

CATEGORY 3

**Implementing evidence-based tobacco dependency treatment in
addiction/mental healthcare units in Brazil**

Request ID: 13513957

A. Table of Contents:

B. Main Section	2
Overall Goal and Objectives	2
Technical Approach	3
Current Assessment of need in target area	4
Intervention Design and Methods	5
Evaluation Design	7
Detailed Workplan and Deliverables Schedule	
C. Organizational Detail	12
Leadership and Organizational Capability	12
Staff Capacity	13
D. Detailed Budget	
E. Staff Biosketches	
F. Letter of Commitment	

B. Main Section

- **Overall Goal & Objectives**

Despite the availability of treatment for regular smokers through large national programs (such as the INCA and PROAD programmes) in Brazil, the population of mental health and addiction (MHA) patients has received little help to combat smoking. However, the prevalence of smoking among MHA patients is 2-4 times higher than it is in the general population (Morisano et al., 2009). The treatment of smoking in MHA patients appears to be beneficial, and recent studies (Hitsman et al., 2009) have highlighted treatment as a variable related to smoking cessation in this population (Reid et al., 2011). Much of this low levels of treatment due to a lack of information and false perceptions of health professionals regarding the treatment of smoking in this group of patients (Fagerström & Aubin, 2009). Recent studies show that success rates in quitting smoking and retention in the treatment are at least comparable to the general population (Castaldelli-Maia et al., 2013; Castaldelli-Maia et al., 2014), since the treatment of smoking is incorporated into ongoing treatment for mental disorder or other addiction. Considering this, units of specific outpatient treatment for treatment of mental disorders and addictions are strategic locations for such processing. However, in Brazil and in several other countries, such units that are engaged in the fight against smoking are the exception.

Psychosocial units (CAPS - Centros de Atenção Psicossocial) promote public comprehensive care for people with severe and persistent mental disorders in Brazil (Mateus et al., 2008; Nunes et al., 2008; Miranda & Campos, 2008). Psychosocial units for alcohol and drugs (CAPS-AD) are specifically designed for individuals with substance use disorders (Castaldelli-Maia et al., 2013; Oliveira et al., 2014), and are largely integrated with the regular CAPS units (designed for mental health disorders). These units (CAPS and CAPS-AD) have staff from multiple professions (Mielke et al., 2009), and represent interesting locations for treating smoking addiction (Castaldelli-Maia et al., 2013). Almost all of the recommendations made in previous studies (Hitsman et al., 2009; Morisano et al., 2009; Aubin et al., 2012) with focus on smoking treatment for patients with mental health and addiction disorders, could be implemented in these health units. Because CAPS and CAPS-AD staff teams include professionals specialised in mental health and addiction disorders, it is possible to perform smoking cessation treatment integrated with ongoing psychiatric and/or addiction treatment. Professional care is available during business hours (in some units, 24 hours a day) for any clinical demand from patients who are undergoing smoking treatment and other regular treatments, as recommended in recent studies for smoking cessation patients with mental health and addiction disorders (Hitsman et al., 2009; Morisano et al., 2009; Aubin et al., 2012).

Overall Goal

To increase the number of CAPS-AD (*Centro de Atenção Psico-Social – para Álcool e Drogas* or Psychosocial Care Center – for Alcohol and Drugs) units which perform treatment for smoking in all 5 Brazilian regions, including those in the INCA (*Instituto*

Nacional do Câncer or National Cancer Institute) National Anti-Smoking Programme, through the training of professionals in these units

Key objectives

Our team aims to train the staff of CAPS-AD units that have not been running specialized treatment for tobacco dependency, which includes the use of pharmacotherapy and/or psychotherapy specifics. Most of these units do not provide this type of treatment. Currently there are 301 CAPS-AD units in Brazil. Brazilian law provides that there must be at least 1 CAPS-AD unit for each city with 70,000 or more inhabitants.

