

Every Second Matters for Emergency and Essential Surgery – Ketamine



Course Manual

REPUBLIC OF KENYA



MINISTRY OF HEALTH



Foreword

Sixty-nine percent of people worldwide do not have access to emergency and essential surgery when needed, with lack of anesthesia services a primary barrier. In Kenya, there are vast regions where the cesarean section rates are less than 1%, the result of which is untold death, disability and suffering. The ‘Every Second Matters for Emergency and Essential Surgery – Ketamine’ (ESM-Ketamine) program is a ground-breaking collaborative effort to address this crisis by providing a bridge solution for the anesthesia gap. The goal of the ESM-Ketamine program is to support the march toward universal health coverage by increasing access to surgery for the most vulnerable populations.

The ESM-Ketamine package was designed and launched by a consortium of innovators from the African Institute for Health Transformation at Sagam Community Hospital, the Kenya Ministry of Health, the Siaya County Health Directorate, and faculty from the Massachusetts General Hospital and Harvard Medical School. Additional collaborators include leaders from the Kenya Obstetrics and Gynecology Society (KOGS), the College of Surgery for East, Central, Southern Africa (COSECSA), as well as the Health Directorates from Wajir, Turkana, Mandera, and Garissa Counties, among others.

This ESM-Ketamine manual contains the material providers must master to safely support emergency and essential surgical procedures when no anesthetist is available. The manual reflects the collaborative efforts of senior surgeons, obstetrician gynecologists, anesthesiologists and anesthetists, emergency physicians, pediatricians, public health experts, policy leaders, and medical society leaders. This course manual complements the ESM-Ketamine training program, which is designed to train non-anesthetist clinicians to become competent ESM-Ketamine providers. The first 1,500 operative cases supported by the ESM-Ketamine program demonstrate the remarkable impact and safety of the pathway in support of emergency and essential surgery when no anesthetist is available.

The ESM-Ketamine program in no way replaces anesthesiologists or anesthetists but in fact is complementary. The ESM-Ketamine package authors’ vision is for a future where every person in need of emergency and essential surgery can access a fully trained anesthetist in a timely fashion. However, the reality of this vision is decades away – thus, the “birth” of the innovation, ESM-Ketamine, which can help propel us toward our shared goal of safe and high quality universal health coverage.

This course manual is intended for educational purposes only. This manual is not for sale and will not result in monetary gains for the authors or institutions involved.

Please send comments or suggestions to mghghhr@gmail.com.

January 2019

We thank the many collaborators and donors for their commitment and support of the ESM-Ketamine Program.



MASSACHUSETTS
GENERAL HOSPITAL
EMERGENCY MEDICINE

Global Health Innovation



Transforming Lives



Research for health
in humanitarian crises

elrha



A
PARTNERSHIP
OF



USAID
FROM THE AMERICAN PEOPLE



Norad

**BILL & MELINDA
GATES foundation**



Grand Challenges Canada
Grands Défis Canada



KOICA
Korea International
Cooperation Agency



Table of Contents

Foreword	3
1. Background	7
2. Every Second Matters for Emergency and Essential Surgery - Ketamine	8
3. Learning Objectives	9
3.1 <i>Skills to Master</i>	9
4. Ketamine: Drug information	10
4.1 <i>Mechanism of action</i>	10
4.2 <i>Indications</i>	10
5. ESM-Ketamine Pathway	11
5.1 <i>Contraindications and warnings</i>	13
5.2 <i>Patient pre-operative assessment and monitoring</i>	14
5.3 <i>Induction of ketamine for emergency and essential operations, and procedural sedation</i>	15
5.4 <i>Maintenance of anesthesia and patient monitoring</i>	16
5.5 <i>Basic Airway Management</i>	17
5.6 <i>Post procedure monitoring and recovery</i>	19
5.7 <i>Ketamine effects</i>	19
1. Laryngospasm	19
2. Hypoxia	19
3. Movement and increased muscle tone	20
4. Hypersalivation	20
5. Hallucinations and agitation (recovery reactions)	20
6. Emesis and Nausea	20
7. Hypertension	21
5.8 <i>ESM-Ketamine Safety Checklist</i>	22
6. Helping Babies Breathe	24
7. Data Collection and Reporting	28
7.1 <i>Adverse Event Reporting</i>	29
8. Acronyms	31
9. References	32
Appendix A: Preoperative Checklist	33
Appendix B: Helping Babies Breathe – Action Plan	35
Appendix C: Serious Adverse Event Reporting Document	36

1. Background

Approximately 5 billion people in the world have limited access to emergency and essential surgical procedures, with a lack of anaesthesia services a primary barrier [1]. Emergency and essential surgeries are critical for prevention of premature death and/or disability [2]. Access to emergency and essential surgical procedures is lowest in the most severely resource-constrained and conflict-prone settings. In many low-income countries, the density of anaesthesiologists and anaesthetists is extremely low [3]. For example, Uganda has 0.06 anaesthetist providers per 100,000 people [4], similar to the number of providers found in other sub-Saharan African countries [3, 5]. Even though the World Health Organization (WHO) has not defined the minimum density of anaesthetists required for safe surgery access and adequate care, several organizations recognize the urgent need for a considerable increase in trained anaesthetists in order to improve access to safe, effective, and life-saving operative care [6].

Ketamine is an ultra-low-cost anaesthetic drug that has been used worldwide for caesarean sections and other emergency operative procedures for over 50 years. Ketamine has an extremely attractive safety record, even in circumstances with limited supporting equipment. In response to the profound anaesthesia gap and ketamine's attractive benefit-to-harm ratio, the use of this drug has been sought as an alternative to support these emergency and essential surgical procedures when no anaesthetist is available.

2. Every Second Matters for Emergency and Essential Surgery - Ketamine

The 'Every Second Matters for Emergency and Essential Surgery – Ketamine' TM (ESM-Ketamine) Initiative by the Massachusetts General Hospital Division of Global Health Innovation and the African Institute for Health Transformation (AIHT) was originally designed to help address the anaesthesia gap in low-income and resource-poor settings, primarily for emergency obstetric and gynaecological operative procedures. The three primary reasons why quality anaesthesia services are in such short supply include lack of infrastructure, equipment and supplies, and trained personnel. The ESM-Ketamine initiative aims to overcome the contributions to the anaesthesia gap that arise from a lack of trained anesthesia providers and lack of anesthesia machines.

