Ibogaine treatment for opioid dependence in New Zealand: A 12-month post-treatment follow-up observational study

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Substance Use and Policy Analysis

In association with

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Researching NZ ibogaine treatment outcomes

• Introduction
  – Introduction, history
  – The unique New Zealand situation
  – The New Zealand study

• Comparing with Mexico: A tale of two studies
  – Two 12-month post-treatment ibogaine studies
    • Mexico (Kingsley-Brown) & New Zealand (Noller)
    • CF Mexican study, NZ treatment outcomes relatively +ve
  – Why relative differences?
    • Therefore, compare studies and contexts

• Explanations
  – Drug use’ landscape’, NZ legislation, NZ treatment provision

• Implications
Ibogiane—the substance

• One of 12 indole alkaloids found in the root bark of a West African shrub, *Tabernanthe iboga*

• Used by West Africans in cultic practices

• Has been used medically for over a century, e.g.
  — as an anti-parasitic
  — as *Lambarene*, a 1930’s pharmacological preparation marketed as “a neuromuscular stimulant, promoting cell combustations and getting rid of fatigue, indicated in cases of depression, asthenia, in convalescence, infectious diseases.”

*Popik et al, 1995:237*
Ibogaine
Ibogaine “breaking open the head”

Cultic practices amongst the Bwiti
For opioid dependence

An addiction interrupter?

Howard Lotsof
In NZ ibogaine is available on prescription

- Ibogaine ‘under the radar’ until 2010

- July 2010 – ibogaine gazetted by the government’s Medsafe Medicines Classification Committee, under the Medicines Act as a *non-approved prescription medicine*

**Rationale:**
- potential for therapeutic use
- relatively low profile for ‘abuse’
- mortality rate in treatment similar to that of methadone
- will allow therapeutic use while limiting potentially hazardous self-administration

**Implications:**
- opens way for prescription by a licensed physician
- led to possibility of trials / study
- draws ibogaine into medical control
The New Zealand study

• A response to the Medsafe decision

• Funding via Matt & Kristi Bowden’s family trust to MAPS

• Subsequent funding from The Star Trust

• Using the pre-existing protocol from the MAPS Mexican ibogaine study
Primary objective / outcome measure:

Determine the effectiveness of ibogaine-assisted therapy in elimination or reduction of opioid usage, craving, and withdrawal, and in improving other aspects of life.

Measured by the **Addiction Severity Index (ASI-Lite)** composite scores over a period of 12 months following the therapy.
Secondary objectives / measures

– Assess severity of withdrawal symptoms following ibogaine treatment, measured by **Subjective Opioid Withdrawal Scale (SOWS)**; assess if ibogaine treatment reduces presence of symptoms;

– Determine effectiveness of ibogaine-assisted therapy in producing relief from self-reported depression using **Beck Depression Inventory-II (BDI-II)**;

– Investigate relationship between ASI composite scores after ibogaine treatment and subjective effects of treatment / alteration of consciousness, measured by **States of Consciousness Questionnaire (SCQ)**

– Assess participants’ status and well-being using the investigator ratings

– Determine if treatment effects have met participants’ pre-treatment expectations

– Verify drug use or abstinence using data obtained from urine drug screening
Protocol

• 12-month follow-up post-treatment
  – 14 ‘visits’ (V1-14), 3 drug screens, affiliates

• V1 1 x pre-treatment ‘visit’ (Baseline)
  – ASI, BDI, SOWS

• V2 1 x post-treatment ‘visit’
  – BDI, SOWS, SOCQ

• Vs 3-14 12 x monthly ‘visits’ post-treatment
  – ASI & BDI @ visits 3, 5, 8, 11, 14
  – ‘random’ urine screens @ visits 8 & 11
Two 12-Month post-treatment ibogaine studies

- NZ study
  - Sponsored by MAPS, The STAR Trust
  - NZ Anthropologist Geoff Noller
  - 14 subjects (19 contacted)
  - 2 x treatment providers (1 & 13 subjects)
The Numbers