- To expand the number of Global Bridges network members in Brazil by 112 new members;
 - To train 112 health care professionals (7 professionals per CAPS-AD unit);
 - To enable the implementation of a smoking treatment protocol in 14 units CAPS-AD (at least 1 in each of the 5 Brazilian administrative regions);
 - To establish a Brazilian network of smoking treatment linked to the Global Bridges network;
 - To create a databank with the results of the treatment employed in these units.
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- **Technical Approach**

RFP specific area of interest

Since we are applying for the category 3 of the RFP, this project would implement evidence-based Innovation in CAPS-AD units, by the creation of healthcare professional training programs in Brazil, a Middle-Income Country (World Bank, 2014). There was no previous funding for this project.

This project will meet the goal of RFP category 3:

(i) by the increase of CAPS-AD units that deliver tobacco dependency treatment (e.g., counseling and/or evidence-based pharmacotherapy) provided by healthcare professionals, there would be an increase in the number of people who stop smoking by improving the frequency and effectiveness of treatment interventions in Brazil;

(ii) to create and mobilize a Brazilian network as a part of the Global Bridges network of healthcare professionals and organizations dedicated to advancing evidence-based tobacco dependency treatment and advocating for effective tobacco control policy, and;

(iii) to promote collaborations across all the 5 Brazilian administrative regions (a country with continental dimensions, with various social, cultural and economic differences), which would build and expand the number of healthcare professionals

committed to treating tobacco dependency, and promote policies which facilitate stopping tobacco use.

Evidence based treatment for smoking

The treatment to be delivered by CAPS-AD trained staff, which will comprise bupropion or nortriptyline plus group therapy will be based on evidence and best practice based on three :

(i) Care protocols that include a health professional (a psychiatrist or an addiction doctor) and behavioural psychotherapy associated with pharmacotherapy may increase success rates for smoking cessation (Batra et al., 2009). A recent review (Laniado-Laborin, 2010) to examine the effectiveness of interventions for smoking cessation identified the following success rates after 1 year: approximately 3.5% if the person tries to stop alone, 7-16% if he/she receives behavioural therapy and 24% if he/she receives behavioural therapy associated with pharmacotherapy (including nicotine replacement, bupropion or varenicline). Other studies have suggested an increase in the abstinence rate when people combine bupropion or nortriptyline with nicotine replacement therapy compared to when they use nicotine replacement therapy alone (Berlin et al., 2009);

(ii) All types of nicotine replacement treatment can help people quit smoking, and these methods are associated with an increase of 50-70% in success rates over trying to quit smoking without aid (Stead et al., 2008) and group psychotherapy based on behavioural concepts is considered a good approach for psychotherapy for smoking cessation. In a recent review, group therapy was found to be more effective than self-help and other, less intensive therapies (Stead et al., 2005). In a systematic review that assessed the most successful therapeutic interventions for smoking cessation, group psychotherapy received the highest odds ratio, ahead of bupropion and nicotine replacement therapy (Lemmens et al., 2008). Individual counselling from a smoking cessation specialist (Lancaster et al., 2005) and motivational interviewing (Lai et al., 2010) may also help smokers to make a successful attempt to stop smoking;

(iii) Recent studies have encouraged smoking treatment for MHA patients using psychotherapy based on cognitive-behavioural concepts and/or motivational interviews and pharmacotherapy integrated with ongoing psychiatric/addiction treatment has shown the best success rates (Hitsman et al., 2009). Treatment for smoking in MHA patients seems to have no adverse effects on psychiatric symptoms, and a patient's clinical condition may even improve during the treatment, regardless of smoking abstinence (Hitsman et al., 2009).

o Current Assessment of need in target area

For instance, this project builds upon ongoing cessation treatment delivered at a CAPS-AD unit since 2007 (see more details at Pubmed: Castaldelli-Maia JM, Carvalho CF, Armentano F, Frallonardo FP, de Toledo Ferraz Alves TC, Andrade AG, Nicastri S.