The ESM-Ketamine initiative's objective is **not to replace** in-country anaesthetists and anaesthesiologists. Rather, ESM-Ketamine aims to provide a solution for when no anaesthetists are available. This training will review the management and use of ketamine as a lone anaesthetic agent in support of emergency and essential surgeries and painful procedures when no anesthetist is available. The goal of this initiative is to train non-anaesthetist clinicians from low-resource settings affected by critical shortages in anaesthesia providers. Addressing the anaesthesia gap in such areas requires innovation, task shifting and a safe, effective and bounded package for implementation. The ESM-Ketamine training program includes lectures and case-based learning on patient assessment and selection, intraoperative monitoring, ketamine pharmacology, respiratory management and documentation in addition to considerable practical experience via hands-on skills development during real surgical operations.

3. Learning Objectives

1. The ESM-Ketamine provider will be able to exercise good judgment in invoking the ESM-Ketamine package when no anaesthetist is available.
2. The ESM-Ketamine provider will be able to provide high quality care in use of the ESM-Ketamine package in emergency and urgent settings when no anaesthetist is available

3.1 Skills to Master

- Ketamine's mechanism of action
- Indications and contraindications for invoking ESM-Ketamine
- Ketamine induction and administration
- Essentials of basic airway management
- Oxygen and fluid therapy
- Helping Babies Breathe
- Recognition and correction of ketamine side effects
- Patient monitoring during and after the procedure
- Record keeping and reporting
- Skills maintenance

For reference and guidance, the ESM-Ketamine Safety Poster (see figures 2 and 3) should be displayed in all operating theatres and procedure rooms. In addition, trained clinical personnel should refer to their pocket Safety Checklist as needed. The pocket checklist is identical to the ESM-Ketamine Safety poster.

4. Ketamine: Drug information

4.1 Mechanism of action

Ketamine is an N-methyl-D-aspartate (NMDA) receptor antagonist that produces analgesia and prevents sensory inputs (e.g. dissociation) to the cerebral cortex and limbic system [7]. By doing so, it produces a cataleptic-like state in which the patient is dissociated from the environment, producing a unique effect often defined as a state between deep sedation and general anaesthesia [8]. Additionally, there is retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability. Therefore, in most cases, no intubation or other advanced airway techniques are necessary.

4.2 Indications

Ketamine is used for analgesia, sedation, and induction and maintenance of anaesthesia. According to the WHO, Ketamine is mainly used for [7]:

- Brief ambulatory, obstetric, surgical and paediatric procedures
- Treatment of burns
- Induction and maintenance of anaesthesia in cardiogenic shock patients.

In resource-limited settings, ketamine has been used for decades in a widespread but unregulated fashion, without structure, protocols, or guidelines. Not only is it used in emergency surgeries such as obstetric emergencies and laparotomies, but also in essential surgeries and procedures when no anaesthetist is available. The following are a few examples of operations and procedures commonly supported by ESM-Ketamine:

- Emergency caesarean sections
- Emergency laparotomies
- Open and closed fracture repairs
- Incising and debriding large infections
- Repair of large wounds
- Repair of 3rd, and 4th degree perineal tears
- Debridement of large burns

5. ESM-Ketamine Pathway

The ESM-Ketamine kits have the following contents (Figure 1):

- Adult and pediatric bag valve masks
- Adult and pediatric oxygen facemasks
- Pulse oximeter
- Bulb suction
- ESM-Ketamine Safety Checklist, including side effect management



Figure 1 - ESM-Ketamine Kit

The approach to ketamine as an anesthetic and deep sedation agent is outlined in **Figure 2**. Before going through the clinical pathway, trainees must obtain a complete medical history from patients requiring surgery. Once there is indication to use ESM-Ketamine, providers must ensure that the equipment is complete and functional. The contents are vital to manage any complications, if they occur.

