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ORIGINAL ARTICLE

The Gestational Triad: A Framework for Integrating Pharmacovigilance, Clinical Care and Community Health in Maternal Medicine

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ABSTRACT

Aim of Study: This study aimed to develop and evaluate a practical, multidisciplinary framework—"The Gestational Triad"—for improving maternal health outcomes by systematically integrating pharmacovigilance (medication safety), evidence-based clinical obstetrics, and community-centered public health strategies.

Study Duration: March 2022 to March 2023.

Study Place: Niazi Medical & Dental College, Sargodha.

Methodology: A mixed-methods design was employed: 1) A retrospective analysis of 1,500 antenatal and postpartum electronic health records (EHRs) to audit drug prescribing patterns and related maternal/neonatal outcomes; 2) Establishment of a prospective, active pharmacovigilance reporting system for obstetric drugs; 3) Focus group discussions (FGDs) and structured interviews with 30 community health workers (CHWs) and 15 obstetricians to identify systemic barriers; and 4) The pilot implementation of the "Gestational Triad" protocol in two intervention community health centers, compared with two control centers.

Results: The EHR audit revealed 22% of pregnant women were prescribed medications from FDA Category C, D, or X, with incomplete documentation of risk-benefit counseling in 68% of cases. The active surveillance system identified nausea and drowsiness as the most common adverse drug reactions (ADRs) to first-line antiemetics. CHWs identified lack of medication knowledge and fear of side effects as top adherence barriers. Pilot sites implementing the Triad framework showed a 40% increase in documented risk counseling, a 25% improvement in adherence to iron-folic acid supplementation, and a 15% reduction in self-reported minor ADRs compared to control sites.

Conclusion: The "Gestational Triad" framework demonstrates feasibility and initial effectiveness in creating a synergistic workflow between drug safety monitoring, standardized clinical practice, and community-based support. Its implementation fosters more rational prescribing, empowered patients, and safer medication use during pregnancy and postpartum, offering a scalable model for resource-constrained settings.

Keywords: Maternal Health, Pharmacovigilance, Community Medicine, Obstetric Pharmacology, Patient Safety, Integrated Care.

INTRODUCTION

Maternal health is a key indicator of healthcare system effectiveness and equality. Despite global improvements, pregnancy and delivery still cause a lot of morbidity and death. Particularly in low- and middle-income countries. Managing medical issues during this important time is quite complicated. This feature exists at the junction of huge societal influences[1], major physiological changes, and the obligation to protect foetal development. Medication is used widely in this complex context, from treating urgent medical issues like hypertension or infection to providing vitamin supplements. Despite this, there remain significant obstacles outside any medical speciality. These difficulties make using prescription and over-the-counter medicines during pregnancy dangerous, although they may have greater advantages than harm[2].

The domains have historically operated separately. Pharmacovigilance, which ensures drug safety, obstetrics, which provides direct clinical care, and community medicine, which promotes community health, have always operated separately. Each section has its own priorities, data streams, and outcomes. Pharmacovigilance systems, frequently coordinated nationally, identify rare and serious adverse drug reactions (ADRs) once a medicine is brought to the market. However, pregnancy-related information is rarely recorded[3]. Clinical obstetricians make prescribing decisions under pressure and often without enough high-quality evidence. Thus, they base their decisions on faulty pregnancy risk classification (FDA A, B, C, D, X). They do this by using structured feedback that is limited to the future impact of these decisions on the community[4]. The community is also implementing medical measures to improve prenatal care. Attendance, nutrition, and birth preparedness may not address home issues like misinterpreted side effects or cost-related non-adherence, even though they directly affect therapeutic objectives[5].

This fragmentation has led to the administration of illogical or teratogenic medications, negative drug reactions that could have been prevented, patients' poor adherence to crucial therapies, and the lack of systematic learning from actual pharmaceutical use in pregnant populations. For instance, a doctor may prescribe an effective antihypertensive medication, but without a community support structure to encourage adherence and watch for adverse reactions like dizziness (which may be misdiagnosed as pregnancy fatigue), the treatment may fail and lead to severe pre-eclampsia[6]. Self-administering over-the-counter prenatal medications is also common. Without professional healthcare monitoring or the pharmacovigilance system, undisclosed dangers occur[7].

Thus, a comprehensive framework that actively bridges the different disciplines is necessary. "The Gestational Triad." is the conceptual and practical paradigm tested in this article. This model was designed to coordinate pharmacovigilance, clinical obstetrics, and community health. According to the theory, the best results from giving mothers medication are the result of the pillars' constant interaction. Pharmacovigilance provides safety science and alert mechanisms, clinical care implements evidence-based prescribing and direct management, and community health supports contextualisation, adherence, and data collection[8]. This hypothesis will be implemented in practice. Our hypothesis is that implementing a structured Triad framework will improve the quality and safety of obstetric drug prescribing, patient knowledge and adherence to treatment, and systematic capture of medication-related difficulties. We want to establish a replicable blueprint to

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improve pregnancy medication safety and efficacy. As intended, we will chronicle the integration process and results. This will transform the discrete pillars of care into a strong, integrated framework that can protect women and their newborns..

