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OXYTOCIN QUALITY AND THE RIGHT TO MATERNAL HEALTHCARE IN INDIA: A SOCIO-LEGAL ANALYSIS OF SUBSTANDARD UTEROTONIC DRUGS

Ms. Himashri Baishya[1], Dr. Matiur Rahman[2]

[1]Ph.D. Research Scholar, Faculty of Law, Gauhati University, Assam, India, himashri1992@gmail.com, Orcid Id-0009-0004-6683-4435
[2]Ph.D. Research Guide, Faculty of Law, Gauhati University, Assam, India, dr.matiurrahman23@gmail.com,

ABSTRACT
Right to health encompasses the maternal wellbeing which constitute an essential component of reproductive rights of a woman. To prevent and manage obstetric complications, particularly Postpartum hemorrhage (PPH), which remains a major and significant contributor to maternal deaths, the availability of safe, effective and quality-assured life-saving drugs/medicines are crucial. Oxytocin, an essential uterotonic agent, is widely used in obstetric care to prevent and control PPH. However, the use of substandard, degraded and spurious oxytocin has drastically endangered many maternal lives and raises concern regarding patient safety, quality healthcare service and adequacy of existing drug regulation at the national level in India. Integrating the broader concerns relating to maternal health, this study adopts a socio-legal approach to examine the issue from a rights-based perspective. The existing legal framework governing civil, criminal and regulatory liability is critically examined to identify potential avenues for enhancing the protection of women's right to safe, effective and equitable maternal healthcare in India.

KEYWORDS: Oxytocin, substandard medicines, uterotonic drugs, maternal healthcare, right to health, legal accountability, India.

INTRODUCTION

Maternal health constitutes an integral component of women's reproductive health, encompassing their well-being during pregnancy, childbirth, and postnatal period. The status of maternal health within a particular geographical area may be assessed through the availability, accessibility and quality of maternal healthcare services. While realizing maternal health, maternal mortality remains a major obstacle in ensuring equitable access to quality maternal healthcare services.

However, an assessment of maternal healthcare is not confined to mortality statistics alone; it also considers safety, quality, and effective medical interventions during pregnancy and childbirth. In this regard, the quality of essential life-saving medicines assumes particular significance. Oxytocin, a uterotonic medicine, which is widely used to prevent and manage PPH, plays a crucial role in obstetric care. If this medicine fails to meet prescribed quality standards, its effectiveness may be compromised, potentially undermining the timely management of PPH and can increase the risk of serious maternal complications. Given that, oxytocin is temperature-sensitive (recommended storage at 2–8°C), so, cold-chain integrity is central to ensure its availability and potency. Therefore, ensuring an adequate and quality-assured supply of oxytocin through effective Government oversight is integral for the protection of maternal health.

Beyond availability, its affordability, accessibility, efficacy, appropriate storage, and proper administration is also equally important under the Constitutional, Statutory and Human Rights principles. These interrelated aspects highlight the broader implication of oxytocin supply and pricing for the effective realization of women's health. In light of these considerations, the present study explores the relationship between timely access to quality-assured oxytocin and the State's liability to protect maternal health by ensuring access to basic healthcare facilities.

India's Commitments under International Human Rights Instruments

United Nation (UN), World Health Organization (WHO), United Nation Children's Fund (UNICEF), World Bank are the key stakeholders while dealing the issue of maternal health. UN treaty bodies, courts and other Human Rights bodies assess whether States are complying their obligations to respect, protect and fulfil Human Rights under International law. As a signatory to various International Human Rights Conventions, India is also obliged to fulfil the Human Rights standards, recognized under International Law. For instance, India is signatory to the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), which under Article 12(1) and 12(2) addresses discrimination in healthcare and appropriate services in connection with pregnancy, confinement, and the postnatal period. India is also a signatory to the International Covenant on Economic, Social and Cultural Rights (ICESCR), which, under Article 12, read with the General Comment No. 14 of Committee on Economic, Social and Cultural Rights'(CESCR), provides a useful basis for pregnancy survival by discussing the availability, accessibility, acceptability, and quality of healthcare, which clarified that States must ensure essential medicines as "core obligation". It identifies four dimensions of accessibility as Non-discrimination, Physical accessibility, Economic accessibility (affordability) and Information accessibility. In this context, Article 24 of Convention on the Rights of the Child (CRC) is also relevant which ensure appropriate healthcare before and after birth. Additionally, the 'WHO Essential Medicines Framework' provides an important international

conventional benchmark for interpreting the State's obligations concerning access to essential medicines under Article 21 of the Indian Constitution.

