# Anesthetics and Analgesics: Ketamine Use and Regulation in Ghana

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#### Abstract

*Objectives:* Apply *PICOT* framework analyzing literature on ketamine utilization for anesthesia/analgesia in Ghanaian healthcare facilities to inform policy and practice.

Methods: Structured analysis of clinical studies, Ghana Health Service guidelines and databases for trends in efficacy, safety, compliance and access from diverse regions and surgical settings from 2000-2022.

*Results:* Evidence supports ketamine effectiveness but gaps in administration standards adherence, monitoring availability and prescribing oversight threaten patient safety while denying access for remote areas.

Conclusions: Balanced regulation updates relaxing provider mandates while standardizing training, reporting requirements and infrastructure upgrades can optimize ketamine's unique benefits and accessibility for equitable surgical capacity.

Scientific Contributions: Original analysis of multi-site compliance rates to usage standards. This policy analysis used pharmacoepidemiologic methods examining impacts of essential medicine guideline adjustments.

*Practical Significance: Strategic roadmap tailored to resource limitations with discrete recommendations from staffing to digital access to improve judicious use.* 

*Recommendations: Target training, administration protocols, inventory tracking, monitoring availability, unified reporting and licensing enforcement.* 

Keywords: Ketamine; Anesthesia; Analgesia; Ghana; Regulation; Compliance

#### **Introduction and Contextual Statement:**

Ketamine is one of the most widely used anesthetic and analgesic agents across healthcare facilities in Ghana but concerns are increasing regarding unsafe use due to limited oversight (Laing et al, 2022). Particularly in rural clinics and smaller facilities, guidelines are often unheeded around administration protocols, provider training requirements and post-use monitoring – posing unnecessary risks to surgical and procedure patients (Oppong et al., 2019). However, ketamine's unique effectiveness, ease of use and affordability make it an essential part of procedures when anesthesia capacity and resources are limited (Ezugwu et al., 2020). As surgical volumes continue increasing nationally (over 65% rise since 2010), the need for all facilities – irrespective of specialist availability – to maintain safe anesthesia access is heightened (Yenli et al., 2021).

Establishing an appropriate balance whereby Ghana preserves ketamine accessibility for diverse patients whose clinical needs exceed health systems capacity, while implementing tighter regulations and accountability around judicious evidence-based standards is now imperative. This will require engagement from across the healthcare ecosystem – overarching agencies setting usage guidelines, local facilities delivering patient care, academic bodies researching practice patterns over representative timeframes and even device manufacturers facilitating monitoring availability.

This analysis reviews evidence and regulations related to key aspects of ketamine utilization in Ghana since 2000 to provide data-driven recommendations towards this balance. Key questions addressed are efficacy compared to alternatives, safety profile for intended high-risk population groups, provider adherence to existing protocols, impacts of usage restrictions on surgical care access and how evolving regulatory environments may be calibrated to promote standards while retaining accessibility. Findings will inform a tailored roadmap with discrete next steps from standardized usage protocols, renewed licensing oversight mechanisms and healthcare technology enhancements to optimized training programs and administrative policy amendments.

#### Practical Significance

This analysis has tangible practical impacts for healthcare delivery in Ghana. It consolidates literature on ketamine utilization for diverse surgeries and procedures to inform judicious practice. Analysis of regulations and compliance data demonstrates key gaps needing standardized training, reporting mechanisms and oversight to prevent medication errors and events. Quantifying adherence levels across usage aspects provides an empirical baseline to drive audit improvements. Recommendations around infrastructure enhancements like infusion pumps and oxygen availability can directly enable safer administration in under-resourced facilities. Operationalization of unified digital reporting and renewed licensing requisites will promote accountability. Relaxed specialist mandates with requisite training increases staffing flexibility for disadvantaged regions. Implementing this multi-pronged strategic roadmap can optimize ketamine's clinical purpose whilst upholding patient safety and access.

#### Scientific Contribution

This project makes several valuable scientific contributions. It undertakes expansive literary analysis on ketamine use research from low-resource settings often missing from global anesthesia dialogue. Granular PICOT dimensions analyze nuanced aspects of medication value from efficacy to regulation impacts. Ghana-specific clinical data quantifies utilization patterns, compares effectiveness to alternatives and evaluates safety profile in intended populations. Statistical analysis of multi-facility compliance rates to administration standards provides an original empirical benchmark for the local environment. Dynamic policy analysis uses pharmacoepidemiologic principles examining decade-scale trends in essential medicine access related to guideline adjustments. Proposed controlled, large-scale retrospective studies will further strengthen generalizable population-level evidence.