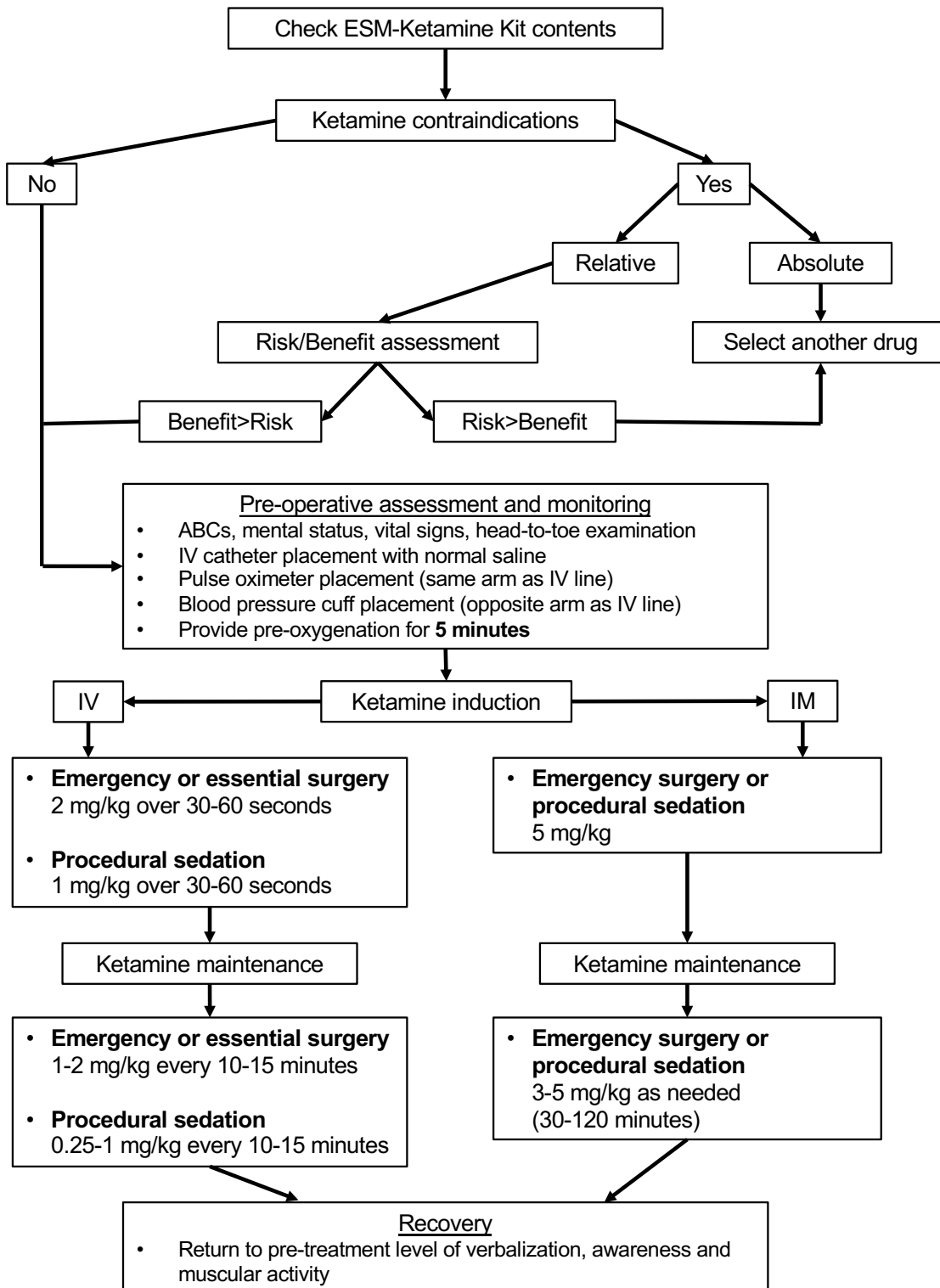


Figure 2 - ESM-Ketamine Pathway

5.1 Contraindications and warnings

After checking the contents of the ESM-Ketamine Kit, providers should screen for ketamine contraindications [9].

5.1.1 Absolute contraindications

Ketamine should almost never be used in patients with the following characteristics:

1. Patients with psychosis or schizophrenia
2. Infants aged 3 months or younger
3. If a patient has a known allergy to the drug

5.1.2 Relative contraindications

In patients with the following characteristics, ketamine should be used with caution, and benefits should be weighed against the potential for harm.

1. Ketamine is a cardiovascular stimulant, thus can cause an increase in blood pressure and heart rate. Therefore, **caution** should be exercised in patients with hypertension of pregnancy (pre-eclampsia, see below), coronary heart disease and congestive heart failure
2. Ketamine increases cerebral blood flow, causing an elevation of intracranial pressure. However, it is also a neuroprotective agent. Hence, additional caution should be exercised in patients with the following conditions:
 - Head trauma
 - Brain aneurysm
 - Stroke
 - Intracranial haemorrhage
 - Intracranial mass or hydrocephalus
 - Substance and alcohol abuse
3. Ketamine may increase intraocular pressure; thus, caution should be exercised in patients with open eye injuries.
4. Ketamine should be used with caution in procedures involving the posterior pharynx or patients with an active pulmonary infection due to an increased risk of laryngospasm.

5.1.3 Ketamine use in pregnancy

Ketamine is well suited for emergency cesarean sections (more on section 6). However, given its propensity to cause hypertension and increase intracranial pressure, an abundance of caution should be exercised when administered in pregnant women with pre-eclampsia or eclampsia.

5.2 Patient pre-operative assessment and monitoring

Once a patient has been deemed eligible for ketamine use, providers should perform a general pre-operative assessment (similar to any surgical procedure with anaesthesia), which should include a preoperative checklist (**Appendix A**) and the following physical examination:

- Airway
- Breathing (check for signs of pulmonary infection)
- Circulation
- Mental status
- Vital Signs
- Head to toe examination

Once a patient has been fully examined and eligibility established, ketamine administration process may begin:

1. Place an intravenous (IV) catheter on the patient's arm and start an infusion with normal saline.
 - Maintenance fluid therapy replaces fluid and electrolyte losses that patients may suffer during the procedure. Patients should be monitored for signs of volume excess (edema) or depletion (i.e. reduced skin turgor, fall in blood pressure).
2. Place the pulse oximeter on the index finger of the same extremity as the IV line
3. Place a blood pressure cuff on the arm opposite to the pulse oximeter and the IV line
4. Place oxygen on the patient, and if possible, pre-oxygenate for 5 minutes before the administration of ketamine.
 - Pre-oxygenation prior to ketamine induction helps reduce the incidence of hypoxic events. Therefore, it should be provided whenever possible.

5.3 Induction of ketamine for emergency and essential operations, and procedural sedation

In low-resource settings, painful procedures are often performed without any anaesthesia or pain relief if no anaesthetist is available. However, ketamine may be provided at an appropriate dose for procedural sedation to alleviate pain and improve quality of care. Always confirm the concentration of ketamine before its administration.

- During the induction phase of **procedural sedation**, **1.0 mg/kg** of IV ketamine should be provided as the initial dose.

The administration of ketamine in emergency operations is very similar to its administration for procedural sedation. The difference is that since emergency operations are typically longer and more complex, a higher dose is necessary to produce complete dissociation.

- During the induction phase of **emergency operations**, **2mg/kg** of IV ketamine should be provided as the initial dose.

During the induction phase of both emergency operations and procedural sedations, it is important to note that ketamine must be slowly pushed into the IV line, over no more quickly than **30-60 seconds**, in order to prevent respiratory depression.

5.1.1 Intramuscular administration of Ketamine

The intramuscular (IM) administration of ketamine is a viable option when IV access is not possible. Similar to IV ketamine, it is ideal to provide 5 minutes of pre-oxygenation prior to administration.

- IM ketamine requires **5mg/kg** for the initial **induction phase**, which will dissociate the patient for **30-120 minutes**. Onset of the dissociative state will take up to 5 minutes.

5.4 Maintenance of anesthesia and patient monitoring

The ESM-Ketamine provider is responsible for patient monitoring throughout and after the procedure. After administration of the initial dose, it is essential to closely monitor the patient's transition into a dissociative state and communicate with the surgeon. Vital signs should be monitored and recorded in the ESM-Ketamine record.

Once the initial **IV** dose has been proven to be effective, the ketamine provider can administer the drug **every 10-15 minutes** as needed for **maintenance of the desired dissociative state** until the procedure is over. The maintenance doses are the following:

- Procedural sedation: **0.25 to 1 mg/kg IV**
- Emergency surgery: **1 to 2 mg/kg IV**

If using **IM** ketamine, maintenance doses of **3 to 5mg/kg** can be administered as needed until the procedure is complete. Keep in mind that the initial IM dose may last up to 120 minutes, so monitor the patient closely to determine the need for additional doses.