METHODOLOGY

Study Design and Setting: A convergent parallel mixed-methods study was conducted over 12 months (March 2022-March 2023) at Niazi Medical College and four affiliated community health centers (CHCs) in Sargodha District. Two CHCs were randomly assigned as intervention sites (implementing the Triad framework) and two as control sites (continuing usual care).

Development of the "Gestational Triad" Framework: The framework was designed through an expert consensus workshop involving obstetricians, clinical pharmacologists, community medicine specialists, and CHW supervisors. It defined specific roles and communication pathways for:

1. **Pharmacovigilance Unit (PVU):** Based at the medical college, responsible for training, maintaining an obstetric-focused ADR reporting system, analyzing data, and issuing safety feedback.
2. **Clinical Obstetric Teams:** Responsible for implementing evidence-based prescribing guidelines, conducting structured medication risk-benefit counseling using a standardized form, and reporting ADRs.
3. **Community Health Workers (CHWs):** Trained to provide medication adherence support, identify and report suspected ADRs or medication errors from the community, and dispel myths about drug safety in pregnancy.

Phase 1: Baseline Assessment (Months 1-3)

1. **Retrospective Record Review:** A random sample of 1,500 antenatal/postpartum EHRs from the past 24 months across all sites was audited. Data extracted included: medications prescribed (with FDA category), indication, documentation of counseling, and any documented maternal/neonatal complications.
2. **System Capability Assessment:** Existing drug safety reporting forms and communication channels between hospital and community were mapped.

Phase 2: Qualitative Exploration (Month 4)

1. **Focus Group Discussions:** Four FGDs were held with CHWs (n=20) and two with staff nurses (n=10) to explore perceptions of medication use in pregnancy, reporting barriers, and community challenges.
2. **Key Informant Interviews:** Semi-structured interviews were conducted with 15 obstetricians to understand prescribing dilemmas, information sources, and attitudes toward community feedback.

Phase 3: Intervention & Prospective Monitoring (Months 5-12)

- **In Intervention Sites Only:**

A **Training:** Separate, tailored training sessions were held for clinicians (on pharmacovigilance principles and counseling) and CHWs (on basic drug information, ADR recognition, and communication).

B **Tool Implementation:** A unified "Gestational Triad Medication Passport" was introduced for patients, containing their drug list, simplified safety information, and space for ADR notes from CHWs or patients.

C **Active Surveillance:** A simplified, mobile phone-based ADR reporting system for CHWs and clinicians was established, feeding into the central PVU.

D **Monthly Triad Meetings:** Representatives from PVU, clinical teams, and CHWs met to review reported ADRs, adherence problems, and resolve care coordination issues.

- **Control Sites:** Continued with standard practice, which included passive ADR reporting and routine antenatal care without the structured Triad tools or meetings.

Phase 4: Endline Evaluation (Month 12)

1. **Prospective Data Collection:** Over the final 3 months, data on prescribing patterns, counseling documentation, and ADR reports were collected concurrently from both intervention and control sites.
2. **Patient Survey:** An exit survey of 200 consecutive antenatal patients (100 per group) assessed medication knowledge and satisfaction.
3. **Adherence Measure:** Pharmacy dispensing records for iron-folic acid supplements were compared to expected refill rates.

Data Analysis: Quantitative data were analyzed using SPSS v.26. Chi-square and t-tests compared proportions and means between intervention and control groups. Qualitative data from FGDs and interviews were transcribed, coded, and analyzed thematically.

RESULTS

*Table 1 Explanation: This baseline audit shows medication management quality and safety issues. Despite supplementing being practically universal among pregnant women, 22% use Category C/D/X medicines, which could harm the foetus. This requires intensive counselling. The low rates of risk-benefit counselling documentation (31.7%) and current drug list recording (41.3%) imply doctor-patient communication difficulties. The 3% adverse pharmacological reaction rate is consistent with pharmacovigilance underreporting, especially during pregnancy. The system is unaware of real-world drug safety experiences. The table suggests a program that prioritises documentation, communication, and surveillance.

*Table 2 Explanation: Theme analysis reveals the fundamental human and institutional barriers to numerical inequality. Community health workers (CHWs) believe they are untrained to address medical issues, missing an opportunity to improve adherence and community-level surveillance. Lack of pregnancy-specific information and time restrictions prevent high-quality care, warn doctors. The general sense of disconnection matters most. Clinical staff and community health workers say the clinical system is not listening to them and uninformed of the prescription process. In the Triad architecture, "silos" reinforce the idea that every group's efforts are questioned without communication and responsibility.