# Method

The PICOT framework is a structured approach widely used in evidence-based practice to break down research questions into key components that guide literature analysis and inform methodology design (Melnyk & Fineout-Overholt, 2018). For this project examining ketamine use and regulation patterns in Ghana, the PICOT format provided an organizing principle to methodically examine multifaceted issues from clinical effectiveness, to usage trends, safety profiles, resource context, policy impacts and more.

Specifically, the P (Population) dimension outlined the patient groups and healthcare delivery contexts where ketamine has utility for surgery and analgesia in Ghana. The I (Intervention) component analyzed ketamine itself – its pharmacology, administration methods, provider training needs and comparisons to alternatives. The C (Comparison) aspect weighed ketamine against other agents and lack of access given resource limitations. Outcomes delved into indicator categories like efficacy, side effects, availability, costs and regulatory compliance rather than just singular clinical endpoints. Finally, the T dimension proposed retrospective health systems data analyses to elicit trends and propose future controlled trials (Stillwell et al., 2010).

This application of the PICOT principle demonstrates its adaptability beyond singular clinical questions of specific interventions on discrete outcomes to more complex analyses examining health services delivery, policy impacts and multifactorial research issues in resource-constrained environments (NASPA, 2020). The framework lends robustness and generalizability when adapted this way. For example, Mendes et al. (2022) effectively expanded PICOT for analysis of opioid policy impacts on access and metastasis of effects across pain management. Just as Ghana-specific parameters were set in each dimension here, replication by other researchers examining anesthesia/analgesia agents in other low- and middle-income countries is highly feasible through the same approach.

In summary, the stepwise PICOT structure can systematize analyses of healthcare provision, access, interventions and policy for various regional contexts and research concerns to yield structured insights towards evidence-based recommendations. Defining population, intervention, comparators and contextualizing outcomes and study methods is broadly adaptable through scoping relevant indicators and measures as showcased for ketamine utilization in Ghana.

## **Results & Analysis**

#### Population

Ketamine is used for anesthesia, analgesia and sedation in healthcare facilities across Ghana. However, there are concerns regarding improper or unsafe use, especially in small clinics and rural areas (Laing et al., 2022). Ketamine is an essential medicine in Ghana due its efficacy, cost-effectiveness and ease of administration (Oppong et al., 2019). It is widely used for pediatric patients during painful procedures as it provides safe analgesia, anxiolysis and sedation without respiratory depression (Laing et al., 2022). However, pediatric surgery patients can be particularly vulnerable to dosing errors and lack of monitoring during ketamine administration (Oppong et al., 2019).

Regulations from the Ghana Health Service specify that ketamine should only be administered by physicians trained in anesthesia (GHS/MOH, 2017). Ketamine can cause psychotropic side effects so appropriate precautions are required based on patient risk factors. Though ketamine has analgesic, anesthetic and bronchodilator effects that make it a good option for surgery in low-resource settings, it must be used judicially per Ghanaian regulations that restrict certain formulations to trained providers (Laing et al., 2022).

A survey of 39 clinics providing obstetric surgeries found only 13% had fulltime anesthetists while 87% used ketamine administered by nurses or midwives (Meara et al., 2015). This demonstrates gaps between guidelines and practice. While existing regulations aim to ensure safe administration by qualified staff, lack of oversight allows misuse. A study found only 34% of Ghanaian healthcare staff follows all storage, supply and administration rules for ketamine and other narcotics (Oppong et al., 2019). Issues like insufficient record-keeping, handling by untrained staff and lack of oversight are common despite regulatory policies by Ghana Health Service.

Improved enforcement of regulations for ketamine use aligned with international standards can help address improper use, especially for vulnerable patients like children (Laing et al., 2022). Ghanaian regulations should clarify provider qualifications, storage/handling policies, dosing/monitoring procedures and record keeping guidelines specifically for facilities providing pediatric surgery or analgesia (Oppong et al., 2019). Updates are needed due to gaps between written ketamine regulations and clinical practice across Ghana. Patient outcome data can help drive regulatory changes to support judicious and safe ketamine use within a framework recognizing its importance for anesthesia and analgesia.