Throughout the entire procedure, the ketamine provider should closely observe the patient to check for signs of waking from the dissociative state. Common signs that the patient is waking include:


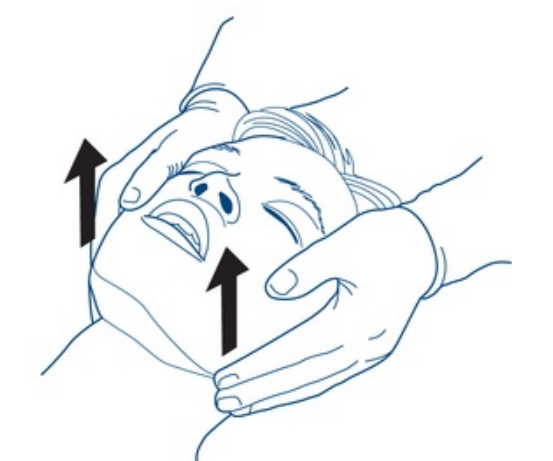
- Spontaneous limb motion
- Spontaneous eye opening
- Gestures of discomfort
- Response to verbal commands
- Verbal activity

If a patient exhibits any of the signs listed above, ketamine re-dosing should be considered.

5.5 Basic Airway Management

Bag-mask ventilation is the cornerstone of basic airway management [10], and all ESM-Ketamine providers must be competent in this technique. In the rare case a patient presents with any signs of respiratory depression, the ESM-Ketamine provider should be prepared to act as quickly and effectively as possible.

Inadequate ventilation is difficult to assess and detection depends on close observation. The provider must evaluate the rate, pattern, and depth of breathing, as well as the use of accessory muscles and presence of abnormal sounds. If inadequate ventilation is suspected, the ESM-Ketamine provider should employ one of the following maneuvers to improve airflow:

<p>Head-tilt chin-lift [11]</p>  A line drawing of a person's head tilted back. One hand is on the forehead, pushing it down. The other hand is under the chin, lifting it up. This action opens the airway.	<p>Used when cervical spine injury is NOT a concern. With one hand, apply downward pressure on the patient's forehead, and with the other, place the tips of the index and middle finger to lift the mandible at the mentum. This will lift the tongue from the posterior pharynx and open the airway.</p>
<p>Jaw-thrust maneuver</p>  A line drawing of a person's head tilted back. Both hands are on the sides of the face, with fingers under the jaw angles. Arrows point upwards, indicating the direction of the thrust. This action displaces the jaw anteriorly.	<p>Used when cervical spine injury is suspected. While standing at the head of the bed, place both palms on the parieto-occipital areas and grasp the angles of the mandible with the index and long fingers to displace the jaw anteriorly.</p>

These maneuvers are appropriate in children as well. Once an open airway has been established, it must be maintained. The ESM-Ketamine provider should place an appropriate-sized mask on the patient's face. The nasal portion of the mask should be placed over the bridge of the patient's nose, while the body of the mask should cover the nose and mouth. The ESM-Ketamine provider should not rest their hands on the patient's eyes. Neither the provider's wrists nor the mask cushion should rest on the patient's eyes. To hold the mask in place, use the single-hand (E-C clamp) technique for bag-mask ventilation in adults and children:



Grab the mask with the web space between the thumb and index finger resting against the mask connector. Place pressure towards the center of the mask. The other three fingers are placed along the mandible to pull it up in a chin-lift maneuver. Only pull the bony parts of the mandible, since putting pressure on soft tissue may occlude the airway. Grab and compress the bag with the other hand.

If the patient's chest does not rise, consider the following:

- Inadequate mask seal
- Improper mask size
- Inadequate airway maneuvers

The bag-mask should not be squeezed excessively (to prevent gastric inflation). The bag-mask should be squeezed steadily over approximately one full second and at a rate of approximately 10 to 12 breaths per minute. The ESM-Ketamine provider performing bag-mask ventilation must carefully monitor the adequacy of technique and should always identify those at risk for difficult ventilation. The mnemonic MOAN is helpful to determine which patients are at higher risk of difficult ventilation:

- **M**ask seal – Factors that make a difficult seal include facial hair, vomit, blood, or facial injuries.
- **O**bstruction/**O**besity – obesity causes resistance due to excessive tissue surrounding the airway.
- **A**ge – Patients aged 55 years or older have more difficult mask ventilation due to a loss of tissue elasticity
- **N**o teeth – due to a lack of structural support for mask seal.

5.6 Post procedure monitoring and recovery

ESM-Ketamine providers should remember that return to consciousness is gradual. Therefore, after the procedure, they should monitor patients closely until patients return to pre-treatment levels of consciousness to detect any side effects from the administration of ketamine. Hallucinations or delirium may occur during this period, which may be reduced by not disturbing of the patient. Slow stimulation may help patients wake up from the dissociative state. Always maintain patients under continuous monitoring (i.e. pulse oximetry, blood pressure monitoring) until recovery is well established.

Vital sign documentation must continue every 15 minutes until the patient is fully awake and returns to pre-treatment level of verbalization, awareness, and muscular activity.

5.7 Ketamine effects

Side effects from administration of ketamine may occur during a procedure and they include: laryngospasm, hypoxia, movement, salivation, hallucinations or agitation, emesis, and hypertension. The ESM-Ketamine Safety Checklist contains a list of medications to help manage these effects. **(Figure 3).**

1. Laryngospasm

Laryngospasm occurs when the vocal chords close in a spasmodic fashion. Laryngospasm is uncommon but can occur during administration of ketamine. A patient suffering from laryngospasm may produce stridor-like sounds, similar to choking. If a patient under ketamine exhibits these signs, the following steps are recommended:

- Remove secretions from the oropharynx
- Ventilate the patient using a bag-valve mask (connected to oxygen). This may require a second person so that a tight seal is obtained
- Ventilate the patient until vocal chords relax

2. Hypoxia

Hypoxia is defined as oxygen saturation lower than 92%. An important cause of hypoxia is the concurrent administration of IV benzodiazepines (BZD) when using Ketamine. Therefore, BZD administration should be limited to intramuscular administration and only as needed. Hypoxia can

be identified by the use and monitoring of the pulse oximeter, provided in the ESM-ketamine kit. If a patient under ketamine has an oxygen saturation below 92% for more than 30 seconds, the provider should:

- Reposition and extend the neck (as shown in basic airway management)
- Increase the oxygen flow rate
- If the pulse oximetry reading remains below 92% consider applying bag-mask ventilation until oxygen levels rise.
- To prevent hypoxic events, pre-oxygenate the patient for 5 minutes before the procedure, if possible.