Table 3 Explanation: This table demonstrates the operational impact of the Gestational Triad framework. Intervention sites showed dramatic improvements in key metrics. The high rate of counseling documentation and Medication Passport possession indicates successful implementation of new communication tools. Most importantly, clinical and safety outcomes improved: better adherence to essential supplements and a 50% reduction in self-reported minor ADRs, suggesting better management and patient reassurance. The ten-fold increase in ADR reporting, with 40% originating from CHWs, confirms the framework successfully activated community-based surveillance, creating a richer safety data stream. These results suggest the Triad model effectively links clinical action to community support, yielding tangible benefits.

Table 4 Explanation: This table operationalizes the Gestational Triad framework, moving from concept to concrete job roles and workflows. It clarifies how each pillar's distinct function contributes to the shared goal. The innovation lies in the specified "Key Actions" and, crucially, the "Integration Mechanism" – the monthly Triad meeting. This forum is where information outputs from each pillar (safety data, clinical reports, community feedback) are synthesized, creating a learning health system. This continuous feedback loop, where community-reported nausea informs clinical counseling and pharmacovigilance monitoring, is the engine that transforms three parallel tracks into a single, coordinated system for safe maternal medication use.

Table 1: Baseline Prescribing Patterns and Documentation from Retrospective Audit (N=1,500 Records)

Prescribing Characteristic	Frequency (n)	Percentage (%)
Records with at least one medication prescribed	1,320	88.0
Most Commonly Prescribed Drug Classes		
1. Iron & Folic Acid Supplements	1,450	96.7
2. Antiemetics (e.g., Doxylamine/Pyridoxine)	685	45.7
3. Analgesics (Paracetamol)	520	34.7
4. Antimicrobials	310	20.7
5. Antihypertensives	95	6.3
Prescriptions involving FDA Category C/D/X Drugs	330	22.0
Documentation of Medication Risk-Benefit Counseling	475	31.7
Documentation of a Current Medication List	620	41.3
Records with any mention of a suspected ADR	45	3.0

Table 2: Key Barriers to Safe Medication Use Identified in Qualitative Analysis

Stakeholder Group	Major Theme	Illustrative Quote
Community Health Workers (CHWs)	Knowledge Gaps & Fear	"Mothers often stop taking iron tablets because they cause constipation or nausea. They fear it is harming the baby, and we don't always know what to say to reassure them correctly."
	Lack of Formal Role	"If we see a problem with medicines, we tell the mother to see the doctor. We don't have a way to tell the hospital directly, and we never hear back."
Staff Nurses	Workflow Burden	"We give the pills and tell them to take them. There is no time to explain each one, and the counseling form is just another paper to fill."
Obstetricians	Evidence Uncertainty	"For hypertension, we have choices, but the data on long-term fetal effects for newer drugs is sparse. I often choose what I trained with, even if it's not ideal."
	Disconnected from Community	"I prescribe folic acid, but I have no idea if the patient actually takes it for 9 months or what problems she faces at home. My feedback loop ends at the clinic door."

Table 3: Outcomes Comparison: Intervention vs. Control Sites (Prospective 3-Month Data)

Outcome Measure	Intervention Sites (n=600 women)	Control Sites (n=600 women)	P-value
Process Measures			
Documentation of Risk-Benefit Counseling	78%	35%	<0.001
Patient possessing "Medication Passport"	92%	0%	<0.001
Adherence & Safety Measures			
Adherence to Iron-Folic Acid (by refill)	85%	60%	<0.001
Self-reported minor ADR (e.g., nausea, drowsiness)	15%	30%	<0.001
System Activity Measures			
ADR reports filed (per 100 women)	18	4	<0.001
of which reported by CHWs	40%	0%	<0.001
Patient-Reported Outcomes			
High confidence in medication knowledge	80%	45%	<0.001

Table 4: The Gestational Triad Framework: Integrated Roles & Action Pathways

Pillar	Core Function	Key Actions in Framework	Information Output
Pharmacovigilance (Safety)	Monitor, Analyze, Alert	- Train clinicians/CHWs on ADR reporting. - Maintain pregnancy-specific ADR database. - Analyze signals, generate safety alerts.	Standardized ADR reports; Quarterly safety bulletins; Urgent risk alerts.
Clinical Care (Prescribing)	Diagnose, Treat, Counsel	- Use evidence-based guidelines. - Conduct structured counseling using passport. - Report all suspected ADRs.	Individualized treatment plan; Completed counseling form; Initiated ADR reports.
Community Health (Delivery & Support)	Enable, Support, Monitor	- Distribute and explain Medication Passport. - Reinforce adherence, identify side effects. - Report concerns via mobile system to CHC.	Community ADR reports; Adherence feedback; Log of patient questions/concerns.
Integration Mechanism	Monthly Triad Meeting	Review: ADR trends, adherence data, patient concerns. Resolve: Specific case management issues. Plan: Targeted education for staff/community.	Updated protocols; Community education plans; Closed feedback loops.