WHO recommends oxytocin as the first-line uterotonic drug for prevention of PPH during third stage of labour to control bleeding after delivery. In the year 2021, Oxytocin was included in the WHO Model List of Essential Medicines; and following the footsteps, Indian Ministry of Health and Family Welfare listed it in the National List of Essential Medicines 2022, reflecting its importance for reproductive care. The significance of oxytocin is further reinforced by the Government of India by identifying oxytocin as the uterotonic of choice for the 'active management of the third stage of labour' (AMTSL) and recommends its administration at a dose of 10 IU intramuscularly, based on evidence concerning the safety and effectiveness of uterotonic agents. It also recommends oxytocin for the prevention of PPH during caesarean section."

Thus, India's commitments under United Nations frameworks and participation in international health initiatives place normative pressure on domestic law to ensure access to essential medical commodities including oxytocin without undue delay or regulatory barriers. However, domestic drug regulation aligns with these obligations is not a policy question alone, but a Constitutional one.

The Constitutional Dimensions of Access to Safe and Quality Medical Services

The Constitution of India does not expressly guarantee a right to health in positive terms. It is only through the judicial interpretation which imposed duties on the Central and State Governments not to give up responsibility where systemic failings result in loss of life.

Under Article 14 ,19(1)(g) and 21 of the Indian Constitution, the Central and the State Governments are bound to ensure equality before the law, freedom to pursue livelihood and the right to life and personal liberty, respectively. The Supreme Court of India has interpreted Article 21 expansively to encompass the right to health and medical care, particularly where the denial thereof leads to preventable mortality. The Supreme Court's decision in 'Pt. Parmanand Katara v. Union of India', is a strong authority for establishing that access to immediate medical assistance is necessary to preserve life as protected under Article 21 of the Constitution of India.

Although the word 'access' does not explicitly appear in the Indian Constitution, the Court has developed it through judicial interpretation and interpreted it as a matter of right. In 'Maneka Gandhi v. Union of India' the Supreme Court expanded Article 21 to include fair, just and reasonable procedures, laying the foundation for substantive rights like access to essential services. Again, in 'Paschim Banga Khet Mazdoor Samity v. State of West Bengal', the Court held that failure of a government hospital to provide timely treatment violates Article 21. This case clearly establishes that access to medical treatment is a constitutional obligation of the State. Finally, in 'Laxmi Mandal v. Deen Dayal Harinagar Hospital', the Delhi High Court explicitly linked maternal healthcare failures to constitutional violations, holding that denial of timely maternal care to pregnant women amounted to infringement of Article 21.

These fundamental rights also correspond with a positive duty on the central and State Governments to ensure that health services are capable of preventing avoidable maternal deaths. This duty extends to guaranteeing that lifesaving drugs like oxytocin are not ineffectively unavailable due to poorly calibrated regulations, inadequate distribution, or health system deficiencies. Because oxytocin is an essential drug for managing PPH, its limited availability or non-availability or substandard availability at the required point of time may contravene the State's Constitutional obligation to protect human life.

Legislative and Policy Framework for Oxytocin

In India, oxytocin is regulated under the 'Drugs and Cosmetics Act, 1940' and the corresponding 'Drugs and Cosmetics Rules, 1945', which govern the manufacture, sale, and distribution of drugs. Oxytocin has been placed in 'Schedule H1' of those rules, meaning it can only be sold on a qualified medical prescription with maintenance of detailed records by the supplier. It was a regulatory response intended to curb its misuse particularly its use in animals for increased milk yield.

