication in PV. Communication of drug safety information.	Roleplay, peer evaluation and feedback
7	Medication errors	Demonstration
8	Hospital visit	

## 5. SYLLABUS

S.No	Topic
<b>THEORY</b>	
<b>1.</b>	What is Pharmacovigilance and what is the need? Introduction: Definition & Importance of Pharmacovigilance (PV), historical aspect, PV in India and world.

2.	<p>Basic aspects of ADRs</p> <p>Adverse Drug reaction (ADR): WHO definition of ADR, identification &amp; different types of ADR.</p>
3.	<p>ADRs of some drugs</p> <p>Regulatory bodies: India (PvPI), Global (UMC), Responsibilities, legal obligations.</p>
4.	<p>'Individual Case Safety Reports' ('ICSRs')</p> <p>Detection of Signal &amp; its management: understanding signal detection, management of the signal, techniques of minimizing risks.</p>
5.	<p>Collection of data and its analysis</p> <p>Different methods of collecting data</p> <p>Analysis techniques and tools</p>
6.	<p>Pharmacovigilance in herbal and alternative medicine</p> <p>Herb drug interaction and adverse events</p> <p>Importance of monitoring herbal and alternative medicine</p>

<b>7.</b>	Pharmacovigilance in Clinical trials Monitoring drugs safety in clinical trials Challenges and considerations
<b>8.</b>	Pharmacovigilance in special population Pediatric and geriatric considerations Pregnancy and lactation safety reporting Monitoring ADR in patient with comorbidities
<b>9.</b>	Benefit-Risk Assessment Understanding benefit risk assessment in PV Factors influencing benefit risk assessment Principles of risk assessment
<b>10.</b>	Ethics in Pharmacovigilance Patient confidentiality and reporting Reporting ADR
<b>11.</b>	Recent trends in pharmacovigilance Role of Big data, artificial intelligence

<b>12.</b>	Sources of Information
<b>PRACTICAL</b>	
<b>S.No</b>	<b>Topic</b>
1	Case study of ADR analysis.
2	ADR Reporting & documentation.
3	PV database & data analysis tools, data entry in VIGIFLOW.
4	Causality assessment, assessment of severity of ADR.
5	Simulation on Signal detection.

6	CommunicationinPV.
7	Benefit/riskassessment

## 6. ASSIGNMENTS

- Once a week theory assignment
- Once a week practical assignment

## 7. ASSESSMENT

### **Formative assessment**

Twice a week

### **Summative assessment**

- Student Logbook having record of daily activities to be maintained and signed by the supervisor with a “meets expectations” (M) grade after completion of electives.
- e-portfolio to be created
  - i) Documentation of cases
  - ii) Documentation of powerpoint presentation done
- 75% attendance & submission of logbook & e-portfolio is compulsory to take Part 2 Summative exams.

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

## **9. PRE/POSTTEST:**

To know the level of understanding prior to the course and knowledge acquired by the participants during the course, a qualitative test will be conducted.

## **10. ASSESSMENT AND EVALUATION:**

Quizzes: Short quizzes covering the key concepts and learning outcomes can be used to assess the understanding and retention of material.

Written assignments: Written assignments that require students to apply the concepts.

Group Projects: Projects that require students to work together to analyze and interpret.

Examinations: Exams that consist of multiple-choice questions, short answers, long answer questions can be used to evaluate the understanding of the material.

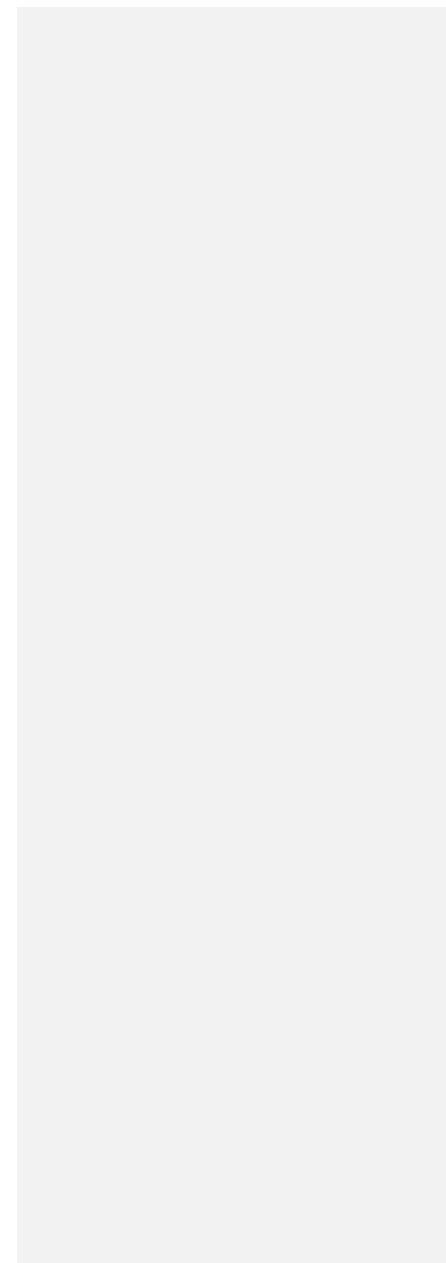
**11. CRITERIA FOR AWARD OF GRADES AND CERTIFICATE:** A candidate shall be declared Pass and eligible for award of grade in certificate course if he/she secures at least 50% marks in both internal assessment and final assessment. A candidate qualifying certificate course will be awarded 10 credits for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

## **12. GRADING OF PERFORMANCE: Letter Grades and Grade Point Allocations:**

A candidate shall be awarded final grade at the end of the course based on the performance. The grades and their

corresponding grade points are as follows:

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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

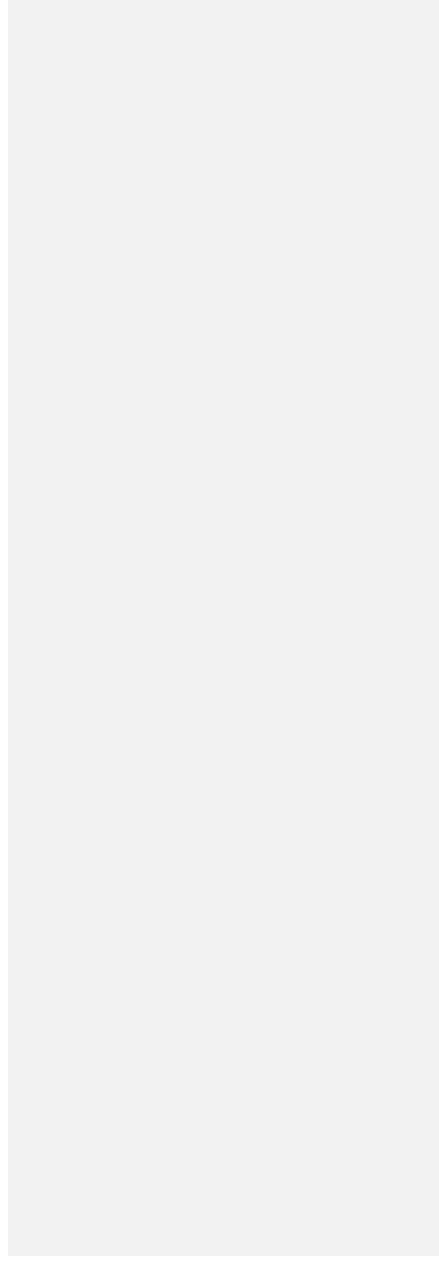
### 13. RECOMMENDEDREADINGANDRESOURCES:

- 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>

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