WFSA Presentation to the Expert Committee on Drug Dependence (ECDD)
Presentation overview

- Ketamine is an essential medicine, especially in LMICs
- The alternatives to Ketamine
- Is it possible to ensure the availability of Ketamine for medical use? Lessons learned.
- Conclusions and Recommendations
### 1. ANAESTHETICS

#### 1.1 General anaesthetics and oxygen

<table>
<thead>
<tr>
<th>Inhalational medicines</th>
<th>Inhalation.</th>
<th>Inhalation.</th>
<th>Inhalation (medicinal gas).</th>
</tr>
</thead>
<tbody>
<tr>
<td>halothane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>isoflurane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>nitrous oxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>oxygen</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 1.1.2 Injectable medicines

<table>
<thead>
<tr>
<th>Anesthetic</th>
<th>Injection: 50 mg (as hydrochloride)/ml in 10-ml vial.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ketamine</td>
<td>Injection: 10 mg/ml; 20 mg/ml.</td>
</tr>
<tr>
<td>propofol*</td>
<td>* Thiopental may be used as an alternative depending on local availability and cost.</td>
</tr>
</tbody>
</table>

#### 1.2 Local anaesthetics

<table>
<thead>
<tr>
<th>Local anaesthetic</th>
<th>Injection: 0.25%; 0.5% (hydrochloride) in vial.</th>
</tr>
</thead>
<tbody>
<tr>
<td>bupivacaine</td>
<td>Injection for spinal anaesthesia: 0.5% (hydrochloride) in 4-ml ampoule to be mixed with 7.5% glucose solution.</td>
</tr>
<tr>
<td>lidocaine</td>
<td>Injection: 1%; 2% (hydrochloride) in vial.</td>
</tr>
<tr>
<td></td>
<td>Injection for spinal anaesthesia: 5% (hydrochloride) in 2-ml ampoule to be mixed with 7.5% glucose solution.</td>
</tr>
<tr>
<td></td>
<td>Topical forms: 2% to 4% (hydrochloride).</td>
</tr>
<tr>
<td>lidocaine + epinephrine (adrenaline)</td>
<td>Dental cartridge: 2% (hydrochloride) + epinephrine 1:80,000.</td>
</tr>
<tr>
<td></td>
<td>Injection: 1%; 2% (hydrochloride or sulfate) + epinephrine 1:200,000 in vial.</td>
</tr>
</tbody>
</table>

**Complementary List**

<table>
<thead>
<tr>
<th>Anesthetic</th>
<th>Injection: 30 mg (hydrochloride)/ml in 1-ml ampoule.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ephedrine</td>
<td><em>(For use in spinal anaesthesia during delivery, to prevent hypotension).</em></td>
</tr>
</tbody>
</table>
Anesthesia Capacity in 22 Low and Middle Income Countries

Daniel Vo1, Meena Nathan Cherian2, Shannon Bianchi3, Luc Noël4, Genaibold Lundeg5, Asadullah Taqdeer6, Bakary Tijan Jargo7, Margaret Okello-Nyeko8, Athula Kahandailyanage9, Olive Sentumbwe-Mugisa10, Andrew Ochroch E11, David Okello12, Jack Abdoulie13, Olainyka O. Ayankogbe14, Olaitan Alice Soyannwo15, Patrick Hoekman16, Paul Bossyn17, Rachid San18, Mary Thompson19, Stephen Mwinga20, Shyam Prasad21, Masasabi Wekesa22, Opar Toliva23, Pascience Kibatala24 and Maureen McGunn1

1University of Pennsylvania, Department of Anaesthesiology & Critical Care, Philadelphia, USA
2World Health Organization
3Health Sciences University of Mongolia, Emergency Medicine Division, Ulaanbaatar, Mongolia
4Mulago Hospital, Kampala, Uganda
5University of Lagos, College of Medicine, Department of Community Health & Primary Care Association of General & Private Medical Practitioners of Nigeria, National Chairman, Research & Data Committee, Lagos, Nigeria
6University College Hospital, College of Medicine, Ibadan, Nigeria
7Coopération Technique Belge (CTB) Programme PAPDS
8Université Abdou Moumouni, Niamey, Niger
9KEMRI/Wellcome Trust Research Programme, Nairobi, Kenya
10Martin Luther Christian University, Meghalaya, Centre for Research in New International Economic Order, Chennai, India
11Ministry of Medical Services, Kenya
12Ministry of Health, Uganda
13Ministry of Health, United Republic of Tanzania
12 countries excluded for providing data for <4 facilities
→ 22 countries, 590 facilities surveyed
Figure 6: Type of anesthesia offered at facilities included in analysis.
Figure 5a: Anesthesia equipment available at facilities included in analysis.
Figure 3: Availability of water, electricity and oxygen in facilities included in analysis.
Figure 5b: Anesthesia equipment available at facilities included in analysis.
Ketamine is also on the WFSA list at ALL levels of health care facility (health centre, district hospital, referral hospital)
All these societies of anaesthesiologists, have written to the ECDD, to ask that no further restriction be placed on Ketamine.