At the service delivery level, oxytocin procurement and distribution in the States operates through the framework of the National Health Mission (NHM), and administered by the State Health Societies. Under NHM guidelines, particularly the LaQshya initiative (Labour Room Quality Improvement Initiative) and Dakshata guidelines, oxytocin is classified as a critical , high-alert and mandatory drug for preventing PPH. Under NHM norms, uterotonics form part of the essential drug basket to be available at District Hospitals, First Referral Units (FRUs), Community Health Centers (CHCs) and Primary Health Centres (PHCs). The Government of India's Operational Guidelines for Maternal Health also mandates availability of life-saving obstetric drugs at FRUs and delivery points.

Notwithstanding these initiatives, the regulatory landscape governing oxytocin underwent a significant shift in 2018 when the Central Government issued a notification restricting the manufacture of oxytocin formulations for domestic use to a single public sector undertaking, citing widespread misuse in dairy sectors. The stated objective was to curb illegal diversion and protect animal health. However, such regulatory measures, while well intentioned to prevent misuse, have raised concerns among public health experts that overly restrictive access can negatively impact pregnant women by delaying or complicating timely use, especially in emergency obstetric settings especially in rural or resource-constrained areas. The impugned notification was challenged before the Delhi High Court through a series of writ petitions instituted by private pharmaceutical manufacturers and industry associations engaged, inter alia, in the manufacture of oxytocin formulations.

The Delhi High Court Bench of Justices Ravindra S Bhat and AK Chawla pronounced its final order on December 14, 2018, by quashing the notification that had banned the manufacture and sale by private manufacturers of Oxytocin. The Court regarded that notification as "arbitrary and unreasonable". The Court held that there was no adequate scientific evidence or empirical material to justify the conclusion that the prevailing availability or distribution of oxytocin

endangered human or animal life, which is a mandatory precondition for the valid exercise of powers under Section 26A of the Act. As a consequence, the impugned notification Did not come into force at all.
However, The Union Government appealed against the Delhi High Court's judgment before the Supreme Court of India. The Supreme Court, in Union of India v. Fresenius Kabi Oncology Ltd, by order dated 22 August 2019, referred the matter to a larger bench. As per publicly available judicial records, the final authoritative pronouncement by the larger bench has not conclusively resolved the matter yet.

Regulatory Findings on the Quality of Uterotonic Drugs in India

India's drug regulatory system has historically faced challenges in quality surveillance and enforcement capacity. There are documented issues and broader evidences related to poor and substandard drug quality in India. In this context, a public interest litigation (PIL) was filed in the Gauhati High Court claiming that medicines supplied under NHM in Assam were substandard not producing desired results for patients, arguing that this could be linked to higher maternal mortality rates in the state. It was contended by the petitioners that they sought information from the respondents through RTI; and, from the information received, it appears that in numerous cases the drugs/medicines supplied by the suppliers are found to be substandard. However, in reply to the RTI quarry NHM Assam claimed that it had never allowed to supply any substandard medicines as it is an issue to quality of health to patient community. The court disposed the PIL with strict direction that "if any case of supply of substandard drugs/medicines is detected, the State authority shall take stern action against the supplier, including penalty, or initiation of criminal proceedings, if law permits to do so". Though, this case fails to show any specific pregnancy harm due to substandard medicine/drug but raised concerns about medicine quality in government health facilities.
Furthermore, regulatory testing within India has repeatedly found significant numbers of drug samples that fail quality tests. For example, in a recent drug quality alert, 112 medicine samples failed quality standards in national testing, indicating they didn't meet required quality and safety. A study using simulated clients buying oxytocin from pharmacies in districts in Karnataka and Uttar Pradesh found that, a noticeable proportion of oxytocin ampoules were outside manufacturer specifications in terms of active ingredient, meaning their ingredient levels did not meet required standards. The report 'No Time to Lose: Fighting Maternal and Infant Mortality through Community Reporting' documented access barriers to maternal healthcare for Adivasi women in northern Assam, citing systemic obstacles like lack of services and emergency care deficiencies conditions that often make life-saving medicines like oxytocin harder to access. A recent cross-sectional survey in the year 2023 assessing drug availability in India found that oxytocin availability in public health facilities was suboptimal, generally, lower than WHO benchmarks and often worse in public than in private facilities. The survey revealed that during that stipulated period of time, oxytocin was stocked at only about 51% of surveyed facilities throughout the country, which is below ideal thresholds to prevent and treat PPH. In the September 2024 'Not of Standard Quality' (NSQ) alert, Oxytocin Injection (5 IU/1 ml) manufactured in 2023 was listed as NSQ due to failures in description, particulate matter and potency parameters. Subsequent reports from late 2024 also mentioned oxytocin among the approximately 49 drugs flagged as NSQ. Central labs have found over 40 critical drugs sold in India to be fake or substandard including some used by pregnant women. In June 2025, NSQ alerts from the CDSCO flagged batches of Oxytocin Injection from certain manufacturers failing quality tests.