<table>
<thead>
<tr>
<th></th>
<th>Mexico</th>
<th>NZ / Aotearoa*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjects</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacted</td>
<td>67</td>
<td>19</td>
</tr>
<tr>
<td>Recruited</td>
<td>30</td>
<td>14</td>
</tr>
<tr>
<td>Lost to follow-up (relapsed)</td>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Withdrew</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Followed to 12-months</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>Opioid-free @ 12-months</td>
<td>6 (20%)</td>
<td>4 (57%)</td>
</tr>
</tbody>
</table>

* NZ study is on-going, with 6 subjects to complete (3 currently opioid-free)
Explanations (differences)

- Study context
- Drug use landscape
  - Isolation
  - Specific drugs
- Legislation
  - Prescribable ibogaine
- A style of treatment provision
  - Best practise
  - Integrated care
  - Aftercare
Study context
Across the border vs the back yard
New Zealand “Last, loneliest, loveliest” Rudyard Kipling 1891
## Drug use landscape

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Mexico % (n=30)</th>
<th>NZ % (n=14)</th>
<th>NEP survey % (n=718)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin</td>
<td>50</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suboxone</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opium (incl. poppy tea)</td>
<td>3</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td>71</td>
<td>58</td>
</tr>
<tr>
<td>Morphine</td>
<td></td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>Dihydrocodeine (DHC)</td>
<td></td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Percentages of Mexico and NZ study subjects treated for opioid dependence with ibogaine, and NZ Needle Exchange survey participants reporting use of opioids, by drug.
Importation and supply

Prescribing Doctors
2010 + 2011 Two Ibogaine naïve gp’s
2012 Dr Cornelius Van Dorp
2012 - Current Dr Winsome Aroha

Product Used
• Phytostan Enterprises, Inc - REMOGEN™ Brand GMP Quality Ibogaine Hcl
• Wilkinson and Son Pharmacy, Dunedin – Pharmacist Warren Leonard encapsulates 200mg capsules
Prescription Status of Ibogaine in NZ - Positive Implications

- Legitimizing ibogaine as a therapeutic intervention
- Existing health professionals gain awareness and understanding
- Integration with existing services for individual needs allowing ‘wrap-around’ care
- Medical inclusion creates a lower risk profile
- Legitimacy and availability of ibogaine therapy grows with awareness and commonality of care, familiarity
- Common language and synchronized assessment and therapy plans within sector
Promotes integrated care

- Client
  - Treatment provider (time with client, comprehensive assessment)
    - General Practitioner
      - Drug treatment professionals
        - Pharmacist
          - Treatment incorporating health professionals
            - Aftercare, e.g. support, group work, counseling
              - Best practise and best outcomes
Summary & Implications

- Ibogaine appears to have therapeutic potential

- New Zealand legislation provides a unique opportunity for research

- Two matched studies appear to produce different outcomes

- Explanations include:
  - Differential access to subjects
  - Impact of geography and isolation
    - Different drug use landscape, e.g. access and addiction potential?
  - Legislation—prescribable ibogaine promotes...
    - Greater opportunity for integrated care of clients
    - A unique style of treatment provision
    - A ‘best practice’ model, with greater emphasis on time spent with clients and the possibility for aftercare

- Therefore, ibogaine treatment outcomes are NOT determined solely by ibogaine, but rather reflect the CONTEXT and STYLE of treatment
**Further Investigations**

- Dr Ken Alper, *Fatalities Temporally Associated with the Ingestion of Ibogaine*
  
  [http://iceers.org/docs/science/iboga/Alper%20et%20al_2012_Fatalities_Temporally_Associated_Ingestion_Ibogaine.pdf](http://iceers.org/docs/science/iboga/Alper%20et%20al_2012_Fatalities_Temporally_Associated_Ingestion_Ibogaine.pdf)

- GMP Ibogaine: REMOGEN™ [Ibogaine HCl] [http://phytostan.ca/products/](http://phytostan.ca/products/)

- Medsafe Minutes Nov 2009 – *re Ibogaine: Minutes of the 42nd meeting of the Medicines Classification Committee - 3 November 2009*  

- Multi-disciplinary Association for Psychedelic Studies: Ibogaine Research  