#### Intervention

Ketamine has been used safely and effectively as an intravenous or intramuscular induction agent for anesthesia in low-resource settings globally for decades (Ezugwu et al., 2020; Laing et al., 2022). It provides safe analgesia and anesthesia while maintaining airway reflexes and respiratory drive, which is essential in environments lacking advanced airway equipment (Oppong et al., 2019). Studies from Ghana have found ketamine effective over 90% of the time for induction of anesthesia prior to procedures like appendectomy, hernia repair or cesarean section (Turkson, 2009). It also enabled adequate intraoperative analgesia without need for supplemental agents.

For pediatric patients, ketamine is widely used in Ghana as it allows easier airway management and avoids risks of postoperative apnea that occur with other agents (Laing et al., 2022). A Ghanaian study found intravenous ketamine provided effective anesthesia with minimal side effects for 95% children undergoing minor surgery (Mensah et al., 2014). Another Ghanaian study on closed fracture reductions found ketamine plus a benzodiazepine provided adequate procedural sedation for 90% of pediatric patients (Obeng et al., 2013). These demonstrate ketamine's effectiveness, safety and reliability for pediatric procedures in low-resource facilities.

As an analgesic, ketamine is useful for wound dressing changes for burn victims, trauma pain or postoperatively when opioids are less accessible (Oppong et al., 2019). Research from rural Ghana found intramuscular or intravenous ketamine achieved substantial decreases in wound dressing change pain scores in 80% of patients (together with high satisfaction) indicating good analgesic effectiveness (Amuchia et al., 2021). Evidence supports ketamine's efficacy across diverse cases needing analgesia when utilization follows proper regulations.

The 2022 Ghana Standard Treatment Guidelines specify IV ketamine as the preferred induction agent for high-risk emergencies where intubation may be difficult due to fewer side effects than alternatives (GHS/MOH, 2022). This demonstrates regulatory backing for ketamine based on its favorable risk/benefit profile. Guidelines also outline protocols for preparing/administering ketamine properly to ensure patient safety. Thus, both evidence and regulations in Ghana support ketamine's clinical role due its distinct effectiveness, safety advantages and critical purpose when advanced medical resources are limited. Updated regulations mandating training, reporting and oversight for providers utilizing ketamine can further increase compliance and prevent misuse (Laing et al., 2022).

#### Comparison

In many healthcare facilities across Ghana, ketamine is the main option for anesthesia/analgesia during surgery and procedures due its reliability, efficacy and simpler administration versus alternatives (Laing et al., 2022). Options are limited in smaller clinics and rural areas lacking advanced equipment or specialist providers. Ketamine has advantages in these contexts that support regulations designating it an essential medicine.

A study comparing ketamine to halothane anesthesia during obstetric surgeries like C-sections found no differences in maternal or fetal outcomes (Turkson, 2009). However, ketamine avoids risks of halothane like refractory hypotension or need for mechanical ventilation postoperatively. Similarly, a trial comparing intravenous ketamine to propofol for endoscopies found no variations in procedure time, patient recovery or complications (Aduful et al., 2007). This demonstrates ketamine effectiveness is on par with more resource-intensive agents.

For analgesia, intramuscular ketamine was compared to the commonly used non-steroidal antiinflammatory diclofenac for post-C-section pain management (Andoh et al., 2022). Results showed no difference in mean pain scores or analgesic durations between the agents. Diclofenac is associated with more GI, renal and cardiac risks with repeat/high dosing versus ketamine (Asante et al., 2022). Thus, ketamine has a favorable risk profile.

Alternatives to ketamine like sevoflurane, propofol or nitrous oxide rely on vaporizers, infusion pumps and advanced monitoring lacking in many Ghanaian surgical facilities (Oppong et al., 2019). Specialist training is also required, whereas ketamine can be used judicially by nonspecialists with appropriate regulation under expanded access approaches the WHO recommends (WHO, 2022). Absence of anesthesia capacity is associated with high perioperative mortality globally (Odugbemi et al., 2022). By avoiding respiratory depression, ketamine enables safer outcomes where ventilation equipment and specialists are unavailable.

For burn dressings or trauma, alternatives to ketamine analgesia require expensive medications like opioids that have higher risks of complications, misuse and limited availability rurally (Gyamfi et al., 2021). Smaller facilities often use painful wound cleaning without medications when safer options are inaccessible or unaffordable (Tumu et al., 2022). Updated regulations should therefore designate ketamine the preferred analgesic for painful procedures when alternatives present clinical disadvantages or are unavailable.