Remedy Mechanisms for the Use of Substandard Drugs

There is no specific unified legislation in India that provides for effective accountability and remedy mechanism for maternal injury or death caused by substandard, spurious, improperly stored, or improperly administered life-saving drug/medicines. However, the principles of Constitutional law, pharmaceutical regulation, medical negligence, consumer protection, criminal liability, and human rights are used to deliver fair justice. In adjudicating such matters, a crucial legal distinction lies in the recognition that, a drug that failing to meet prescribed quality standards is not necessarily spurious, and that harm following its administration does not, by itself, establish a causal link between the drug and the resulting harm. Where an oxytocin batch fails to meet its applicable identity, potency, purity, or other prescribed quality test, the relevant statutory provisions may be engaged; but, if the problem, instead, arises from improper storage, expired stock, incorrect administration, or inadequate monitoring, then, different forms of liability will apply. Therefore, the drug's quality, causation, responsibility of the manufacturer, supplier, healthcare provider and public authority must be examined separately.
In India, the Drugs and Cosmetics Act, 1940 is the central legislation for accountability for substandard, adulterated, misbranded, or spurious medicines. Under Section 18 and Chapter IV of the Act, it is illegal to manufacture, sell, stock, or distribute any drug that is substandard, misbranded, adulterated, or spurious. Section 27 of this Act penalize manufacturing, selling, or distributing substandard or adulterated drugs that fail to meet prescribed standards with strict legal action where penalties range from imprisonment from a minimum term extending to several years, or up to life imprisonment in severe cases where the drug causes death or grievous harm alongside heavy financial fines and confiscation of stocks.

Furthermore, the Consumer Protection Act, 2019 provides civil remedy where the facts satisfy the statutory requirements, including applicable consumer status and product-liability rules. Sections 82 to 87 of this Act set out the product-liability framework, including liability of manufacturers, product sellers, and service providers. Under Section 39 of this Act, the District Consumer Disputes Redressal Commission may grant appropriate relief, including removal of defects, replacement of goods, refund, compensation for loss or injury caused by negligence, and punitive damages in appropriate circumstances. Potential defendants may include a manufacturer, seller, or service provider, depending on the facts and