3. Movement and increased muscle tone

A patient may move during a procedure while dissociated from ketamine. This movement can range from a flicker of the finger to movement of an entire limb. If the patient's movement interferes with the procedure, the surgeon should pause the procedure. The most appropriate solution is to re-dose the patient with ketamine.

4. Hypersalivation

Excessive salivation is common after ketamine administration. If a patient hypersalivates, the provider should:

- Remove saliva from the oropharynx
- If the patient continues to salivate, administer atropine **0.5mg IV**

5. Hallucinations and agitation (recovery reactions)

A patient may present olfactory, sensory, visual, or auditory hallucinations. This is commonly seen after the procedure, during recovery from dissociation. If the patient exhibits signs of hallucinations and/or agitation, the following is recommended:

- Diazepam **5mg IM** (2.5 MG IV one time is a secondary alternative)
- Monitor the patient closely subsequent to diazepam administration

6. Emesis and Nausea

Patients may vomit or gag after ketamine administration or during recovery. If this occurs, the following are recommended:

- Rotate the patient's head laterally to avoid aspiration
- Administer an anti-emetic such as promethazine
 - Promethazine **25mg IM** can be administered once or as a scheduled dose every 2 hours.

7. Hypertension

A patient under ketamine may become hypertensive. In the event of dangerous blood pressure elevations (generally over 220/120), the provider should alert the surgeon. If the surgeon and the ESM-Ketamine provider agree to continue with the procedure, the following steps are recommended:

- Administer hydralazine **5mg IV** slowly
 - Dose may be repeated every 20 minutes, for a total of 4 doses.
- Closely monitor patient's blood pressure


5.8 ESM-Ketamine Safety Checklist

The ESK-Ketamine Safety Checklist is designed to remind providers how to safely and effectively conduct the induction and maintenance phases of dissociation with ketamine (**Figure 3**).


ESM – KETAMINE™ SAFETY CHECKLIST

For emergency/essential surgery and procedural sedation


- ☐ Complete ESM-Ketamine Clinical Record
- ☐ Confirm ketamine concentration
- ☐ Confirm equipment function
 - Pulse Oximeter
 - Blood Pressure Device
 - Oxygen Source/Facemask
 - Suction
 - Bag Valve Mask
- ☐ Place IV of normal saline
- ☐ Place pulse oximeter onto the same side as the IV
- ☐ Place blood pressure cuff on arm opposite the pulse oximeter and IV
- ☐ Place oxygen on patient
- ☐ Titrate appropriate IV ketamine dosing:
 - 1) Emergency/Essential surgery:
 - 2 mg/kg initially over 30-60 seconds
 - 1-2 mg/kg every 10-15 minutes
 - 2) Procedural Sedation:
 - 1 mg/kg initially over 30-60 seconds
 - 0.25-1 mg/kg additionally as needed
- ☐ Complete ESM-Ketamine Clinical Record




MASSACHUSETTS
GENERAL HOSPITAL




GOVERNMENT OF
THE UNITED KINGDOM




USAID
UNITED STATES AGENCY
FOR INTERNATIONAL
DEVELOPMENT




BILL & MELINDA
GATES FOUNDATION




WELLCOME TRUST



UKAID



SAGAN



GATES FOUNDATION

Figure 3 - Front view of ESM Ketamine Checklist

Additional Potentially Useful Medications in Adults Undergoing ESM – Ketamine

- Diazepam 5 MG IM (discourage IV use! If IV, give 2.5 mg over 60 seconds x 1 only) for agitation and/or hallucinations. May repeat IM x 1
- Promethazine 25 mg IM (do not give IV!) or prochlorperazine 10 mg IV for nausea and/or vomiting, every 2 hours as needed
- Atropine 0.5 mg IV for hypersalivation x 1
- Hydralazine 5mg IV given slowly over one minute for a pregnant patient who has severe preeclampsia or eclampsia and who has high blood pressure. Dose may be repeated every 20 minutes up to 4 doses.

PLEASE NOTE:

**No medications other than as stated on this card are allowed
in the ESM - Ketamine clinical pathway**

Version December 20, 2016



Figure 4 - Back view of ESM Ketamine Checklist

6. Helping Babies Breathe

This is a brief overview of Helping Babies Breathe (HBB), which is a newborn resuscitation training program created by the American Academy of Pediatrics. HBB focuses on 'The Golden Minute', when stimulation to breathe and ventilation with bag and mask can save a life. This is not intended to replace a full HBB training course, which usually requires 1 to 2 days of training. Opportunities for full courses are posted on the website: helpingbabiesbreathe.org.

Increasing access to cesarean sections is one of the main reasons why the ESM-Ketamine package is important in resource-limited settings. Perinatal asphyxia is the third most common cause of neonatal death (23%) and has an incidence of 1 to 6 per 1,000 live full-term births [12]. Fortunately, newborn resuscitation is one of the most effective interventions in medicine, and can prevent multiple deaths attributable to perinatal asphyxia. 90% of babies have good outcomes and often only require thorough drying. 9% may need additional interventions, such as airway clearing, stimulation, or bag-mask ventilation. Less than 1% of babies need major resuscitation maneuvers like chest compressions, intubation or medications.

Prior to any birth, providers must follow these four simple steps:



1. Identify a helper and review the emergency plan.

- a. Prepare the birth companion or another skilled helper to assist if the baby does not breathe. One birth companion can help the mother while another helper can assist in caring for the baby. The emergency plan should include communication and transportation to advanced care.

2. Prepare the area for delivery

- a. It should be clean, warm, and well-lit.


3. Wash hands

- a. This prevents the spread of infection



4. Prepare an area for ventilation and check equipment.

- a. Prepare a warm, dry, flat, and safe space for the baby to receive ventilation if needed.