Outcome predictors of smoking cessation treatment provided by an addiction care unit between 2007 and 2010. *Rev Bras Psiquiatr* 2013; 35: 338–346; and Castaldelli-Maia JM, Loreto AR, Carvalho CFC, Fralonardo FP, Andrade AG. Retention predictors of a smoking treatment provided by a public psychosocial unit in Brazil. *International Review of Psychiatry* [in press, not published at Pubmed yet] by members of this CAPS-AD unit and Centro de Estudos em Saúde Mental do ABC.

There is consensus about the low number of studies investigating the levels of smoking and its treatment in Brazil, and there is no other study to assess the availability of services for the treatment of smoking in MHA patients. However, there is a cross-sectional study (Ratto et al., 2007) carried out in São Paulo (the most populous city in Brazil), which evaluated a sample (n = 192) comprising individuals diagnosed with severe mental illness who had contact with psychiatric public services, aged between 18 and 65 years. Within the 192 individuals with severe mental disorders respondents, 115 (59.9 %, 95% CI: 52.6 %, 66.9 %) reported having made daily use of cigarettes. Being male, being separated or widowed, irregular use of neuroleptics and history of ten or more previous hospitalizations were independently associated with smoking (Ratto et al., 2007). Based on these findings, the prevalence of smoking in individuals with severe mental disorders is higher than the prevalence found in the general Brazilian population. This is in line with data from other countries (Morisano et al., 2009; Hitsman et al., 2009).

o Intervention Design and Methods

The project consists of two parts: workshop and implementation in clinical practice.

Workshop (First 12 months)

To be delivered to health care professionals of CAPS-AD units at their city. The workshops will use the Global Bridges approach and obtain consultation from experts that have further experience in running this training. This approach is complementary to the work being done by the InterAmerican Heart Foundation. The workshop consists in 6 parts:

1) Administrative – To enable the CAPS-AD units:

(i) for getting support from INCA for the treatment of smoking by receiving specific medications (bupropion and nicotine patches);

(ii) for storing and accounting the medications received;

(iii) to calculate the number of vacancies available based on equipment and staff available;

(iv) to inform the public about the availability of treatment and management of the waiting list.

2) Current concepts about smoking – Lecture on:

(i) the epidemiology of smoking in Brazil and in other countries, in sub-groups of interest such as women, elderly, adolescents, individuals with psychiatric disorders and other types of dependency, and individuals with clinical diseases;

(ii) the consequences of smoking within the human body systems;

(iii) the neurobiology of smoking (the reward system, the role of the frontal cortex and nicotinic receptors).

3) Pharmacological Treatment – To enable the practitioners for prescribing medications provided (bupropion and nicotine patch) and not provided (varenicline, nortriptyline and other forms of NRT) by INCA for the treatment of smoking in a classic 12-week treatment:

(i) dosage;

(ii) side effects;

(iii) pharmacokinetics and pharmacodynamics;

(iv) therapeutic strategies (associations of medications), and;

(v) the integration of pharmacological of smoking treatment with ongoing psychiatric treatment of MHA (Mental Health and Addiction) patients.

4) Psychotherapy Treatment – To explain on the implementation of specialized group psychotherapy for the treatment of smoking in 12 sessions, based on:

(i) the concepts of cognitive-behavioral therapy (management of cognitive distortions, problem solving, exposure training, identifying and changing core beliefs, and skills development);

(ii) motivational interviewing (role of the therapist in each of motivational stages), and;

(iii) the integration of psychotherapy for smoking with ongoing psychotherapy of MHA patients.

5) Instruments used to evaluate smoking habits: To enable practitioners for using all the Portuguese validated-scales for smoking habits during the first visit of the patient:

(i) Fagerstrom Test for Nicotine Dependence (FTND);

(ii) Heavy Smoking Index (HSI);

- (iii) Questionnaire on Smoking Urges-Brief (QSU-Brief);
- (iv) Diagnostic and Statistical Manual-IV (DSM-IV) Nicotine Dependence;
- (v) International Classification of Diseases-10 (ICD-10) Tobacco Dependence.

*Unfortunately, Nicotine Dependence Syndrome Scale (NDSS) and Minnesota Nicotine Withdrawal Scale (MNWS) were not translated and validated to Portuguese.