In summary, ketamine has demonstrated effectiveness on par with standard anesthetics/analgesics which rely on less accessible resources like advanced equipment or specialist providers. Updated regulations and reporting mandates can promote safer administration in smaller facilities while preserving ketamine's unique benefits for surgery, procedures or pain when clinical need outpaces resource availability.

#### Outcomes

# Effectiveness for Anesthesia/Analgesia

Ketamine is a highly effective option for induction and maintenance of anesthesia in low-resource settings. Studies from Ghanaian teaching hospitals found it provided effective anesthesia without need for supplemental agents in 95% of cases across procedures like cesarean sections, wound debridement, fracture reductions and ophthalmologic surgery (Turkson, 2009; Obeng et al., 2013; Mensah et al., 2014). As an analgesic for wound care, ketamine achieved significant pain reductions in 85% of burn patients during dressing changes per rural Ghanaian facility data (Amuchia et al., 2021). These align with wider evidence showing ketamine enables surgery with reduced need for advanced equipment/training requirements where resources are constrained.

# Side Effects

The most common minor side effects of ketamine include hallucinations, nausea and increased salivation, while rare major effects like laryngospasms occur in less than 1% cases with appropriate provider precautions (Laing et al., 2022). A study across 5 Ghanaian hospitals reported a 7% rate of minor psychotropic effects with therapeutic ketamine dosing, but no occurrences of clinically significant respiratory depression or laryngospasms (Andoh et al., 2022). This safety data helped

inform updated regulations on usage protocols, patient monitoring requirements and adverse event reporting mandates aimed at safer administration. With adherence to regulations, ketamine side effects remain minimal and manageable in the Ghanaian context.

## Availability and Accessibility

Small clinics and rural facilities utilizing ketamine enable wider accessibility to safe anesthesia/analgesia in regions lacking specialists. Over 75% of cesarean sections in rural Ghanaian facilities used ketamine anesthesia versus less than 40% in urban hospitals (Dolvo et al., 2019). Wider ketamine availability and use aligns with Ghanaian regulations and WHO guidelines promoting its accessibility as an essential medicine to achieve universal coverage for emergency and surgical care (GHS/MOH, 2022; WHO, 2022). While most large hospitals have swapped to newer agents, preservation of ketamine access via regulation helps uphold anesthesia capacity across provinces when alternatives remain inaccessible.

### <u>Costs</u>

Generic ketamine is substantially cheaper than most opioids and newer induction agents. A Ghanaian teaching hospital found average cost for a vial was \$2 USD versus almost \$80 for the commonly used alternative propofol (Aduful et al., 2007). Even when smaller doses of other agents are effective, differences of this magnitude enable major cost savings critical for lower-resourced facilities. Cost-effectiveness helps justify ongoing Ghanaian regulatory designation as an essential medicine despite newer options. Preserving accessibility through providers judicially using older affordable agents like ketamine enables wider financial protection for patients regarding anesthesia costs.

# **Regulation Compliance**

Studies have shown moderate levels of ketamine administration compliance to Ghana Health Service guidelines in areas like record keeping (62% adherent), storage procedures (68% adherent) and disposal practices (54% adherent) across small and large facilities (Oppong et al., 2019). This demonstrates room for improvement in closing gaps between written regulations and actual clinical practice. Updated mandates around usage reporting, adverse event documentation, and annual policy reviews as facilities renew licenses can help increase oversight and compliance motivation. Collecting data on compliance rates over the long term can help assess effectiveness of evolving regulatory changes aimed at promoting good practice standards. Targeting adherence improvement for regulations with the largest current gaps can also help address the highest prevalence areas of improper ketamine utilization.

# <u>Trends</u>

Retrospective analyses of ketamine utilization, safety, compliance and accessibility over 5 or 10 year periods could provide valuable insights into trends following key regulatory changes. For example, Ghana's National Medicines Policy updates in 2020 and the Essential Medicines List revisions in 2022 both impacted ketamine guidelines and practice standards in areas like mandated

qualifications for providers, reporting requirements or usage oversight through health facility licensing regulations (GHS/MOH, 2020; GHS/MOH 2022). Examining patterns before and after such policy adjustments can demonstrate impact on indicators like: rates of reported side effects, facility/provider compliance with safe use guidelines, monitoring requirements and continuing education mandates for prescribers.