DISCUSSION

This research shows that the "Gestational Triad" approach, which combines pharmacovigilance, clinical obstetrics, and community health, is feasible and effective in addressing systemic drug safety issues for pregnant women. Previously theoretical paradigms now have empirical evidence. This is because intervention sites have improved significantly. Improvements include better documentation, adherence, adverse drug reaction reporting, and patient understanding[8,9]. Our findings showed that taking drugs while pregnant is multidisciplinary. To solve these issues, integrated solutions are needed.

Table 1 shows that the baseline audit supported the literature on pharmacovigilance deficiencies in LMICs and pregnant women[3,10]. The audit revealed a frequent problem of fragmented care, including the widespread use of potentially hazardous drugs, insufficient communication recording, and nearly no adverse drug reaction reporting. Table 2's qualitative findings supported fragmentation and showed that clinicians, community health workers, and patients get caught in separate threads of activity. CHWs do not have an official feedback role, a valuable and underutilised resource for public health surveillance[12]. However, doctors' evidence conundrum supports the need for pregnancy-specific pharmacokinetics and outcomes research[4,11].

The Triad intervention (see Table 3) worked because it actively made missing links. The "Medication Passport" connected the clinic to the home, empowering patients and giving community health workers (CHWs) a structured mechanism for involvement. This likely doubled iron-folic acid adherence, a chronic concern in antenatal care that can avoid maternal anaemia and neural tube abnormalities[13,14]. Self-reported mild adverse drug reactions (ADRs) have decreased. Better management is more likely to explain the decrease in incidence than a true drop. Community health workers (CHWs) can reassure patients about expected side effects, such as iron-induced constipation, suggest mitigation measures like dietary fibre, and escalate legitimate concerns, preventing unnecessary treatment discontinuation[15].

Adverse drug reaction reports increased more than fourfold, causing the most apparent rise. Community health workers caused 40% of these complaints. This supports the hypothesis that decentralising pharmacovigilance to the community could solve underreporting. This applies notably to pregnancies[16,17]. These reports address a huge data gap by providing information on "minor" worrisome symptoms, which helps determine how a

medicine affects pregnant women. Once pooled and examined in Triad meetings[18], this information can inform local counselling priorities and prescriptions.

Our framework supports "social pharmacovigilance" and expands on it.[19]. The idea is to use community networks to monitor drug safety. Through a structured link between clinical and community environments, we may ensure that reports are clinically assessed and considered. This lets us go beyond data collection to better care. Through the monthly Triad meeting (Table 4), the operational heart of this integration, data from all sources was transformed into collective learning and action to promote continuous quality improvement in healthcare[20]. This integration relied on this practice[20].

Our study was conducted in one district, which may limit its generalisability. The short implementation period for seeing unexpected, severe consequences limits the investigation. Participants' behaviour at intervention sites may have been affected by the Hawthorne effect. The institution's dedication and ability to scale the reporting system digitally also determine the concept's feasibility.

Future research should focus on long-term sustainability, cost-effectiveness analysis, and adapting the Triad model to high-risk treatment areas like mental health and HIV during pregnancy. The PVU and community health workers' communication channels and adverse drug reaction (ADR) reporting procedures may be scaled up via digital mobile health (mHealth) platforms[21].

Simply expressed, the "Gestational Triad" diagnoses and solves moms' fragmented medication management problem. By formalising the interaction between pharmacovigilance, the physician, and the community health worker, pregnant women receive more robust, responsive, and safe treatment..

CONCLUSION

This study shows that the "Gestational Triad"—actively integrating pharmacovigilance, clinical care, and community health—closes harmful system gaps. The idea improved prescription documentation, patient adherence, community safety, and patient empowerment by explicitly defining roles, providing shared tools like the Medication Passport, and creating a specialised communication platform called the Triad meeting.

This framework transformed community health workers from peripheral to vital sentinels and supporters. Clinicians also gained vital information from patients' settings. This led to an efficient closed-loop system. It might discover safety signals from scratch and turn them into better patient education and treatment. The Triad can be replicated in low-resource environments to respect "first, do no harm" in pregnant women at risk, maximising the benefits of pharmacotherapy and minimising its risks. Despite scalability and sustainability issues, this is true.

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