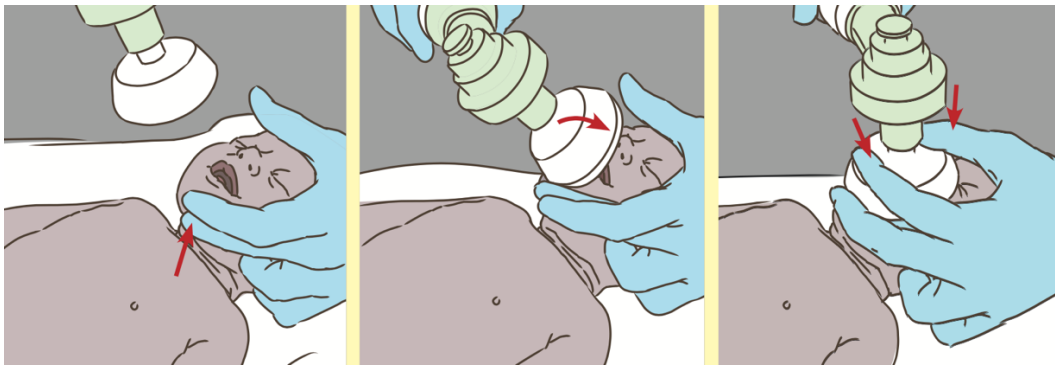
In HBB, 'The Golden Minute' means that babies must be breathing well or ventilating by 60 seconds of life (**Appendix B**).

<p style="text-align: center;">Dry thoroughly</p> 	<p>Immediately after birth, all babies must be placed on top of their mother's abdomen and dried thoroughly with multiple dry towels. If the baby is crying, then they should be kept warm and breathing should be checked continuously.</p>
---	--

Note that there is no great urgency to cut the umbilical cord. It is recommended anytime within 1 to 3 minutes of life. The exception is if the newborn does not respond to initial stimulation and more advanced measure become necessary.

<p>Stimulate breathing</p> 	<p>If a baby is not crying, he/she must be stimulated and the airway cleared. To stimulate the baby, rub the back 2 or 3 times gently, but firmly. Do not delay or stimulate longer.</p>
<p>Clear the airway</p> 	<p>To clear the airway, use the bulb syringe included in the ESM-Ketamine kit. Squeeze the bulb before inserting the tip into the mouth and release before withdrawing. Then clear the nose.</p>

If the baby is still not breathing, providers should begin ventilation with the bag-mask included in the ESM-Ketamine kit (remember this should be done within 'The Golden Minute'). Tie and cut the cord and bring the baby to the resuscitation area, which has been previously identified and prepared.



Check that the mask size is correct. The mask should cover the chin, mouth, and nose, but not the eyes. Stand at the baby's head. Lift chin slightly, ventilate at 40 to 60 breaths per minute, and look for chest rise.

If the chest does not rise, the ventilation technique should be improved:

- Head: Reapply the mask to make a better seal and reposition the head to open the airway.
- Mouth: Check the mouth, back of throat, and nose for secretions. Open the baby's mouth slightly before reapplying the mask.
- Bag: Squeeze the bag harder to give a larger breath.

Cease ventilation efforts when the baby is breathing well and has a heart rate greater than 100 beats per minute. Feel the pulse in the umbilical cord where it attaches to the baby's abdomen. If no pulse can be felt in the cord, the heartbeat should be evaluated with a stethoscope. Listen over the left chest and pause ventilation for several seconds to hear the heartbeat. If there is adequate ventilation and heartbeat, the baby can remain with the mother under close monitoring.

Improving care saves lives. Knowing the right care to give is not always enough to save babies' lives – that knowledge must be put into practice! Full courses are posted on the website: helpingbabiesbreathe.org.


7. Data Collection and Reporting

All ESM-Ketamine providers must report each case to AIHT and/or the MGH Division of Global Health Innovation within a week of the procedure. Data collection and reporting is essential when using ketamine as a dissociative agent in support of emergency and essential procedures when no anaesthetist is available. Data collection cards should be completed for each case (**Figure 5**).


- Identify and record patient history, pertinent medical history, weight, allergies, current medications, and any ketamine effects
- Identify and record ketamine provider's full name and contact information
- Record patient's ABC's and mental status prior to the procedure
- Indicate why ketamine was used for a procedure. **Ketamine should only be administered if no anaesthetist is available or if no anaesthetist would previously have been called.**
- Record number and concentration of ketamine doses
- Check and record the patient's vital signs, including oxygen saturation, before administering the first dose of ketamine
- Check and record the patient's vital signs at **30 seconds, 2 minutes, and every 5 minutes** after the initial dose of ketamine
- Record vital signs on the ESM-Ketamine Clinical Record every time they are checked
- Take note of any medications and doses that were provided during the procedure
- Check and record vital signs at the end of the procedure
- Check and record vital signs once the patient is awake
- Record the length of the case, defined as the time from anesthesia induction to procedure conclusion.
- Document any side effects, adverse events (AEs), or serious adverse events (SAEs):
 - Hallucinations, desaturations, emesis, and hypersalivation should be documented in the table section of the cards under Y/N cells and circled Y. If there are no side effects or adverse events, every N should be circled.
 - AE and SAE documentation should be maintained after ketamine has been stopped and until the patient is alert and oriented.

7.1 Adverse Event Reporting

Adverse events (AEs) are oxygen saturations below 92% for less than 30 seconds. Serious adverse events (SAEs) include deaths and desaturations lower than 92% for more than 30 seconds. If and when either of these occur, it is imperative to contact the in-country research coordinator immediately (who will contact Dr. Burke within 24 hours). In addition, the ESM-Ketamine provider must fill out an SAE document and provide it to the Principal Investigator (PI) at MGH for review. This SAE document can be found in **Appendix C**.



ESM – Ketamine Clinical Record



Date _____ Facility _____ ESM - Ketamine Provider name _____ ESM - Ketamine Provider cell phone _____
 Surgeon/proceduralist name _____ Patient Name _____ Patient cell phone _____
 Patient Age _____ Patient Gender _____ Patient Weight (best estimate) _____ Procedure being performed _____
 Pertinent past medical and surgical history _____
 Current medications _____ Allergies _____
 Complications _____

If you previously (prior to ESM-Ketamine training) would have called an anesthetist for the procedure/operation, please attempt to call for an anesthetist prior to proceeding.