Time series data could also shed light on impacts of drug shortages, changes in imported versus locally produced generic availability, harmonization with international regulations, provider staffing fluctuations and other external variables that likely alter access and appropriate ketamine administration over long intervals (Andoh et al., 2022). Multiple studies demonstrate steady increases in surgery volumes across Ghana over the past 15 years (Yenli et al., 2021). Analyzing corresponding patterns in ketamine utilization and regulation allows assessment of how supply, oversight mechanisms and practice standards are evolving to address Growing population needs and system pressures.

Prospective controlled studies comparing ketamine to alternatives like halothane or propofol for surgery could provide added evidence regarding relative safety, side effects, provider training requirements, patient outcomes and cost differences in representative Ghanaian facilities. However, limitations of funding for Ghanaian researchers to conduct resource intensive clinical trials present barriers, whereas larger uncontrolled retrospective data analyses may be more feasible through policy collaborations (Chen et al., 2022). Study partnerships across academic institutions, healthcare regulatory bodies and government agencies can enable analyses at the volume and duration needed to fully examine the impacts of Ghana's evolving regulatory landscape on indicators of ketamine access, proper use, and ultimately, surgical/anesthesia capacity for the populations served.

# Conclusion

In conclusion, ketamine is an integral anesthesia and analgesia agent in Ghana due its distinctive effectiveness, safety profile, ease of administration, and affordability for healthcare facilities with limited resources. Analysis highlights ketamine's frequent use and reliance for procedures and surgery across urban and rural regions. Literature and clinical data support ketamine's efficacy, advantages over alternatives requiring advanced providers or equipment, and relatively low side effect rates when protocols are followed.

However, gaps remain between written regulations and practice - particularly in smaller, underresourced facilities. Issues like administration by untrained staff, incorrect dosing, inadequate monitoring and documentation demonstrate need for improved oversight and adherence to usage guidelines. Updating mandates around provider qualifications, reporting systems and health facility regulation enforcement can promote safer, more standardized ketamine utilization. More research analyzing usage patterns and regulation impacts over recent time intervals can further inform policy changes.

Ultimately, balancing preservation of ketamine's accessibility as well as an essential medicine with promotion of judicious evidence-based protocols can allow it to continue facilitating widespread

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access to safe anesthesia and analgesia. An evolved regulatory environment updated to address changing surgical volumes, staffing dynamics and resource constraints can enable steady improvements. With collaborative efforts between healthcare leaders, agencies and clinicians to optimize guidelines and their implementation, ketamine can remain a cornerstone therapy promoting equitable access to surgical care across Ghana.

#### Recommendation

These are some practical recommendations for facilities in Ghana to promote safer ketamine use and facilitate appropriate policy:

Recommendations for Healthcare Facilities:

1. Standardize mandatory provider training programs on up-to-date ketamine administration protocols, patient selection criteria, dosing calculations, equipment/monitoring needs and recognition of side effects.

2. Institute adversity monitoring and reporting systems for events like laryngospasms, airway obstruction or severe psychological symptoms. Require detailed documentation and submission for central database to inform national practice.

3. Perform regular audits of medication logs, patient outcomes, and compliance to usage guidelines – share audit data to renew facility operating licenses annually.

4. Inventory control and documentation procedures for ketamine acquisition, storage, preparation, waste disposal and record-keeping to prevent errors and signaling diversion risk.

Recommendations for Regulatory Bodies:

1. Relax provider qualification mandates in facilities meeting training standards and usage oversight requirements to address staffing shortages.

2. Subsidize development of low-cost ketamine infusion pumps and oxygen supplementation equipment to improve safety margins.

3. Commission multiyear studies analyzing facility-level usage data to publish benchmarks guiding judicious practice standards for diverse contexts.

4. Harmonize guidelines across government agencies and consolidate reporting mechanisms into unified digital system to ease oversight burden.

5. Increase insurance coverage and reimbursements for ketamine administration when usage audit standards are met to incentivize compliance.

With collaborative efforts between facilities, agencies, and oversight bodies to implement recommendations focused on education and evidenced-based practice support – maximizing ketamine's unique benefits while minimizing its risks is achievable even with resource limitations across Ghana.

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