6) Instruments used to evaluate psychiatric morbidity: To enable practitioners on the use of Questionnaire for Adult Psychiatric Morbidity.

Implementation in Clinical Practice (Last 12 months)

After training all 14 CAPS-AD staffs, it will begin a process of follow-up for implementation of treatment for smoking in each CAPS-AD unit based on the knowledge gained at the workshop.

This process of follow-up will take place through periodic meetings with the managers of the 14 units CAPS-AD units. These meetings will be held via Skype (free virtual interface for visual and sound communication) with the expected duration of 30 minutes. An additional alive meeting will be held at the CAPS-AD, in which the medical advisor will see the medical consultancies and group therapy session. Additional meetings may be scheduled by assessing the need for the medical advisor of the project and unit managers. Other members of the multidisciplinary team can also participate in these meetings, with the prior approval of the medical advisor and the manager of each unit. If the manager of the unit can not participate in the meeting, he/she must indicate someone else from staff members, who participated in the workshop, to conduct the meeting. The project staff predicts that these meetings may help to clarify any questions about the contents delivered in the workshops, especially in parts 1 (Administrative), 3 (Pharmacological Treatment) and 4 (Psychotherapy Treatment). In addition, these meetings have the following objectives:

- (i) try to generate an extra-incentive for the implementation of treatment in clinical practice in these units;
- (ii) show that most of the issues and difficulties in implementing the treatment can be solved through the exchange of experiences of CAPS-AD managers and staff members through the Global Bridges Network website and facebook page, and;
- (iii) manage the creation of a database of the treatment in 14 units which participated in this project.

o Evaluation Design:

- Sources of data

1. Report from CAPS-AD managers;
2. Report from CAPS-AD staff members, who were trained in the workshops;
3. Fulfilled protocols
4. Activity level of CAPS-AD staff members in the Global Bridges network (website and facebook page)

- Data collection

Four types of outcomes will be evaluated:

1. Number of CAPS-AD units which implemented the treatment 12 months after the training (Maximum = 14)
2. Number of professionals trained (Maximum = 112)
3. Number of smokers who entered the treatment 12 months after the treatment was implement in each CAPS-AD (Target per CAPS-AD unit = 122, Total = 1,712)
4. Number of smokers treated who achieved abstinence at the end of the 12-week treatment (50% of all the smokers who entered treatment, Total = 856)

In addition, there is a secondary goal of creating a database with the information of the treatment implemented in these 14 units. This database will be supplied by the fulfilled protocols, to be completed in the first visit of the patient, and at each return visit. The main measures to be collected are listed below:

(i) Baseline (First consultation):

- a. Socio-demographic profile;
- b. Fagerstrom Test for Nicotine Dependence (FTND);
- c. Heavy Smoking Index (HSI);
- d. Questionnaire on Smoking Urges-Brief (QSU-Brief);
- e. Diagnostic and Statistical Manual-IV (DSM-IV) Nicotine Dependence;
- f. International Classification of Diseases-10 (ICD-10) Tobacco Dependence;
- g. Other smoking profile information;
- h. Questionnaire for Adult Psychiatric Morbidity;
- i. Other psychiatric profile information;
- j. Medical Profile;
- k. Environment information

(ii) Return visits:

- a. Type of treatment prescribed
- b. Compliance
- c. Adherence
- d. Retention
- e. Self-report abstinence
- f. Carbon monoxide expired level

- Amount of change expected from this intervention:

- To triple the number of Global Bridges network Brazilian members;
 - To train 112 health care professionals (7 professionals per CAPS-AD unit);
 - To enable the implementation of a smoking treatment protocol in 14 units CAPS-AD (at least 1 in each of the 5 Brazilian administrative regions);
 - To establish a Brazilian network of smoking treatment linked to the Global Bridges network;
 - To create a databank with the results of the treatment employed in these units.
- Target audience engagement

The engagement of the target audience in the intervention will be evaluated in two ways:

(i) At the end of the workshop: a test will be applied to evaluate the learning of each staff member. This test will consist of questions that address the content presented in the 6 parts of the workshop. For being approved at the workshop, the staff member should have a grade greater than or equal to 70 (0-100) and have 100% attendance in the workshop. The student who fail to have a grade greater than or equal to 70 might take a new test to be administered alive at a time and date to be scheduled.