Anesthetist called: (name) _____ Time: _____

Reason not available (circle one): Emergency Delay would compromise care Financial Other (please indicate reason): _____

	Vitals Before Ketamine	At 30 seconds	At 2 minutes	At 5 minutes							Vitals at End of Procedure	Vitals once Awake
Time												
Dose												
RR												
HR												
BP												
PO												
Hal	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Emesis	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
RS	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Hypersal.	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N	Y / N
Oxygen flow rate	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L	_____ L
MS	A / D	A / D	A / D	A / D	A / D	A / D	A / D	A / D	A / D	A / D	A / D	A / D
Other drug?												
Dose												
Time												

RR – respiratory rate

HR – heart rate

BP – blood pressure

PO – pulse oximetry

Hal – hallucinations (yes – Y / no - N)

Emesis – (yes – Y / no - N)

RS – respiratory support (yes - Y / no - N)

MS – mental status (Awake – A / Dissociated – D)

Hypersal. – hypersalivation – (yes – Y / no - N)

Baby alive at delivery - (yes - Y/ no - N)

Baby alive at discharge - (yes - Y/ no - N)

Baby Apgars

Min 1: _____

Min 5: _____

Min 10: _____

Lowest PO during procedure _____

Length of time PO <92% _____

Check box if any of the following medications below were used, and write the total dosage used:

☐ Diazepam: _____

☐ Hydralazine: _____

☐ Promethazine: _____

☐ Compazine: _____

☐ Atropine: _____

Rev. 6/23

Figure 5 - ESM Ketamine Clinical Record.

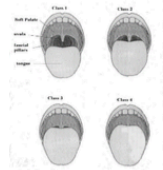
8. Acronyms

AIHT	African Institute for Health Transformation
MGH	Massachusetts General Hospital
ESM	Every Second Matters
IV	Intravenous
IM	Intramuscular
LMIC	Low and Middle Income Countries
NMDA	N-methyl-D-aspartate receptor complex
PI	Principal Investigator
WHO	World Health Organization
HBB	Helping Babies Breathe
SAE	Serious Adverse Event

9. References

1. Anderson, R.E., et al., *Defining the anesthesia gap for reproductive health procedures in resource-limited settings*. Int J Gynaecol Obstet, 2014. **127**(3): p. 229-33.
2. WHO. *Emergency and essential surgical care*. 2017; Available from: <http://www.who.int/surgery/en/>.
3. Meara, J.G., et al., *Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development*. Lancet, 2015. **386**(9993): p. 569-624.
4. Hodges, S.C., et al., *Anaesthesia services in developing countries: defining the problems*. Anaesthesia, 2007. **62**(1): p. 4-11.
5. Chao, T.E., et al., *Survey of surgery and anesthesia infrastructure in Ethiopia*. World J Surg, 2012. **36**(11): p. 2545-53.
6. Ozgediz, D., et al., *The burden of surgical conditions and access to surgical care in low- and middle-income countries*. Bulletin of the World Health Organization, 2008. **86**(8): p. 646-647.
7. *Ketamine, Update Review Report*, in *Expert Committee on Drug Dependence Thirty - sixth Meeting*. 2014, World Health Organization. p. 1-45.
8. Bergman, S.A., *Ketamine: review of its pharmacology and its use in pediatric anesthesia*. Anesth Prog, 1999. **46**(1): p. 10-20.
9. Green, S.M., et al., *Clinical practice guideline for emergency department ketamine dissociative sedation: 2011 update*. Ann Emerg Med, 2011. **57**(5): p. 449-61.
10. Wittels, K.A. *Basic airway management in adults*. 2017; Available from: <https://www.uptodate.com/contents/basic-airway-management-in-adults>.
11. Lim, J., B. Waxman, and M. Favilla. *Chapter 13 - Problems in the injured patient*. 2015; Available from: <https://clinicalgate.com/problems-in-the-injured-patient/>.
12. Lawn, J.E., S. Cousens, and J. Zupan, *4 million neonatal deaths: when? Where? Why?* Lancet, 2005. **365**(9462): p. 891-900.

Appendix A: Preoperative Checklist

Pre-Operative Checklist			
Patient Name: _____		Date of Birth: ____/____/____	
Pre-Operative Diagnosis: _____			
Procedure to be Performed: _____			
Operative Procedure (Circle One): Emergent / Urgent / Elective			
Case Classification (Circle One): Major / Minor		Date of Surgery: ____/____/____	
PART 1. CLINICIAN WARD CHECKLIST			
Surgical Consent Signed?		YES / NO	Theatre List Completed? YES / NO
Blood Ordered?		YES / NO	Blood Available? YES / NO
Name of Consultant Responsible: _____			
Pre-Operative Antibiotics Ordered?		YES / NO	Surgical Site Marked? YES / NO
PAST MEDICAL HISTORY			
Hypertension? YES / NO	HIV Status: Pos / Neg / N/A	Date: ____/____/____	Diabetes? YES / NO
Other Medical History: _____			
Medications: _____		Allergies: _____	
INVESTIGATIONS			
Positive Physical Exam Findings: _____			
Blood Group: _____	Hemoglobin: _____	Urine Pregnancy Test: Pos / Neg	
Radiologic Studies: _____			
Urinalysis: _____		Other: _____	
Clinician's Name: _____		Signature: _____	Date: ____/____/____
PART 2. NURSES WARD CHECKLIST			
IV Access?		YES / NO	IV Fluid Running? YES / NO
Foley Catheter in Place?		YES / NO	Pre-Operative Antibiotics Given? YES / NO
Patient Clipped/Shaved?		YES / NO	Patient NPO past 6 hours? YES / NO
Patient Jewelry Removed?		YES / NO	Patient in Hospital Gown: YES / NO
Patient given chlorhexidine soap?		YES / NO	X-Ray sent with Patient? YES / NO
Blood Pressure: ____/____ Heart Rate: ____ bpm Temperature: ____ °C			
Oxygen Saturation: ____ Respiratory Rate: ____ breaths/min Measured Weight: ____ kg			
Nurses' Name: _____		Signature: _____	Date: ____/____/____
PART 3. KETAMINE PROVIDER / ANESTHETIST WARD CHECKLIST			
Surgical Consent Signed?		YES / NO	Blood Products Available? YES / NO
Time Last Time Ate or Drank?		IV Access Functioning? YES / NO	
Dentures? YES / NO		Missing/Loose Teeth? YES / NO	
Cardiac Status: Can the patient walk a flight of stairs without shortness of breath? YES / NO			
Type of Anesthesia? (circle one): General Tracheal Intubation / Regional / MAC / Ketamine			
Mallampti Score Anesthetists Only Circle One:		ASA Score Anesthetists Only (circle one):	Class 1. Normal Healthy
			Class 2. Mild Systemic Disease
			Class 3. Severe systemic disease limiting activity
			Class 4. Incapacitating disease –life threatening
			Class 5. Moribund Patient
Other Comments: _____			
Ketamine / Anesthetist's Name: _____		Signature: _____	Date: ____/____/____