statutory requirements. But, the main legal contention here is that, if healthcare facilities are delivered free of charge in a public hospital, then such cases will be out of the jurisdiction of this Act.
For criminal liability, the Bharatiya Nyaya Sanhita, 2023 (BNS), is relevant where maternal injury or death results from criminally negligent conduct or another offence established by the evidence. Section 106(1) of this Act describe criminal liability for causing death by a rash or negligent act, where the statutory elements are satisfied. Additionally, Section 125 of the Act will be applicable if rash or negligent acts endanger human life or personal safety, including causing hurt or grievous hurt in the circumstances covered by this section. While applying such provisions, the legal challenge which generally occurs is that a maternal death following administration of a drug does not automatically establish criminal negligence. Investigators must establish the relevant offence, the accused's conduct, and the required causal connection.
A healthcare professional or hospital may face civil liability, if a breach of the applicable standard of care causes injury. However, establishing civil liability in cases of maternal harm caused by substandard oxytocin presents significant evidentiary challenges. Whether the medicine was properly selected, stored, prescribed, and administered; whether its batch number, expiry date, and quality status were verified; whether adequate monitoring was undertaken; and whether adverse reactions were promptly recognized and managed may be particularly difficult for affected women and their families. These difficulties are compounded by their limited access to hospital records, procurement documents, drug-testing reports, and expert medical evidence; much of which may remain under the control of the institutions or professionals whose conduct is being questioned. Furthermore, establishing a direct causal link between the alleged drug defect and maternal injury or death may require specialized scientific and medical evidence. Consequently, the burden of proof will create a substantial practical barrier to get an effective legal remedy, potentially widening the gap between the formal recognition of legal rights and their enforceability in practice.
In addition to the above, when maternal death or harm is caused due to the application of substandard uterotonic drugs, different remedy mechanism is applied. A petition under Article 226 or Article 32 of the Indian Constitution may be considered before the relevant High Court or the Supreme Court, respectively. Invoking Article 32 requires establishing violation of fundamental rights, although Article 226 extends to the enforcement of other legal rights. Beyond this, from the perspective of Administrative and Human Rights Law, aggrieved persons may seek redress by filing Complaints to the relevant health department, hospital grievance authority, or competent human-rights commission, in accordance with the applicable statutory frameworks. These channels may be relevant to investigating procurement failures, inadequate supervision, medicine shortages, and failures in patient safety.
Though, the existing legal provisions provides several potential routes to identify the accountability gaps, but, their mere existence does not necessarily ensure effective implementation in practice. India's existing legal framework is not precise enough to adequately connects drug-quality regulation, maternal-death investigation, individual compensation, and institutional accountability. Instead, these areas operate in silos under different laws and jurisdictions. This separation leads to systemic fragmentation of wrongdoing, rendering the ecosystem reactive rather than preventative.

Critical Analysis and Discussion
In India, there are credible documents reporting insufficient availability of oxytocin and other essential life-saving maternal medicines in public healthcare institutions. Though the Constitutional jurisprudence requires the Indian States to actively ensure conditions necessary for life and health, but few unique and structural challenges like geographic remoteness, riverine and flood-prone terrain, inadequate emergency obstetric care, power supply instability, Shortage of specialist doctors at government health facilities makes the timely access to healthcare facilities quite difficult.
Government drug quality testing alerts are being regularly published by regulatory bodies, but these typically report, which medicines failed lab quality tests, but, not the clinical outcomes among patients. For instance, in the year 2025, The 17th CRM report, published by NHM observed that, in several states, including Assam, there were stock-outs of essential maternal health medicines such as oxytocin in public facilities affecting services. However, very particular details abouts these crises including patient’s name and details, its impact over patients, aftermath review etc.were missing in the report. In such situation, it’s become very difficult for the enforcement agencies to trace the problem at the bottom level. Thus it can rightly be argued that India’s screening mechanisms is insufficiently developed yet to identify the gap i.e. which can prove that pregnant women in India were harmed because they took specific substandard or spurious drugs during pregnancy by causing miscarriage, birth defects, or maternal complications.

CONCLUSION
Drug safety plays a vital role in maternal health , which requires, not merely the availability of essential medicines but also effective mechanisms to guarantee their quality, safety, and appropriate use. Based on the foregoing discussion, supported by available literature, reports and legal analysis, it may reasonably be infer that, there is a need for a more responsive and accountable unified legal framework to protect women from preventable maternal harm associated with substandard uterotonic medicines. It is the positive duty of the States to maintain more robust systems from licensed supply lines, routine training of healthcare workers in appropriate usage, to emergency obstetric care systems that operationalize access to oxytocin.

In the existing system of Maternal Death Surveillance and Response (MDSR) under NHM, the monitoring and accountability mechanism for substandard drugs is purely close door nature intended to protect healthcare providers rather than obscure data. This creates a significant transparency gap for the public to investigate the maternal deaths and rectify the systemic failures. It is therefore imperative that drug surveillance mechanism must be strengthened, and the means for accessing justice to be improved to safeguard maternal health in India.

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