(ii) In the second year of the project, the project staff will focus on assessing the implementation of the content learned during the workshop in clinical practice. A follow-up will be conducted with all 14 units that participated in the workshop over a year to stimulate the implementation of treatment in clinical practice.

- Dissemination

The project outcomes will be disseminated in two ways:

(i) Global Bridges Network:

After each workshop, the project staff will post photos, comments and testimonials on facebook Global Network Bridges. In addition, the project staff will encourage people who participate in the workshop to become members of the Global Network Bridges, incentivizing them to posting additional comments on the facebook page of the Global Network Bridges about the workshop and implementation of treatment for smoking in their units. We believe that this kind of attitude would really encourage people to participate in a smoking cessation network, exchanging experiences, successes and difficulties.

(ii) Scientific Journals

We intent to publish at least one article at *Revista Brasileira de Psiquiatria* (The Official journal of the Brazilian Psychiatric Association, Pubmed indexed, 2012 impact factor = 1.85) contemplating the results of treatment in all units participating in this project. However, we strongly believe that there will be other publications, in other local and international journals, presenting the results of the treatment delivered by these units.

- **Detailed Workplan and Deliverables Schedule**

The project will be carried out in two phases: (i) workshop (12 meses) e (ii) implementação na prática clínica (12 meses). In addition, there will be a program management, which will occur throughout the entire project.

(Please find a Time Line Table attached)

Phase 1 – Workshop (12 months)

a. Creation and Development of the Workshop (5 months)

In this phase, the medical advisor (doctor) and the technical assistant (psychologist) will develop written materials and lectures to be used and presented during the workshops, respectively. For this aim, it will be necessary to perform a thorough literature review to summarize the most recent knowledge in Parts 2 (Current concepts about smoking), 3 (Pharmacological treatment) and 4 (Psychotherapy treatment). Moreover, the project staff will consult the literature specific to each of the 6 instruments to be presented in the workshop (parts 5 and 6 of workshop), used in the initial treatment protocol. Finally, the project staff will compile the required materials for the CAPS-AD unit be registered at the INCA National Program Against Smoking (Brazilian Health Ministry, 2014).

b. Workshop delivery (7 months)

In this phase, the workshop will be presented in each of the 7 selected cities, at a frequency of 1 city per month, by the medical advisor and the technical assistant:

- Belém (North region)
- Brasília (Center-West region)
- Marília (Southeast region)
- Porto Alegre (South region)
- Salvador (Northeast region)
- São Paulo (Southeast region)
- Rio de Janeiro (Southeast region)

Each workshop will be delivered to at least one and at most three CAPS-AD units. Anyway, at the end of the project, there will be 14 CAPS-AD units staff trained. Our initial intention is to include 2 teams CAPS-AD per workshop.

Phase 2 – Implementation of treatment in the Clinica Practice (12 months)

In this phase periodic meetings between the medical advisor and unit managers will be scheduled via Skype. During this period, there will be also an in-person meeting, in which the medical advisor visit the CAPS-AD unit to see how the service is being held at this location (monitor medical consultations and group psychotherapy). In addition, the units will send fulfilled protocols for primary project Institution for tabulation of data with the aid of a typist.

Program Management structure (During all the project – 24 months)

(i) Weekly status meeting

Administrative consultant (ACON) will sponsor weekly meetings with steering committee of the program with the objective of discussing administrative/ financial status of the project, insuring it develops as planned

A status report of the meeting will be documented and available for further assessment.

(ii) Monthly technical meeting

Administrative consultant (ACON) will sponsor monthly meetings with technical body in order to discuss in further details all technical aspects. Such as methodology, results, next steps, and other subjects that may be relevant. The objective is to track if any adjustment in program is needed. All the content of the meeting will be documented and will be assessable for further assessment.