AIMS | COLLEGE OF PHYSIOTHERAPY

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Approved By : Govt. of Maharashtra Affiliated to : Maharashtra University of Health Sciences (MUHS),Nashik & Maharashtra State OTPT Council, Mumbai

Pharmacovigilence Committee

1. Purpose

To establish a systematic process for detecting, assessing, reporting, and preventing Adverse Drug Reactions (ADRs) and physiotherapy-induced adverse events observed in practice, ensuring patient safety and compliance with India's Pharmacovigilance Programme of India (PvPI). This SOP emphasizes physiotherapy-specific contexts like drug effects during gait analysis, neurorehabilitation, and therapy-related harms.

2. Scope

Applies to all physiotherapy faculty, students, and clinical staff in college clinics, OPDs, and affiliated hospitals. Covers ADRs from medications impacting rehab (e.g., statins causing myopathy, antihypertensives inducing dizziness). Includes physiotherapy-induced adverse events (e.g., post-manual therapy soreness).

3. Definitions

i. ADR: Harmful, unintended response to medication at normal doses, observed during therapy (e.g., neuropathy worsening balance).
ii. Physiotherapy-Induced Adverse Event: Unintended harm from PT interventions (e.g., increased pain after manipulation, falls during gait training).
iii. Physiotherapy-Relevant Event: Any drug or therapy effect altering gait, strength, mobility, or rehab outcomes.

4. Committee Composition

Role	Physiotherapy-Specific Criteria	Responsibilities
Chairman	Dr. Abhijit Satralkar	Approves reports, chairs meetings.
Coordinator	Dr. Samika Wagh	PvPI, Vigiflow reporting, training.
Members	Dr. Sheetal Bamhane	ADR and PT event assessment in rehab contexts.

	DR. Unika Purohit	
	Dr. Shruti Patil	
	Dr. Omeshree Meshram	
	Dr. Nitin Wagh	
	Dr. Namrata Parekh	
	Dr. Rahul Kuril	
Student Rep	Third-year BPTh student Stavanraj Pillai.	Awareness campaigns.

Appointment: Nominated by Dean based on PvPI training completion; 2-year term.

5. Procedure

5.1 Detection (Physiotherapy Focus)

- During assessments/sessions: Note drug-related changes (e.g., statin weakness in gait lab) or PT-induced issues (e.g., soreness post-mobilization).
- Use SOAP notes: Flag "Suspected ADR/PT Event: [Drug/Intervention] → reduced ROM/mobility."
- Differentiate via baseline comparison (e.g., pre/post therapy metrics).

5.2 Reporting Process

- Faculty/student completes Individual Case Safety Report (ICSR) form within 24 hours for ADRs/serious PT events.
- Submit to Coordinator via email/portal; include PT metrics (e.g., Timed Up and Go score, pain scale pre/post).
- Coordinator assesses causality (Naranjo for ADRs; clinical judgment for PT events); forwards ADRs to PvPI Vigiflow within 48 hours (serious: 24 hours). Log all PT events internally.
- Feedback loop: Update patient therapy plan (e.g., modify exercises for dizziness or add ice for soreness).
- Physio-Specific Form Fields: Pre-therapy baseline (gait speed, strength, pain VAS). Observed change (e.g., "Amlodipine → orthostasis during balance training" or "Manipulation → transient neck soreness").

5.3 Analysis and Risk Mitigation

- Quarterly review: Trends in drug ADRs (e.g., anticonvulsants → fatigue) and PT events (e.g., manual therapy complications).
- Update protocols: E.g., screen for statin myopathy pre-strength training; contraindications for high-risk manipulations.

6. Training Requirements

- Mandatory PvPI Skill Development Programme for Coordinator/members (online, ipc.gov.in).
- Annual workshops: "ADRs and PT Adverse Events in Rehab" for students (case-based: gait deviations from analgesics or post-exercise falls).
- Track via certificates; 100% faculty coverage target.

7. Documentation and Records

- Maintain combined ADR/PT event log (Excel/PvPI portal): Confidential, 5-year retention.
- Meeting minutes, reports archived digitally.

8. Monitoring and Audit

- Metrics: # ADRs/PT events reported quarterly; training attendance.
- Annual internal audit; report ADRs to PvPI/IPC. Non-compliance escalates to Dean.

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