The WFSA alone includes 123 member societies who represent anaesthetists from over 140 countries.
Alternatives

Thiopentone + analgesic opioid
Anaesthetic gases
Local anaesthesia for some procedures

These alternatives are also dependent on
• Availability
• Equipment, oxygen, electricity

Require higher skills and training of anaesthesia provider
Emergency Care in LMICs

Médecins sans Frontières: Ketamine used for
• 90 % of C-Sections
• 95 % of procedures in Trauma centres (mainly minor wound surgery)

→ Ketamine remains essential
→ The alternatives are limited
Is it possible to ensure the availability of Ketamine for medical use if labelled as a controlled drug?

The example of morphine:
One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances.

Most national laws were found not to contain measures that ensured adequate provision of opioid drugs for medical and scientific purposes. Moreover, the model legislation provided by the United Nations Office on Drugs and Crime did not establish an obligation on national governments to ensure the availability of these drugs for medical use.

Access to essential medicines that are controlled under the UN conventions is often limited, especially in LICs.

Access to morphine for pain treatment has increased over the past two decades - but only in a small number of countries.

2003:
6 HIC accounted for 79% of the total global morphine consumption
LIC, representing 80% of the world's population, accounted for just 6%.
In November, 1985, India enacted the **Narcotic Drugs and Psychotropic Substances Act**.

The resulting string of procedures to acquire opioids and narcotics for scientific or medicinal purposes is dizzyingly complex: **up to six licenses are required** for every consignment of morphine.

Many hospitals and medical schools have reacted by simply **not stocking morphine**. Most manufacturers, which are subject to the same legal restrictions, in turn **have stopped producing it**, and over the years, since the N.D.P.S. Act came into force, **treatment for acute pain in India has greatly diminished**.

**Data from the International Narcotics Control Board and World Health Organization** shows that **medicinal use of morphine dropped by ninety-seven per cent in the country after the law was enacted, from seven hundred kilograms in 1985 to a low of eighteen kilograms in 1997.**
Any legislation regarding Ketamine must consider the effects before it is enacted.

Any such recommendation must be based on complete data and on a sufficient number, depth and quality of trials or pilot studies to consider access and availability for medicinal purposes.
Baghdad, Iraq 05/16/03 A man screams in pain as a stab wound in his arm is stitched without anaesthetic in the Yarmouk hospital emergency room. Due to shortages in supplies the doctors were unable to treat the man with anaesthetic, or sterile sutures and gauze. Photo / Thorne
“Although the Single Convention and interpretations of the Convention made by competent international authorities are clear about national governments’ obligation to ensure that opioid drugs are available for medical and scientific purposes, balanced legal provisions were scarce among national laws.

Less than half the countries we studied had laws that acknowledged an intention to implement international drug conventions. Even fewer acknowledged responsibility for ensuring drug availability”

Examined Data from 15 countries: Armenia, Australia, Georgia, India, Jamaica, Jordan, Kenya, Nepal, Nigeria, Philippines, Serbia, Sierra Leone, Uganda, United States, Vietnam
Conclusions and recommendations

a) Very good evidence of the reliance upon Ketamine as a safe anaesthetic drug, particularly in LMICs.

b) Past experience indicates that further restriction on essential drugs can and does limit availability for medical purposes.

c) There is some evidence concerning the abuse of Ketamine, but in most LMICs this is not reported, more data is needed.

d) Therefore, any decision to further restrict Ketamine is premature at the very least, and - more alarmingly - a potential risk to large numbers of patients around the world.
The WFSA therefore calls upon the ECDD not to recommend any further restriction on Ketamine pending the collection of more reliable and complete data on the effects that this might have on the availability of an essential anaesthetic drug, and on patient outcomes around the world.

Should any initiative to restrict Ketamine be approved this should concurrently create tried, tested and easily navigable pathways for the legitimate medical use of Ketamine, and ensure that these can be and are being implemented at national level and at all levels of the health care system.
THANK YOU

admin@wfsahq.org

facebook.com/WFSAOrg

@WFSAOrg

World Federation of Societies of Anaesthesiologists

Subscribe to our quarterly e-newsletter:
Email us at admin@wfsahq.org

www.wfsahq.org

Dr Jannicke Mellin-Olsen