Brief Operative Note

Pre-Operative Diagnosis: _____

Surgeon: _____
Assistant: _____

Operative Findings: _____

Implants? _____

Estimated Blood Loss: _____

Intra-Operative Complications: _____

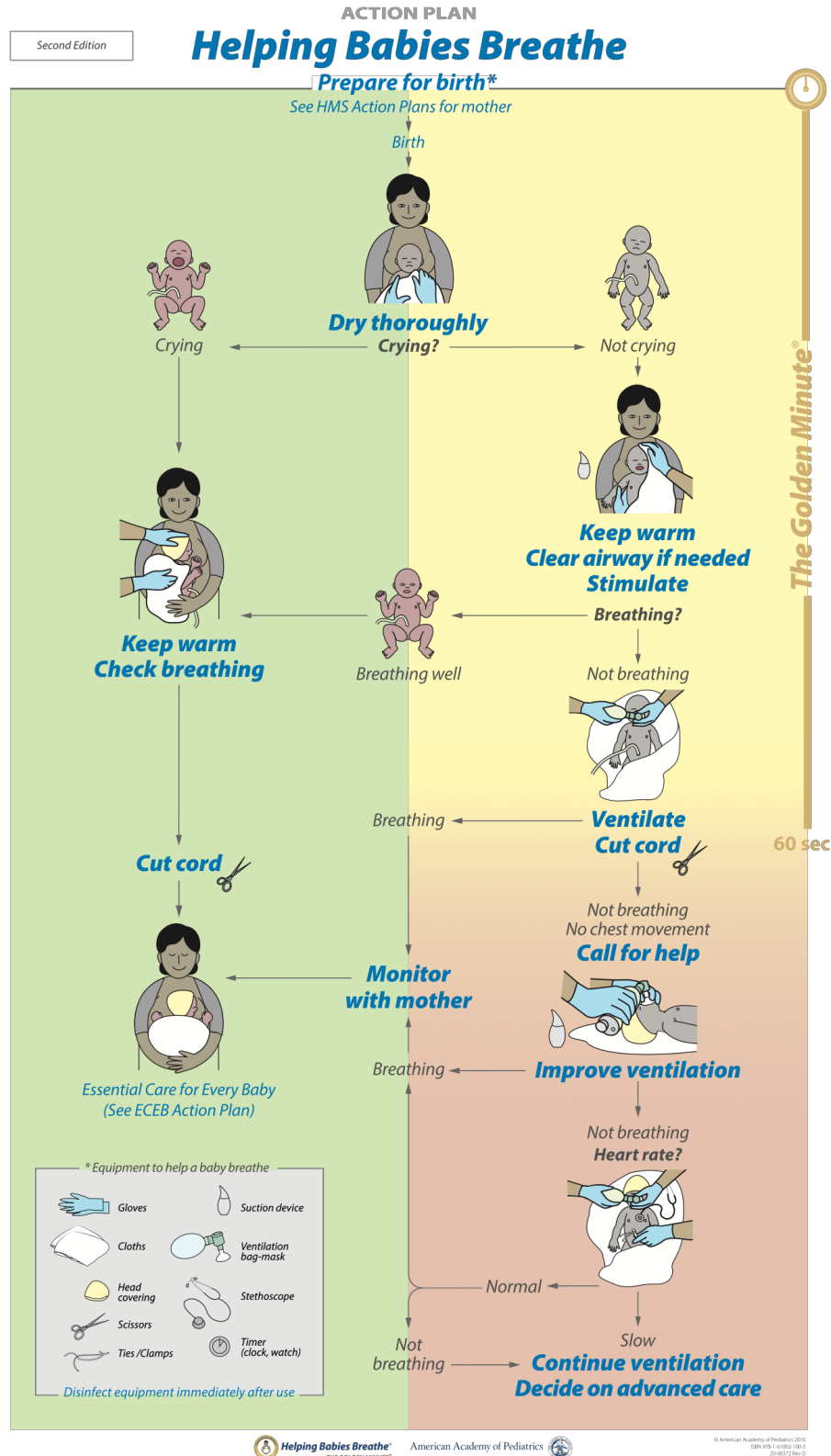
Scrub Nurse: _____

Anesthetist: _____

Operative Note

This image shows a blank sheet of white paper with horizontal ruling lines. The lines are evenly spaced and extend across the width of the page. There is a double-line margin at the bottom. The paper appears to be from a notebook or a standard writing template.

Appendix B: Helping Babies Breathe – Action Plan



Appendix C: Serious Adverse Event Reporting Document

ESM Ketamine Serious Adverse Event (SEA) Report

1. Type of reportable serious adverse event:
 - a. ☐ death
 - b. ☐ pulse oximetry desaturation below 92% for more than 30 seconds
 - c. ☐ Other _____
2. Patient name: _____
3. Date of incident: _____ Date report filed: _____
4. Procedure(s) performed: _____
5. Providers in the room or at bed side:
 - a. ESM-Ketamine Provider: _____
 - b. Proceduralist (Surgeon): _____
 - c. Assitant: _____
 - d. Nurse: _____
 - e. Others: _____
6. Ketamine Dosing:
 - a. Total does administered for the procedure: _____
 - b. Dose immediately prior to the SEA: _____
7. How far into the procedure (hours, minutes) did the adverse event take place?

8. Medications and doses administered in addition to ketamine:

9. Describe the suspected complications leading up to the SEA:

10. Describe the SEA in detail:

11. In hindsight, which of the following could have improved (check all that apply):
 - a. ☐ Oxygen administration

- b. ☐ Readiness with equipment
- c. ☐ Pulse Oximeter
- d. ☐ Assessment of patient's other medical conditions
- e. ☐ Appropriate (slow) administration of ketamine
- f. ☐ attention to vital signs

Explain checked boxes:

12. Please provide a summary of your best explanation of what caused the SEA:

13. Recommendations for improvement:

Name of person who completed this form:

Signature:
