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Feasibility Study

Opioid Substitution Treatment in Egypt



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UNODC expresses its gratitude to the following contributors:

From the Ministry of Health and Population: Dr. Amani Haroun El Rashid, Professor, Ain Shams University Medical School; Dr. Tamer El Amroussy, Addiction Unit Director, the General Secretariat of Mental Health and Addiction treatment (GSMHAT); Dr. Manal Abed, Addiction Unit, GSMHAT; Dr. Khaled Siagy, Mental Health Council; Dr. Walid Kamal, Manager ,National AIDS Programme(NAP); Dr. Fadila Amer, Director, Central Agency for Pharmaceutical Affairs (CAPA); Ms. Samah Ragab, Technical Officer, CAPA; Ms. Rania Ashraf, Technical Office Deputy Director, CAPA; and Mr. Rasha Abu Shadi, Head of Pharmaceutical Procurement Department, CAPA.

Ministry of Interior: General Montasser Abou Zeid, former Director, Anti-Narcotics General Administration (ANGA), Brigadier Nabil Hassan and Colonel Emad Gheith, ANGA.

Mr. Amr Othman, Director, National Council for Drug Control and Treatment/National Fund for Drug Control and Addiction Treatment; Prof. Dr. Inas El Gaafarawy, National Centre for Social and Criminological Research; Prof. Dr. Laila Abdel Gawad, in charge of the national drug hotline; National Centre for Social and Criminological Research; and Judge Wael Abou Eitta, Human Rights Department at the Ministry of Justice.

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Dr. Hendrik Jan Bekedam, World Health Organisation (WHO) Country Representative, Ms. Joumana Hermez, Technical Officer at the AIDS and STD Unit, WHO East Mediterranean Regional Office (EMRO); Dr. Khaled Saeed, Technical Officer, Mental Health and Substance Use Unit, WHO EMRO, Dr. Hala El Henawy, Technical Officer, WHO Country Office; and Dr. Ahmed Khamis, the Joint United Nations Programme on HIV/AIDS (UNAIDS) Egypt Country Coordinator.

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LIST OF ACRONYMS

ANGA	Anti-Narcotics General Administration
BBSS	Bio Behavioural Surveillance Survey
CR	Consultant's Recommendation
EHSIMS	Egyptian Hazardous Substances Information and Management System
EMRO	Eastern Mediterranean Regional Office
EU	European Union
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GSMHAT	The General Secretariat of Mental Health and Addiction treatment
M&E	Monitoring and Evaluation
MENA	Middle East and North Africa
MOHE	Ministry of Higher Education
MOHP	Ministry of Health and Population
MOHP	Ministry of Health and Population
MOI	Ministry of the Interior
MOJ	Ministry of Justice
MSM	Men having sex with men
NAHR	Network of Associations for Harm Reduction
NAP	National AIDS Programme
NAS	Neonatal abstinence syndrome
NGO	Non-Governmental Organisation
NSP	National Strategic Plan
OST	Opioid Substitution Treatment
PWID	People Who Inject Drugs
PLWHA	People Living With HIV/AIDS
ROMENA	Regional Office for the Middle East and North Africa
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

EXECUTIVE SUMMARY

Under the guidance of the General Secretariat for Mental Health and Addiction treatment (GSMHAT), Ministry of Health and Population (MOHP) of Egypt, HIV/AIDS Section, UNODC Headquarters, Vienna and UNODC Regional Office for the Middle East and North Africa (ROMENA), Cairo, a team of two international consultants has been contracted to conduct a study with the following objectives:

- To understand the national context and current situation of people who inject drugs (PWID);
- To explore the feasibility of establishing an Opioid substitution treatment (OST) programme in Egypt;
- To suggest an integrated intervention programme;
- To provide accurate information to serve and benefit the national decision-making process;
- To initiate an advocacy process for OST programme; and
- To identify an appropriate operational service delivery model that can be adapted for the Egyptian context.

OST is not available in Egypt; methadone has still not been used. Due to the increasing numbers of patients infected with blood borne diseases through sharing injecting equipment, the model of harm reduction has been adapted to the Egyptian context.

Substitution maintenance treatment is one of the most effective treatment options for Opioid dependence. It is a safe and cost-effective Opioid dependence modality management as well as an extensively researched treatment modality. There is strong evidence, from research and monitoring of service delivery, that such treatment is a valuable and critical component of the effective management of Opioid dependence and the prevention of human immunodeficiency virus (HIV) and viral hepatitis among injecting drug users. It can decrease the high cost of Opioid dependence to individuals, their families and society at large by reducing heroin use, associated deaths, blood borne disease risk behaviours and criminal activity. Pharmacotherapy has also been found effective in assisting people dependent on pharmaceutical Opioids (containing analgesics or prescription opioids) to stabilize their use of Opioids, avoid the risks and other consequences of problematic use.

Methadone is the medication that is most commonly used for OST. Methadone is a synthetic opioid that is typically administered orally as a liquid. Higher doses of methadone are generally associated with greater reductions in heroin use than either moderate or low doses. Methadone maintenance treatment is associated with the low incidence of side-effects and with substantial health improvements.

Discussions with the medical staff in Egypt indicated that they possess good knowledge and understanding of OST and that most of them had high expectations about the effectiveness of the OST Programme.

The need for a minimum of two programmes: one in Cairo and one in Alexandria, was expressed initially. This was later changed so that OST would be piloted in two hospitals in Cairo for a total of 200 beneficiaries, and that only methadone would be prescribed as a medication for substitution. The importance of having at least one university training hospital funded by Ministry of Higher Education (MOHE) was also highlighted.

It was expressly agreed that OST is going to be a governmental project and thus organised in public hospitals. The first two OST programmes would hence be opened inside psychiatrist hospitals in Cairo Governorate: Heliopolis Psychiatric (Airport) Hospital and Ain Shams University Medical School.

A. Criteria for Client Admission and Retention

Agonist maintenance treatment is indicated for all patients who are opioid dependent and are able to give informed consent, and for whom there are no specific contraindications. Pharmacological treatment of opioid dependence should be widely accessible for everybody in need of treatment and who fulfils the inclusion criteria.

To achieve optimal coverage and treatment outcomes, treatment of opioid dependence should be provided free of charge or be covered under public healthcare insurance.

Recommendation for admission criteria for OST operational research in Egypt:

- Heroin or Tramadol addiction is one of the international diagnostic criteria for opioid dependence;
- Minimum of one to three years of opioid addiction;
- A minimum age of 21;
- History of failed treatment attempt(s); and
- Strong motivation to enter treatment.

These criteria should be adopted after evaluation and when more treatment slots are available.

It is recommended that the groups with more specific needs, as listed below, are given priority over the general opioid dependent population:

- Pregnant women;
- Opioid users with small children;
- Young people;
- People with HIV/AIDS (should not entail compulsory HIV-antibody testing of patients);
- People with viral hepatitis;
- People with mental health problems;
- Poly-drug users; and
- PWID in custodial settings (prisons, jails) and under police arrest.

Whenever the issue at hand has been raised, different authorities and treatment providers have emphasized that overcrowded custodial settings are preventing the development of OST services in penitentiary system as well as the continuity of services from the community to custodial settings and vice versa, even though such actions are strongly recommended by numerous international organisations and stakeholders.

B. Venues, Storage and Distribution Mechanisms

The two new OST centres should be redesigned to have a room of about 100-120 square meters dedicated to medical care and the OST programme.

Methadone should be kept in a secure area according to local requirements. The amounts should be checked and witnessed by a second party daily to ensure the amount used is reconciled with the amount dispensed.

There should be a monitoring system to supervise the safety of the treatment service, including the extent of medication diversion. Documented processes should be established to ensure a safe and legal procurement, storage, dispensing and dosing of medicines.

To maximize the safety and effectiveness of agonist maintenance treatment programmes, policies and regulations should encourage flexible, individualized dosing structures with low starting doses and high maintenance doses; this is to be done without placing restrictions on dose levels and the duration of treatment.

C. Methadone

- The average effective dosage of methadone is 60–120 mg (WHO, 2009).
- Average dosage 100 mg x 100 patients x 365 days = 3,650,000 mg.

We recommend methadone solution/syrup, with the concentration of 1 ml = 1 mg. The other possibility would be a solution of 1 ml = 5 mg, or 1 ml = 10 mg that is available on the market as well. It is easier to manipulate, but the possibility of diversion is higher, however, it is usually dispensed by being mixed with water or juice. We recommend purchasing the medication for additional three months intended for post-evaluation period and before new medications are purchased.

Prior to dispensing OST medications, dispensing staff should establish the identity of the patient and:

- Confirm this with the name on the prescription;
- Confirm that the patient is not intoxicated;
- Check that the prescription is valid and that the current day is a dosing day (for alternate days or three-times-a-week buprenorphine prescriptions); and
- Confirm the dose of the prescription.

Psychosocial support should be available to all opioid dependent patients in association with pharmacological treatment. At a minimum, this should include assessment of psychosocial needs, supportive counselling and links to existing family and community services. Treatment plans should include a long-term perspective. In addition, on-site psychosocial and psychiatric treatment should be provided for patients with psychiatric comorbidity.

D. OST Structure

The system of OST patient referral to services (such as HIV infection, viral hepatitis and TB) should be done through existing services for drug users and, if possible, at OST provision sites. Recommendations on the treatment of opioid dependent patients with HIV, hepatitis B, C or TB should be included in treatment protocols. In addition, the centres should make sure that People Living With HIV/AIDS (PLWHA) and those infected with viral Hepatitis

have access to prevention and treatment services. Moreover, if possible, hepatitis B virus vaccination should be offered to all opioid-dependent patients.

It is strongly recommended that OST “Operational research” is implemented not only in the health care systems, but also in co-ordination with other governmental services (police, justice system...) as well as in the form of the civil society-based outreach and drop in centres.

E. Monitoring and Evaluation (M&E)

There should be intermittent or ongoing evaluation of both the process and outcomes of the treatment through the National Task Force on OST and the Anti-Narcotics General Administration (ANGA).

Indicators:

- The retention rates in the programme after a year
- Adherence to treatment for patients followed (actual number of days of treatment)
- The reasons for patients’ dropout/leaving or possible re-entering
- Illicit drug use during treatment (measured by self-report questionnaires and correlated analyses of urine collections)
- The evolution of risky behaviour (self-administered questionnaires on practices, injection, injection frequency, reuse and sharing of equipment)
- Improving the health status of patients (WHO questionnaires - SF12)
- The feelings and feedback of patients as a response to treatment (satisfaction and dissatisfaction causes, side effects)
- The incidence and causes of death (including death from overdose)
- The incidence of criminal events (number of days in jail over/throughout the year)
- Social inclusion
- HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) prevalence among patients admitted and the existence of possible seroconversion
- The proportion of patients starting Antiretroviral Therapy (ART) treatment

Reviews should be done regularly, but not later than every six months.

F. Training and Advocacy Plan

The MOHP and partners should ensure training of the staff, including exchange visits with other countries in the Middle East and North Africa (MENA) region (Morocco, Lebanon) and European Union (EU) countries (Slovenia). In addition, conducting training sessions in Cairo by hiring experts who will accompany the first phase of OST prescription would also be much needed. UNODC should contribute to trainings on drug dependence treatment in a close partnership with MOHP.

It is necessary to develop educational material for OST patients and to inform PWID throughout the wider community. In addition, advocacy briefs for key audience (MOI, Religious leaders, psychiatrists...) should be developed.

G. Recommendations

- OST “Operational research” should be started with the most widely used medication, methadone, as a part of existing services in addiction units of psychiatric hospitals.

Heliopolis Psychiatric (Airport) Hospital:

For the minimum of 100 to maximum of 150 patients in OST methadone maintenance programme.

Ain Shams University Medical School:

For 100 patients in OST with methadone (though they have mentioned that their capacity cannot exceed 50-60 patients, and they would rather treat with buprenorphine (buprenorphine + naloxone); however this might be done in the second phase) partly during detoxification and partly in the OST maintenance programme.

For 200 patients within the period of 15 months the methadone dosage of 9,100,000 mg = 9,100g (litres) 1mg=1ml solution should be provided.

Naloxone should be made available for treating opioid overdose.

- Increase OST coverage and retention in care
- Optimize service delivery to improve access to testing, prevention and treatment of blood borne diseases
- Increase drug users involvement through patients advocacy groups and cooperation with non-governmental organisations (NGOs)
- Ensure continuity and equivalence of care in penitentiary institutions
- Introduce OST pilot with buprenorphine after a hopefully/desired successful outcome of evaluation of this operational research
- Introduce OST in custodial settings

Finally, these recommendations need to be viewed as dynamic, and should be constantly updated and adapted when and where (for each OST site) necessary, in response to any adverse incident or circumstances arising after the beginning of the programme.

I. INTRODUCTION

A. Background

Egypt's commitment to control HIV epidemic has been clearly demonstrated since the detection of the first AIDS case in the country in 1986. Egypt has a low HIV prevalence among the general population (below 0.02%), with a concentrated epidemic among men having sex with men (MSM) (Cairo 5.4% and Alexandria 6.9%) and PWID (Cairo 7.7% and Alexandria 6.7%) as detected by the latest Bio Behavioural Surveillance Survey (BBSS) completed in 2010 (BBSS 2010-second round). This is the second wave of biological/behavioural surveillance survey following the first round BBSS conducted in 2006. This earlier study only demonstrated a concentrated prevalence of HIV among MSM in Alexandria at 5.9 per cent. This increase in the number of detected HIV positive cases could be explained by the efforts of National AIDS Programme (NAP) to improve HIV surveillance, testing and reporting. The prevalence of HIV in the country appears to remain below 0.02 per cent, and a population-based survey has never been conducted in Egypt.¹

Through the BBSS conducted by MOHP, several risk behaviours were reported for PWID in Cairo (275 PWID) and Alexandria (285 PWID). Among sampled PWID, 22.9 per cent in Cairo and 40.5 per cent in Alexandria shared needles with one or more persons in the 30 days preceding the survey. Additionally, only 24.59 per cent of surveyed PWID reported using a condom in their last sex with a commercial partner. 4.76 per cent of sampled PWID reported using a condom during their sexual intercourse with a non-commercial regular partner. Condom use at last sex with non-commercial, non-regular partner was reported 14.28 per cent among PWID.²

The National Strategic Plan on HIV and AIDS is the most comprehensive framework for HIV and AIDS National response in Egypt. The Plan comprises all national priorities on HIV and remedial actions. "The Plan's 12-16 overarching goal is to stabilize the epidemic growth and prevent new infections within the population most at risk and improve health outcomes for [people living with HIV] PLHIV".³

It seems that the Egyptian Government is exerting a real effort to co-ordinate the national response and enhance universal access to HIV prevention, treatment, care and support.

For several years the collaboration of FHI360 with the Government of Egypt and NGOs to combat the stigma surrounding people living with HIV or AIDS and remove social as well as cultural barriers to prevention and treatment through behaviour change communication has been a successful initiative for implementing a comprehensive approach to HIV, HBV and HCV Prevention in Egypt. This model of integrating several strategies, including the outreach

¹ Egyptian National AIDS Programme, the Joint United Nations Programme on HIV/AIDS (UNAIDS), The Global Aids Response Progress Report. Available from http://www.unaids.org/sites/default/files/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_EG_Narrative_Report%5B1%5D.pdf

² FHI360, Egyptian Ministry of Health, Egyptian National Aids Program, The Behavioural Biological Surveillance Survey Egypt. Available from http://www.fhi360.org/sites/default/files/media/documents/BBSS%202010_0.pdf

³ Arab Republic of Egypt, Egyptian Ministry of Health, Egyptian National AIDS Programme, *HIV/AIDS Strategic Framework 2012-2016*, Available from <http://wac.egypt.org/resources/HIV%20Strategic%20Framework%20Ministry%20of%20Health%20Egypt.pdf>

to high-risk groups, peer education, voluntary counselling and testing, clinical care and management of sexually transmitted infections (STIs) as well as home-based care and support groups for PLWHA, is a solid platform enabling the country to achieve efficiency in interventions among high-risk groups. Rising demands for treatment have been reported along with the increase in injecting drug use and reported cases of HIV infection and hepatitis B, C among PWID in Egypt.

B. Main Objectives

Under the guidance of GSMHAT of MOHP, UNODC HIV/AIDS Section and ROMENA, a team of two international consultants has been contracted to conduct a study which aims to explore the feasibility of establishing an OST programme in Egypt. The following report is the result of the field mission in Cairo conducted in November 2013.

The mandated main objectives for this mission were:

- To understand the national context and current situation of PWID
- To assess the feasibility of an OST programme
- To suggest an integrated intervention programme, according to the existing services

The ultimate objectives of the current work area:

- To provide accurate information to benefit the national decision-making process
- To initiate an advocacy for the OST programme
- To identify the appropriate operational-service delivery model which can be adapted to the Egyptian context

C. Methodology

This report is based on the literature review of the key documentation (that has been made) available through ROMENA, in addition to the data obtained during the official five-day mission to Cairo and the interviews with the key national stakeholders.

The assessment methodology included discussions with treatment providers, policy makers and some drug users enrolled in drug free abstinence-oriented treatment programmes.

To complete the study, the two experts, Dr. Kastelic and Dr. Asouab worked together closely with Ms. Karine Shalaby and Dr. Tariq Sonnan, shared their knowledge and expertise with national experts, and also with health and social agents from institutions and NGOs.

The National Fund for Drug Control and Addiction Treatment, an inter-ministerial council and fund for treating drug dependence in Egypt, along with the university-based addiction units, ANGA, and GSMHAT which is in charge of planning and implementation of the national strategies for combating and treatment of addiction, were consulted during the consultation period.

Stakeholders consulted included:

- GSMHAT, MOHP
- NAP Manager

- Central Administration for Pharmaceutical Affairs at the MOHP
- Representative of ANGA, MOI
- The Inter-Ministerial Committee for Fighting against Drugs
- National Fund for Drug Control and Addiction Treatment
- Health professionals
- Partners and UN agencies
- Civil society representatives
- Heroin and black market Tramadol users

The results of this Feasibility Study should be presented to GSMHAT, for review and dissemination to the NTF on OST. This NTF was re-convened by GSMHAT and UNODC in March 2015.

GSMHAT plans to present the findings to the Minister of Health, in order to request the official nomination of focal points from each relevant department across MOHP, MOI, Ministry of Justice (MOJ) and MOHE covering university teaching hospitals.

Financial issues: A budgeted plan for OST pilot should be presented to donors and the Global Fund to Fight AIDS, TB and Malaria (GFAMT) in advance of the New Funding Model application for Egypt.

A concrete fund raising strategy should be devised for the long-term OST programme; in addition, the National Fund for Drug Control and Addiction Treatment should consider funding the OST Programme in the future.

The expectation had been to launch the first OST centres inside/within two psychiatric hospitals in Cairo and one in Alexandria, but the number of facilities was later reduced to two facilities in Cairo as a pilot project.

Legislation and regulation aspects: in the case of OST Programme in Egypt, the legal drug scheme is planned to be a hierarchical process instigated in an appropriate and efficient way to avoid possible diversion according to Egyptian standards and laws (see Annex 3: Relevant regulations and laws on substances handling). The plan is also to go through the **Tripartite Committee on Narcotic Drugs** where ANGA, the Central Authority for Pharmaceutical Affairs and MOJ are represented. This committee meets twice a year to review new drugs being legislated and scheduled.

Training plans: MOHP and UN partners will ensure the training of staff for operating OST in Egypt, which includes study visits to other countries in the MENA region (Morocco, Lebanon) and EU countries (Slovenia). On-the-job training sessions in Cairo are to be held, as well as later support by further consultations with the foreign experts personally or by email correspondence during the first phase of OST programme. UNODC will contribute to the training on drug dependence treatment/harm reduction in close partnership with MOHP.

Monitoring: As part of the next stage of the programme, information system should be established to provide a standardized mechanism of data collection and analysis.

II. THE NATURE OF THE EPIDEMICS OF INJECTING DRUG USE IN EGYPT

A. Drug Use Consumption Situation and Patterns

Egypt was a party to the 1961, 1971 and 1988 international UN drug control conventions. Its national drug control laws are generally assessed as adequate. The lists of scheduled drugs are regularly updated according to developments in drug trafficking and illicit consumption.

In Egypt, the inter-ministerial National Council for Drug Control and Treatment is also the national body that determines policies and interventions against drug abuse. A subsidiary body, the National Fund for Drug Control and addiction treatment is the field operational arm as it implements the national policies and action plans decided by the National Council. It is the funding body for the 24-hours hotline service as well. Several counterparts work together: MOJ, ANGA at MOI, MOHP, Ministry of Education and the National Council for Childhood and Motherhood.⁴

Counter-narcotic efforts are controlled by ANGA which is headed by an Assistant Minister and has branch offices in all major cities, airports and ports. It conducts year-round cannabis eradication and an annual opium poppy eradication campaign. ANGA has been both a regular and an active participant in the Arab Bureau for Narcotic Affairs which is part of the Council of Arab Interior Ministers (CAIM) of the League of Arab States. ANGA also regularly attends the Commission on Narcotic Drugs (CND).

The Government of Egypt continues to aggressively pursue a comprehensive drug control strategy developed in 1998. ANGA, the Egyptian MOI, the Coast Guard, the Customs Service and select military units all cooperate in task forces designed to interdict narcotics shipments. Government and private sector demand that supply reduction efforts exist, but are hampered by financial constraints and logistical challenges.

A 2003 study conducted by the Government of Egypt showed that the narcotics problem costs the Egyptian economy approximately \$800 million annually, including the amounts spent on illegal drugs and Government spending on tackling the problem.

According to the US State Department's 2005 report, late in 2004, a joint investigation conducted by the Drug Enforcement Agency, United States Department of Justice and ANGA, Egyptian MOI uncovered a 3,4-methylenedioxymethamphetamine (MDMA), also known as Ecstasy, laboratory located in a small apartment building in Alexandria, Egypt. ANGA raided the laboratory, arrested four individuals, and seized chemicals, paste and equipment. This was the first known discovery of an MDMA laboratory in Egypt, and according to DEA, the first in the Middle East. This discovery might have represented a new trend toward shifting artificial drug labs in the region due to its relatively lax regulations on commercial chemical products. With the passage of the first anti-money laundering law in 2002, which criminalized the laundering of proceeds derived from trafficking in narcotics and numerous other crimes, seizures of currency in drug related cases have amounted to over 3 million Egyptian Pounds (US\$ 485,000).

⁴ United Nations Office on Drugs and Crime (UNODC), Egypt country profile. Available from https://www.unodc.org/pdf/egypt/egypt_country_profile.pdf

B. Injecting Drug Use Epidemics

In the World Health Organisation (WHO) Eastern Mediterranean Regional Office (EMRO) technical paper on the addiction and substance use (Atlas: substance use in the Eastern Mediterranean Region, 2012), a survey including 19 countries in the region, the analysis showed that the substance use among youth (15–24 years) has been increasing in 13 countries. The average age of those who use addictive substances range from 33-44 years.⁵

The Eastern Mediterranean region has become an active market for drug dealing, with new countries starting cultivation of addictive plants. The reasons behind the increase in prevalence of addiction and substance use in the region are:

- The geographic location and openness of the region to the three continents
- The presence of many sea ports permitting drug dealing
- Decrease in the age of initiation of substance use from 14–18 to 11 years of age
- Socioeconomic factors, one group can afford buying illicit drugs, while another is poor and unemployed, thus encouraged to use substances.

The 3rd phase of the National Addiction Survey in the years 2005–2007 covered eight governorates, representing 0.25% of the target population. The study showed those who used drugs at least once were 9.8% of the total population, whereas experimental use was 3.1%, regular use 4.8% and dependence 1.6%. The most common substances were cannabis and its derivatives 93.5%, then alcohol and its derivatives 22.6%, pharmaceutical drugs 11.7%, opioids and its derivatives 7.3%, amphetamines 5.3% and synthetic drugs 0.31%.

Despite an overall lower HIV prevalence among the general population in Egypt, emerging data from a recently conducted BBSS (2010) among key populations, including PWID, Sex Workers (SW), MSM, and Street Children in three governorates, have revealed a concentrated epidemic among PWID (6.8% in Cairo and 6.5% in Alexandria) and MSM (5.7% in Cairo and 5.9% in Alexandria).

Hepatitis C virus and PWID: UNODC estimates that the global prevalence of HCV among PWID is 51.0 per cent, meaning that 8.1 million people who inject drugs are living with HCV (UNODC, World Drug Report 2013). For PWID, sharing contaminated needles and syringes is the most common mode of HCV transmission. Sharing other equipment, such as spoons, tourniquet and filters used for the preparation of drugs, is also associated with HCV transmission. HCV is substantially more infectious and can survive longer outside the body than HIV, and many PWID are repeatedly exposed to HCV. This results not only in higher incidence rates, but also in re-infection after clearance of HCV. The epidemiology of HCV/HIV co-infection is not that known. HIV/HCV co-infection is common among HIV-infected PWID, close to 100 per cent in a number of countries (WHO, Guidance on Prevention of Viral Hepatitis B and C among People Who Inject Drugs, July 2012). HCV can cause acute inflammatory hepatitis that can result in fulminant liver failure. Chronic infection can result in liver fibrosis and ultimately cirrhosis and hepatocellular carcinoma.

⁵ General Secretariat of Mental Health in Egypt, Pompidou Group Council of Europe, Med Net Group, Filling the Gap Meeting the Needs for Treatment and Treatment Centres in Egypt. Available from https://www.coe.int/T/DG3/Pompidou/Source/Activities/MedNET/2012_MedNET_Egypt_FillingTheGap_Report_2010-2012.pdf

Both HBV and HCV can complicate HIV treatment, and HCV can accelerate the progression of HIV disease and result in high mortality of PWID.

Egypt has the highest prevalence of hepatitis C in the world. Around 10 per cent of the population between 15-59 years are infected with the virus and there are 150,000 new infections every year (The National HCV Plan 2013). The underlying challenge for Hepatitis C control lies at the health system level. Medical procedures, including unsafe injection practices and blood transfusion are the primary transmission modes of Hepatitis C in Egypt.

According to NAP and Mental Health Directorate of MOHP there are an estimated 100,000 individuals who inject drugs in Egypt. UNODC estimates that the prevalence of HCV among PWID in Egypt is 55 per cent, meaning that 55,000 people who inject drugs are living with HCV.

III. NATIONAL RESPONSE TO THE EPIDEMIC OF HIV AND HCV AMONG DRUG USERS IN EGYPT

Egypt has a low HIV prevalence among the general population (below 0.02 per cent) with concentrated epidemics among MSM and PWID in some governorates as detected by the latest BBSS of 2010.

A. Role of the General Secretariat of Mental Health and Addiction Treatment

GSMHAT has been supervising drug dependence treatment units technically and executively over the past several years as well as providing them with funding and logistical support. Furthermore, GSMHAT is considered the coordinating party between different organisations in the MOHP, other governmental and private stakeholders in drug dependence services such as this initiative.

For example, Heliopolis Psychiatric Hospital usually hosts multiple international and accredited modules regarding specific in addiction treatment such as UNODC treatment cascades.

B. Regulations, Laws and Legislation Related to Substances in Egypt

The Mental Health Act 71 from 2009 has concentrated on human rights issues of patients within psychiatric facilities and on monitoring all processes and treatment procedures within these facilities.

There is an article in the Egyptian *Anti Narcotic Law 122 of 1989*, stating that an offender may be involuntary referred for treatment in case of committing a crime under the influence of illicit drugs. According to *Article 37 of the Egyptian criminal law* a convicted dependent drug user may be referred to a specialized facility for treatment rather than imprisonment. This compulsory treatment should last from 6 months to 3 years, during which monitoring and evaluation of treatment should be performed by a multidisciplinary committee. However, such article is inactive for unknown reasons.

As in all the Middle East and almost all the Arab countries in EMRO region including Egypt, chemical control legislations are not very easy to access, as they are spread across many different agencies, ministries and regulatory bodies. The relevant context according to government laws, regulations and policies, or authorities related to the purchase, transfer and storage of controlled substances is as follows:

The Egyptian Environmental Affairs Agency, under the Ministry of State for Environmental Affairs is the main body responsible for chemical control in the country. It administers environmental laws and regulations, formulates general policies for the protection and promotion of the environment and implements these in coordination with other authorities.

Law No. 4 for the Protection of the Environment of 1994 and the Executive Regulation of Law No. 4 (the Ministerial Decree No. 338 of 1995) provides the principal regulatory

framework for handling hazardous substances, including permits, storage, transport, packaging and labelling. A number of additional regulations governing imports, manufacturing, trade and usage of chemicals have been issued under the jurisdiction of other ministries. Consequently the authorities introduced the *Egyptian Hazardous Substances Information and Management System (EHSIMS)*, an online initiative to facilitate the procedure for obtaining licenses for handling hazardous substances and provide consistency.

Egypt does not have an existing chemical substance inventory or a new chemical notification scheme, and a permit is required for handling hazardous substances. Law No. 4 prohibits anyone without a permit obtained from the competent authorities from handling hazardous substances and wastes, but requires anyone who produces or handles hazardous material, to take necessary precautions to ensure that no environmental damage occurs. Detailed information, requirements and conditions for granting such permits are prescribed in the Executive Regulation (Decree No. 338). (See Annex 3: Relevant regulations and laws on substances handling).

C. Current Services and Accessibility

Drug dependence services in Egypt are stretched over several governorates. GSMHAT is offering 90 per cent of mental health services in Egypt and detailed data about its services are available.

Psychiatric governmental hospitals are located mainly in the greater Cairo region; the biggest and oldest hospitals available are Abbasia, Khanka and Heliopolis. Drug dependence services are also located in Lower Egypt such as Alexandria, Tanta and Shobrakass hospitals. Although the services are deficient in Upper Egypt, there exist two hospitals with drug dependence treatment wards (Aswan and Assiut). Finally, one hospital in the Canal area offers drug dependence services as well (Port Said hospital).

Drug dependent people who are admitted via the hotline to the governmental hospital do not pay for their treatment as it is fully covered by the National Fund; otherwise, drug dependent people financially contribute to their treatment. The financial contribution within the governmental hospitals varies between EGP 600 (the usual cost of treatment is about EGP 2,550 per month) and EGP 3,000 per month according to the type and setting of service. The NGOs received funding mainly from private donations.

With the exception of Heliopolis Hospital, which was built in 1996 and considered one of the WHO accredited training centres, none of the previously mentioned hospitals exclusively specialises in addiction services. They all have drug dependence treatment units along with psychiatric wards. As for the university hospitals, only four (Cairo, Ain-shams, Alexandria, and Assiut) have specialized addiction treatment units.

Cairo University Hospital has a specialised inpatient unit for management of drug dependence with 25 slots for males and 18 slots for females.

There are no governmental rehabilitation facilities or community centres specialized in providing any kind of services to fulfil the needs of drug dependent people or their families.

Khanka Hospital is the main specialized hospital in forensic psychiatry in Egypt. It is also specialized in the treatment of all types of drug dependence and the only hospital where judges refer cases based on Law No 122/1989. While Abbasiya hospital (located in Cairo) and

Mamoura hospital (located in Alexandria) have forensic psychiatry units that accommodates patients that are in conflict with the law, these facilities do not have compulsory admissions for the mentioned cases.

Narcotic Anonymous has a strong presence in the community and is part of the International Society of Narcotic Anonymous. Narcotic Anonymous collaborates with GSMHAT in providing awareness and information sessions about its programmes and services to patients admitted to drug dependence wards. GSMHAT also allows Narcotic Anonymous to hold its meetings in multiple hospitals such as Abbasiya, Heliopolis (Cairo) and Mamoura (Alexandria).

The private sector is known to deal with addiction within a wider scope. There are several private units in Abou El-Azaym hospitals, all based in Cairo and its surrounding areas. The biggest unit has 30 inpatient detoxification slots and 35 for rehabilitation; while the smallest unit has 15 detoxification slots and 15 for rehabilitation; Behman Hospital has an addiction unit with 29 slots and Dr. Sadek Hospital has a drug dependence unit with 20 slots.

A report issued by the National Fund for Drug Control and Addiction Treatment, the country's official drug dependence body, indicated around 19,700 drug dependent people finished treatment programmes at medical centres in the first six months of 2012 compared to 18,000 in 2011.

D. Models of Therapy

Most of the governmental and university hospitals rely on the cognitive-behavioural approach. Private hospitals on the other hand, rely on either the cognitive-behavioural approach or the 12-step model. Group therapy is widely used across sectors either within in-patient settings or as out-patient sessions. OST is not available in Egypt; methadone has still not been used. Due to the increasing numbers of patients infected with blood borne diseases through injecting equipment sharing, the model of harm reduction has been adapted to the Egyptian context. Needle/syringe exchange programmes have existed since 2008. Sterile needles and syringes are provided for distribution, but there are no syringe/needle exchange programmes for fear of police arrest by potential providers.

As far as therapeutic settings (therapeutic communities) are concerned, such facilities are only present in two NGOs (Caritas, and Wadi al Natroun). Their combined bed capacity is around 100 beds. In addition, half-way facilities are still not officially available in Egypt. The only form available in governmental hospitals is day-care centres, which are located in Abbasiya, Heliopolis and Alexandria hospitals.

The 24-hour hotline is activated in four governmental hospitals funded by the National Fund for Drug Control and Addiction Treatment.

E. Harm Reduction Services for People Who Inject Drugs in Egypt

PWID in greater Cairo have access to HIV services through NGOs since 2006 by Freedom NGO and by Waey, Hayat, Befrienders NGOs since 2008 (). These NGOs have been technically supported by FHI360 and NAP MOHP and received funding from Drosos and Ford Foundations. They offer comprehensive care centres in urban areas and provide free and anonymous access to condoms, syringes, voluntary counselling and testing (VCT),

clinical care and drug dependence counselling. These NGOs reached around 3,136 PWID during the reporting period of 2010-2011.

In November 2010, UNODC launched a one-year-community outreach project targeting PWID in Alexandria. The project, which adopted a drop-in centre outreach model with free rapid tests and condom and syringe distribution, was implemented by the national NGO “Youth Association for Population and Development”. This project benefited from the technical and financial support provided by UNODC and the European Commission. Outreach activities started in March 2011 in Alexandria and a total number of 329 PWID was outreached within that same year.

F. Expenditures on Health

In 2008-2009, Egypt spent EGP 21 billion on drugs, that is 31 per cent of Egyptians’ spending on health care. The per capita amount is EGP 800.1 and the percentage of GDP spent on health is 5.9 per cent. Nearly 20 per cent of this amount is spent on antibiotics. The high utilization rates of pharmacies and the ability to buy drugs without a doctor’s prescription have aggravated an already bad situation. Unsuitable ordering, transportation, storage and distribution techniques are the dominant feature.

About 2 per cent of the health budget in Egypt is dedicated to mental health, but there is no clear data about the size of spending on drug dependence services. This is largely due to lack of separate services or a budget line for drug dependence.

G. Expenditures on HIV

UNAIDS has developed a results framework and a monitoring and evaluation framework for the UN response to HIV in Egypt extending over the period between 1 July 2013 and 31 December 2015.

The estimated budget for 2013-2015 has increased by approximately 7 per cent compared to that of 2010-2011. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has the largest allocation for HIV response in Egypt at about US\$ 900,000 followed by United Nations Children's Fund at about US\$ 490,000. UNODC, United Nations Population Fund (UNFPA) and the International Organisation for Migration have the similar level of allocated funds at US\$ 380,000, US\$ 340,000, and US\$ 280,000 respectively followed by United Nations High Commissioner for Refugees and WHO.

Table 1

Estimated budget, allocated resources by each UN agency and programme

<i>Estimated budget (in US\$):</i>	4 017 000
<i>Allocated resources (in US\$):</i>	2 425 500
• United Nations High Commissioner for Refugees	30 000
• United Nations Children's Fund	486 500
• United Nations Development Programme	0
• United Nations Population Fund	340 000
• United Nations Office on Drugs and Crime	380 000
• International Labour Organisation	0
• United Nations Organization for Education, Science & Culture	0
• World Health Organization	22 000
• United Nations Joint Programme on HIV/AIDS	887 000
• UN Women	0
• International Organization for Migration	280 000
• United Nations Information Centre	0
<i>Funds to be mobilized (in US\$):</i>	1 591 500

Source: *The UNAIDS 01 July 2013 to 31 December 2015.*

Expenditures on HIV and AIDS in Egypt from national and international resources cannot be reported in detail for 2010-2020. However, the latest National Aids Spending Assessment (NASA) conducted from 2007 to 2008 highlighted that expenditures on HIV from international and national resources in 2008 accounted for US\$ 7,538,436. The Government of Egypt contributes almost 50 per cent of the expenditures on HIV response. National resources are provided by the Ministry of Finance. The largest external donor for HIV is GFAMT followed by the United Nations.

Egypt is a lower-middle-income country. External sources for AIDS are estimated at US\$ 4,151,900 as per the World Bank.⁶ (Egypt Situation, Response and Gap Analysis, 2010).

External sources were made available through GFAMT, as MOHP was selected the principal recipient of the Round 6 Grant with a five-year grant agreement of US\$ 10,469,362.00.

Due to the cancellation of GFAMT Round 11 and the elimination of non-essential funding for Egypt in 2013 under the Transitional Funding Mechanism, NAP has recently undergone restructuring and will be receiving technical support from UN partners through a population size estimation study led by UNAIDS, UNODC and UNFPA and the recruitment of UNAIDS HIV officer to work at NAP.

⁶ Egyptian National AIDS Programme, UNAIDS, National AIDS Spending Assessment in the Arab Republic of Egypt 2007-2008. Accessed from http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/dataimport/pub/report/2012/NASA_Egypt_07-08_En.pdf

NAP, UNAIDS, and the Country Coordination Mechanism are preparing for the New Funding Model application, currently at the stage of country dialogue and concept note development. Other external resources are availed by UN agencies and bilateral organisations such as the U.S. Agency for International Development (USAID), Italian cooperation and private foundations, for example Ford and Drosos Foundations.

Civil Society Organisations are technically supported by the UN, GFAMT and to a lower extent by other donors in order to implement peer education and prevention projects on HIV for vulnerable groups (street children, refugees and prisoners); in addition, currently there exist several outreach and prevention projects for most-at-risk populations including PWID, MSM and sex workers.

H. National Response to HIV and HCV among Drug Users in Egypt

Under the National HIV/AIDS Strategic Framework for 2012-2016, seven priority areas ensure provision of comprehensive prevention packages for most-at-risk, vulnerable and general population, increased coverage of treatment, care and support for people living with HIV, stigma and discrimination free environment promotion, and effective leadership as well as governance of the programmes.⁷ The framework identifies most-at-risk population as sex workers, MSM and PWID, vulnerable population as women, mobile population, street children, prisoners and young people. Increase coverage of prevention interventions for most-at-risk populations is noticed. An increase in the coverage of prevention interventions for such most-at-risk populations can now be observed.

National task force on OST

During the November 2013 GSMHAT meeting, the National Task Force for implementing OST strategy was established. This meeting also provided a platform for interviews and opinion exchange that enabled the consultants to develop some aspects existent in the present report.

It was agreed that the NTF on OST would act as the Secretariat of the OST initiative in Egypt, led by GSMHAT, and that it would be introduced into the Strategy of the National Fund for Drug Control and Addiction Treatment.

Hence, the nomenclature agreed by members of this first NTF is “Harm Reduction Committee (in Arabic: الحد من المخاطر)”. (Technical Committee Members: Annex 2).

⁷ Ibid.

IV. DEVELOPING A FEASIBILITY STUDY AND RELATED SITUATIONAL NEEDS ASSESSMENT

There are an estimated 100,000.00 persons dependent on illicit opioids in Egypt. Based on the literature review along with the assessment, it seems that half of them are dependent on Tramadol and the other half on heroin.

One of the international recommendations for the goals of OST is to attract the treatment of at least 50 per cent of persons dependent on opioids.⁸

Based on the literature review and mapping of injecting drug use in Egypt and its related characteristics, it is estimated that 50,000.00 people who use drugs are in need of OST.

OST with methadone and buprenorphine is considered an effective way to reduce the consumption of opioids and other substance abuse, criminal activity and mortality. The two medications are also linked to positive effects in harm reduction and other risk behaviours associated with injecting drug use, including the risk of transmission of HIV, Hepatitis C and STIs. Therefore, OST improves physical, mental, social life and the quality of life.⁹

With the assumption that OST is one of the therapeutic options for people dependent on opioids, the prescribed medications are based on similar pharmacological activity to the psychoactive substance (heroin) responsible for addiction.

- The summary of the discussions undertaken in the presence of responsible officials, partners and professionals responsible for issuing and managing the product regarding the implementation of the OST programme concluded these main recommendations: Taking into account the situation of the country (as expressed by professionals and partners)
- Building a feasible and prudent programme
- Leaving open expectations for change in the future

A. Opioid Substitution Maintenance Therapy

Opioid dependence is a complex health condition that often requires long-term treatment and care, and is associated with a high risk of HIV, HBV and HCV infection when opioids are injected using contaminated injection equipment. Drug dependence treatment is an important strategy to improve the well-being and social functioning of people with opioid dependence and to reduce its health and social consequences, including HIV infection. As no single treatment is effective for all individuals with opioid dependence, sufficiently diverse treatment options should be available. Substitution maintenance therapy is one of the most effective treatment options for opioid dependence. It can decrease the high cost of opioid dependence for individuals, their families and society at large, by reducing heroin use,

⁸ European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), EMCDDA Statistical Bulletin. Available from <http://www.emcdda.europa.eu/stats12/hsrfig1a>.

⁹ Organization Department of mental health and Substance Abuse, World Health Organization (WHO), Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. Available from http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf.

associated deaths, HIV risk behaviours and criminal activity. OST substitutes an illicit drug with a medically safe and long-acting agonist licit medication.

It is prescribed by a medical doctor and administered under the supervision of a trained nurse or pharmacist. It results in the elimination of the craving for the illicit drug. In addition, it blocks the effect of illicit opiate drugs if used by the drug user while he/she is on the OST, thereby gradually leading to total abstinence and recovery.

Substitution maintenance treatment is an effective, safe and cost-effective modality for the management of opioid dependence. Repeated rigorous evaluation has demonstrated that such treatment is a valuable and critical component of the effective management of opioid dependence and the prevention of HIV and viral hepatitis among PWID.

Methadone and buprenorphine are the well-studied medications used for oral substitution treatment.

Methadone

Methadone is the medication that is most commonly used for substitution therapy of opioid dependence. Methadone is a synthetic opioid that is typically administered orally as a liquid. Methadone maintenance treatment is also an extensively researched treatment modality. There is strong evidence, from research and monitoring of service delivery, that substitution maintenance therapy with methadone (methadone maintenance treatment or MMT) is effective in reducing illicit drug use, reducing mortality, reducing the risk of spread of HIV, improving physical and mental health, improving social functioning and reducing criminality. Higher doses of methadone are generally associated with greater reductions in heroin use than either moderate or low doses.

Methadone maintenance treatment is associated with a low incidence of side-effects and substantial health improvements.

Around three quarters of people who commence substitution maintenance therapy with methadone respond well to it.¹⁰

Buprenorphine

Buprenorphine is a prescribed medication with weaker opioid agonist activity than methadone. Buprenorphine is not well absorbed if taken orally, therefore the usual route of administration in the treatment of opioid dependence is sublingual. As a partial agonist, buprenorphine has a better pharmacological safety profile than methadone. With increasing doses of buprenorphine, the effects reach a plateau. Consequently, buprenorphine is less likely than either methadone or heroin to cause an opioid overdose condition, even when taken with other opioids at the same time. Although deaths have been reported where buprenorphine has been used in combination with other sedatives, the rate of

¹⁰ World Health Organization (WHO), United Nations Office on Drugs and Crime (UNODC), the Joint United Nations Programme on HIV/AIDS (UNAIDS). Position paper Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention.

buprenorphine-related deaths is estimated at 0.2 per 1000 patient years, which is much less than the mortality of untreated heroin dependence.

The effectiveness of buprenorphine is similar to that of methadone in adequate doses, in terms of reduction of illicit opioid use and improvements in psychosocial functioning, but buprenorphine may be associated with lower rates of retention in treatment.

Buprenorphine tablets have a high potential for abuse. Wherever buprenorphine has been prescribed to injecting drug users, the result has been an associated epidemic of buprenorphine injecting, with patients presented for treatment using buprenorphine as their first and primary drug of abuse. While some methadone injection occurs, it is rare – particularly when take-home doses are given diluted to 200 ml per dose – and it can be managed by supervised dosing of methadone.

Buprenorphine supervision is more difficult, because the tablet can easily be sequestered in a corner of the mouth as it takes up to 15 minutes to dissolve. The tablet should be dispensed into a clean container and tipped into the mouth of the patient, under the tongue. Periodic examination should reveal the tablet in various stages of dissolution.

Buprenorphine + naloxone 4:1 combination product

A combination product of buprenorphine and naloxone in a 4:1 ratio is available in two-dose strengths (2 mg buprenorphine: 0.5 mg naloxone and 8mg buprenorphine: 2mg naloxone).

While buprenorphine is absorbed sublingually, naloxone has only a 5–10 per cent sublingual absorption. It is thought that this results in too low a dose to have an effect clinically. As buprenorphine and naloxone have similar affinity for opioid receptors, the buprenorphine effect dominates since it is present in much higher concentrations in the blood. However, if the buprenorphine + naloxone combination product is injected, the dose of naloxone can induce opioid withdrawal, depending on the circumstances. In the dependent user of heroin or other opioid agonists, the injection of the buprenorphine + naloxone combination product results in opioid withdrawal. Higher doses of buprenorphine+ naloxone induce more significant withdrawal. In the non-dependent opioid user, injection of the buprenorphine + naloxone product does not induce opioid withdrawal, but the opioid effect of buprenorphine is attenuated by the naloxone, resulting in a delayed and reduced opioid effect. For patients in treatment using buprenorphine, or for those using buprenorphine illicitly, injection of the buprenorphine + naloxone product does not appear to induce withdrawal, either because higher doses of naloxone are needed to displace buprenorphine or because the half-life of naloxone is too short in comparison with the slow dissociation of buprenorphine from opioid receptors.

Take-away doses may be provided for patients when the benefits of reduced frequency of attendance are considered to outweigh the risk of diversion, subject to regular review. To allow doses of opioid medications (methadone) they need to be used at home for patients in stable remission on an individual basis. Patients should be responsible for the use of their medications according to medical recommendations.¹¹

¹¹ Ibid.

Table 2
Opioid Substitution Agents (Prisons and Health, 2014)

<i>Medication</i>	<i>Frequency</i>	<i>Optimal recommended dose</i>	<i>Route of administration</i>	<i>Overdose risk</i>	<i>Withdrawal</i>	<i>Notes</i>
Methadone	Every 24 hours	60–120 Mg/day	Oral (syrup, tablets) Injectable	+++	+++	Optimal dose level dependent on subject; it can be <60 mg or >120 mg, according to individual variability
Buprenorphine Buprenorphine + naloxone (4:1 ratio) – developed to reduce potential misuse and diversion	Every 24 to 48 or 72 hours	8–24 mg/day	Sublingual	+ (With additional drugs)	+	Start 6–8 hours after the last heroin intake or on appearance of withdrawal symptoms. If the person was previously using methadone, methadone has to be tapered until 30 mg/day and buprenorphine can be administered every 48 hours after last methadone dose or during the appearance of withdrawal symptoms.

Considerations and duration of Treatment

All medications can be used in inpatient and outpatient settings. Methadone and buprenorphine can be administered at once-daily supervised doses, to reduce diversion and increase safety. In cases when take-home doses of buprenorphine might be used (not during the pilot, but might be used in future) a buprenorphine + naloxone combination product is preferred over mono-buprenorphine.

The gradual reduction of methadone and buprenorphine used in detoxification can reduce the severity and increase the length of opioid withdrawal. Such gradual reductions improve treatment retention, but reduce the rate of successful completion of withdrawal.

Conclusions

- Buprenorphine is suitable for once-daily administration; it leads to less severe withdrawal and higher rates of completion than alpha-2 agonists (Clonidine).
- Methadone carries no risk of precipitated withdrawal.
- Methadone is suitable for use in pregnancy.
- Buprenorphine is currently more expensive than methadone.

Recommendations

The best possibility to cover different patients' needs is to have both OST medications: methadone and buprenorphine. But for this **“Operational Research” and for all the above-cited reasons, including the cost-effectiveness and the lesser possibility of misuse and diversion, methadone is recommended.** After evaluation of this methadone OST pilot project and with hopefully good results from buprenorphine pilot, the project should/could be launched. Further recommendations for choosing the right medication for the individual patient could be developed during potential “second pilot” together with future staff trainings.

B. Site Selection Criteria for the OST Pilot in Egypt

One of the objectives of the assessment for the current Feasibility Study and Operational Plan for OST in Egypt is to establish the criteria for the OST pilot site and substance (Methadone or Buprenorphine/Buprenorphine-Naloxone) selection.

To reach this goal, visits to three psychiatric hospitals were organised in November 2013 as follows:

- *Heliopolis Psychiatric (Airport) Hospital*: Contact persons were Dr. Mahmoud El Gawish, Director, as well as patients, doctors, counsellors, social workers and lab technicians.
- *Ain Shams University Medical School, Faculty of Psychiatry/Addiction*: contact persons were Dr. Amani Haroun El Rashid and fellow doctors.
- *Behmen Psychiatric Hospital*: Contact persons were Dr. Nasser Loza, Director, and Dr. Mairose Doss, Head of Geriatrics.

On the basis of these first discussions, it was clearly outlined that there was a need for implementing at least three well controlled high quality OST programmes, with an estimated total number of 300 patients (approximately 100 patients each). This issue was also confirmed by clinicians, policy makers, NGO representatives and other stakeholders. The need for a minimum of two programmes: one in Cairo and one in Alexandria, was expressed at the beginning. It was later changed so that OST is piloted in two hospitals in Cairo for a total of 200 beneficiaries. This pilot programme should be assumed as “operational research” as expressed by the task force and in this phase only methadone is to be prescribed. The importance of having at least one university training hospital funded by MOHE was also highlighted.

Attitude of medical staff towards OST

Discussions with the medical staff indicated that they had good knowledge and understanding of OST and most of them had high expectations about its effectiveness. They all expressed awareness of harm reduction principles (reduction of blood borne diseases such as HIV and viral hepatitis, TB, reduction of overdoses, criminal behaviour, economic costs, etc.) and perception of opioid dependence as a chronic disease. However, some of them were more abstinence oriented and preferred OST as a new possibility for detoxification. The most recurrent questions were about the duration of treatment. They had much better knowledge of methadone than buprenorphine. Also, they would prefer lower doses of both medications to higher dosages, however, the awareness of individualized dosing was presented.

Patients' knowledge of and attitudes toward OST

The assessment showed that patients in treatment as a part of existing drug-free programmes within the visited psychiatric hospitals had no idea about OST, and nearly none of them had ever heard of methadone nor buprenorphine. Therefore, it is not possible to assess the perception of OST among drug users, but there were at least no preconceived ideas or misconceptions about methadone or buprenorphine treatment.

Physical setting

- A first condition for an OST programme is that it ensures safety for patients, staff and medication. Safe in the sense that patients can trust the workers and that personal information is treated confidentially in line with medical standards, and is not given to third non-medical parties. It may seem obvious, but it is essential for a successful programme that people are treated with respect and that their privacy and confidentiality are ensured. A non-judgmental attitude of treatment staff is important. Some research has shown that in a methadone maintenance programme where the staff can be identified as “abstinence-oriented”, patients will leave quicker than when a programme is maintenance-oriented. This difference became evident after the corrections in methadone dosage.
- The location of the programme should meet some important conditions. Since patients will have to attend the programme regularly, and in many cases daily, it is important that it is centrally located. Easy access to public transport is an advantage.
- Opening hours should be flexible to accommodate clients who work. Ideally, the programme should open early mornings or at the end of the working day, allowing people to attend the programme without having to miss a part of their productive day.
- In order to avoid stigmatization, it may be important to have a neutral façade. For example, the outside sign should read something like “health service” instead of “drug dependence treatment unit”.
- It is recommended to seek contact with the local police in order to explain the importance of attracting people with drug dependency to join the programme without fear of coming into contact with the police. Agreements should be made to avoid the presence of police posting outside the centre.

- When starting a new service in a given area, it is recommended to seek contact with community groups and representatives. Precise information should be given in terms of the rules and regulations within the Centre.
- The potential benefits of service provision, in particular the likely impact the provision of treatment has on reducing neighbourhood crime, should be discussed. It may be important to set out rules and regulations for the clients to abide by in order to minimize any potential nuisance for the environment. An important rule would be to prevent clients from hanging around outside the premises.¹²

It is clear that these recommendations have to be adapted to specific local contexts (e.g.: Heliopolis “Airport” Psychiatric Hospital and Ain Shams University addiction unit), taking into account the opportunities and challenges in relation to the degree of awareness of the environmental partners and representatives of authorities as well as the community. A priority should be assigned to enhancing sensitization to human rights of patients/PWID in general, and emphasizing the effectiveness of harm reduction programmes for the general population in particular. Many interventions could enhance the environment by ensuring the success of such a project and by implementing anti-stigma activities or advocacy workshops.

Staff requirements

There is considerable variation across countries as to who can prescribe OST medication for the treatment of drug dependence. Nevertheless, it always involves a medical doctor who might be an addiction specialist, general practitioner or psychiatrist.

Table 3
Proposed optimal staff composition of quality services for 100 OST patients

Staff / specialists	No estimation
Psychiatrist	2 x 0.5
General Practitioner	1 or 2 x 0.5
Nurse	5 x 1
Psychologist	1 x 1
Social worker	2 x 1
Counsellor	2 x 0.5
Cleaner/agent for maintenance	2 x 0.5
Security guard	2 x 1

Team work

¹² Annette Verster, Ernst Buning. Methadone Guidelines, Euro-Methwork. Available from <http://www.vad.be/media/124853/european%20methadone%20guidelines.pdf>.

- Medical practitioners should not prescribe methadone in isolation. A multi-disciplinary approach to drug treatment is essential.
- A clear description of each position, including a detailed list of tasks, is vital, as well as regular supervision. Regular team meetings will facilitate collaboration and case management of clients who need to see more than one staff member. Clear procedures within a programme are not only important for the staff, but will also have an impact on the expected treatment outcome for the clients.

C. Recommendations on OST Start Sites in Egypt

Heliopolis Psychiatric (Airport) Hospital

For minimum 100 to maximum 150 patients in OST (methadone maintenance programme).

Ain Shams University Medical School

For 100 patients in OST with methadone (though they have mentioned that their capacity cannot exceed 50-60 patients, and that they would prefer to treat them with buprenorphine (buprenorphine + naloxone) - but this might be done in the second phase, partly in detoxification and partly within the maintenance OST programme.

It was clearly understood that the OST is going to be a governmental project and hence organised in public hospitals; the consultants have found this a good solution at least in the beginning (the initial phase of the programme).

As there are many publicly funded (public) OST programmes around the world, as well as in private hospitals performed under the same conditions as in public hospitals (and in this case) with both types of programmes being free of charge (or with minimal participation), the patients themselves might view this as a future possibility.

- **Recommended approach:** As the drug dependence treatment services in Egypt are exclusively in psychiatric hospitals, it was strongly recommended by everybody met in the assessment visit that this **“Operational research” with OST should be started as a part of existing services in addiction units of psychiatric hospitals.**
- Due to the different needs of people who use drugs, the type of treatment (detoxification versus maintenance – though maintenance is recommended for the majority of patients), the ability of hospitals and their preferences, the **consultants recommend to start OST with the most widely used medication which is methadone and maybe later, within the next few years the buprenorphine.**

Pharmacotherapy has also been found effective in assisting people dependent on pharmaceutical opioids (containing analgesics or prescription opioids) by stabilizing their use of opioids and thus avoiding the risks as well as other consequences of problematic use.¹³

Care continuity and equivalence in cooperation with penitentiary institutions

¹³ Victoria, Australia, Department of Health, *Policy for maintenance pharmacotherapy for opioid dependence* (Melbourne, 2013).

Whenever the issue at hand has been raised, different authorities and treatment providers have emphasized that overcrowded custodial settings are preventing the development of OST services in penitentiary system as well as the continuity of services from the community to custodial settings and vice versa even, though such actions are strongly recommended by numerous international organisations and stakeholders.

D. Recommendations on Controlled Substances and Scenarios for Coverage

Methadone

International Recommendation: The average effective dose of methadone is 60mg – 120mg.

Consultant's Recommendation (CR) : Average dosage 100 mg x 100 patients x 365 days = 3,650,000mg.

We recommend methadone solution/syrup, with the concentration of 1 ml = 1 mg.

We recommend purchasing medication for an additional three months intended for post-evaluation period and before purchase of new medications.

3,650g (for 365 days) + 900g (for 90 days) = 4,550g (litres) (for 15 months for 100 patients) - if there are presumably more patients (200-300), just multiply the quantity).

For 200 patients for 15 months 9,100,000mg = 9,100g (litres)

For 300 patients for 15 months 13,150,000 = 13.150g (litres) 1mg = 1ml solution.

The other possibility would be the solution of 1 ml = 5mg or 1ml = 10mg that is available on the market as well. It is easier to manipulate, but the possibility of diversion is higher, though it is usually dispensed mixed with water or juice.

For providing methadone please find the list of some methadone producers in Annex IV.

Buprenorphine (buprenorphine + naloxone) – future possibility:

International Recommendation: Average buprenorphine maintenance doses should be at least 8mg per day.

It is recommended to use 8–24mg daily.

CR: Average dosage 16mg x 100 patients x 365 days = 584,000mg + 144,000mg =

728,000mg (for 15 months). Half in 8-mg tablets and the other half in 2-mg tablets.

E. Storage and Distribution Mechanisms, Strategies to Prevent Diversion

International Recommendation: There should be a system for monitoring the safety of the treatment service, including the extent of medication diversion. Documented processes should be established to ensure the safe and legal procurement, storage, dispensing and dosing of medicines.

Monitoring of potential drug diversion should be strictly applied. An information system, assessment of documentation accuracy as well as regular evaluation are all important measures to ensure that the drug is not diverted. . A technical support scheme should be planned by the NTF on OST to highlight these issues within the context of international partnerships.

Finally, these recommendations have to be seen as dynamic, adaptable and constantly updated when and where (for each OST site) necessary. These updates or tailoring of the recommendations can be adapted in response to any adverse incident or circumstances which might arise following the start of the programme. Reviews should be done regularly, but not later than every six months.

Most countries have regulations that govern the procurement, storage, dispensing and dosing of medicines, and these often contain special provisions for opioids and other medications of abuse and dependence. In reference to EU recommendations.¹⁴ The regulations usually stipulate storage of methadone and buprenorphine in locked cabinets, with two staff members witnessing any movement/ transport of medication. These measures reduce the risk of medication theft, particularly the risk of diversion by staff members. Methadone and, in some circumstances buprenorphine, can be fatal if the wrong dose is dispensed or a dose is dispensed to the wrong patient. Various systems can be used to ensure that the correct dose is being dispensed to the correct patient.¹⁵

F. OST Centre Design and Security

Recommendations for a local OST clinic (centre)

Two new OST centres should be redesigned to each have a space of about 100 to 120 m² dedicated to medical care and OST programme. It should consist of:

Three offices for care:

- Two offices for physicians/therapists
- A nurse office with a water point and a bench to be able to perform nursing care in hygienic conditions,
- A waiting room of about twenty square meters
- A multipurpose group therapy/conference room
- A room dedicated to storage equipment and pharmaceuticals
- A security system for OST medications (safe) for methadone.

These are minimal standards. They should be increased if additional activities are developed or in case of an increase in the number of patients served and/or professionals.¹⁶

¹⁴ John Strang, Teodora Groshkova and Nicola Metrebian, European Monitoring Centre for Drugs & Drug Addiction (EMCDDA). *INSIGHTS: New heroin-assisted treatment, recent evidence and current practices of supervised injectable heroin treatment in Europe and beyond.*

¹⁵ Ibid.

¹⁶ Euro-Mythwork, "Virtual Clinic", Available from <http://www.q4q.nl/euomethwork/home/virtual-clinic/>.

The recommendations can be easily adapted to local sites, for example, the sites visited, namely Heliopolis Psychiatric Hospital and Ain Shams University Teaching Hospital. This includes identifying adequate persons and a short training plan for the identified staff.

With respect to the OST medication security system, a clear identification of a medication circuit and a locally responsible person (with managing competencies) is encouraged. In time, a short training plan should also be expected for building capacities of different agents.

Table 4

Standard equipment needs of the OST pilot site.¹⁷

SPACE/OFFICE	COMPONENT	QUANTITY	ESTIMATED BUDGET?
Nursing care	• Computer	1	
	• Consultation chair	1	
	• Desk	1	
Counselling room	• Cupboard with a glass door	1	
	• Computer	1	
	• Desk	1	
	• Consultation chair	2	
	• Desk	1	
Dispensation Area	• Cupboard with a glass door	1	
	• Metallic cupboard (for files/cases)	1	
	• Computer	1	
	• Consultation chair	1	
	• Desk	1	
	• Metallic cupboard	1	
	• Opaque store for the window	1	
	• Safe Mechanical Code storing box: capacity for housing a maximum consumption of methadone for three months	1	
	• Folding screen (space separation)	1	
	• Air conditioning	1	
	• one bathroom /water source for urinary analysis (with a glass window on the door)	1	
	• Urine analysis tests+ consumables utensils	1	
• Person scale (weigh)	1		
Staff	• Psychiatrists / addictologists	2	
	• GPh/addictologist	2	
	• Psychologist	1	
	• Social worker	2	
	• Nurses	4	
	• Counsellor	1	
	• Cleaner /agent for maintenance	2	
• Guard/ security agent	4		
Urine tests	100 patients (Mean twice per month for three substances (at least heroin, tramadol, methadone) for 12 months)	7200 tests	
Naloxon	100 persons	100 doses	

¹⁷ Morocco, Ministry of Health, *Guidelines for Moroccan OST programme* (Rabat, 2008).

G. OST Medication Storage

Both methadone and buprenorphine are narcotic medications. Due to their resale value on the black market it is necessary to ensure strong vigilance over their management to avoid misuse and abuse. It is necessary to organise transport and storage under safety conditions. The hijacking of the OST medications would be very detrimental to the success of the initiative, especially during the start-up phase of the programme and project evaluation. In addition, the resale by criminals and its use by drug users who would acquire the medications on the black market would expose them to a high risk of overdose.

Methadone should be kept in a secure and safe place, in line with local requirements. The amounts should be checked and witnessed by a second party daily, to ensure the amount used is reconciled with the amount dispensed.

Accurate and reliable counting of methadone should be organised. It is therefore necessary to enlist individual/separate information requirements and dispensations of the substance system. Given the risk of drug interactions, other prescribed and dispensed psychotropic medications should be subjected to the same precautions. This guarantees time saving and treatment traceability allocation to patients. Furthermore, it allows daily monitoring of quantities of narcotic substance involved and holds the stock updated.

Within each centre, narcotic substance should be stored in high security cabinets (or safes) equipped with locks, and if possible accessible by a numeric code known to experienced professionals only. It has to be changed regularly, two or three times a year at least, and as a precautionary measure after the turnover of each professional.

It is also important that the centre does not open its doors to the public during periods dedicated to the delivery of the substance. Every day, only the amount necessary for the dispensation of the day will be removed from the safe and this should take place before the centre opens to patients. Quantities of safe outputs for the dispensation of the day should not be left within reach and sight of patients, in order to prevent theft attempts. The safe must be kept locked during the hours when the centre is open for patients. Each office should be equipped with a lock, especially the room dedicated to dispensing the medication.

As previously stated, it is necessary that the access to the centre itself is secure to discourage any temptation to rob the centre during the closing hours. . An access door with a lock and installation of metal shutters or bars on the windows and ground floor door seems essential. The enclosure has to be sealed to the ground if its weight is insufficient to prevent removal.

H. Registration/Accreditation Required for Service Providers and Service Provision Sites to Pilot OST

The OST pilot as operational research should be launched by the Egyptian MOHP together with practitioners and experts in the use of pharmacotherapy in treating opioid dependence. The policy is intended to provide advice to assist prescribers, pharmacists and other health practitioners to treat opioid dependent patients in a legal, safe and effective manner.

This “Operational research” advises practice standards that are consistent with a safe clinical practice. Individual prescribers, pharmacists and other health practitioners administering

doses are responsible for decisions about the safety and effectiveness of treatment used for each patient. In practice, ensuring safety of supply is paramount to these decisions.

A proper staff training programme (most of the clinicians we met had been included in UNODC TreatNet Training Programme) is recommended. There should be an additional good practice-orientated training for the staff before starting the “Operational research”. The staff should visit at least two “best practice” international OST programmes, maybe one MENA region and/or one in EU.

When patient management involves health professionals as part of the OST programmes, it is important to ensure that their roles and responsibilities are clearly documented and understood. In any situation, decisions about the appropriateness and safety of prescribing and dispensing pharmacotherapy remain the responsibilities of the treating prescriber and another physician. As with the prescribing or dispensing of any drug, such decisions should be based on an adequate clinical assessment.

It is therefore important that all the services offered to patients have a mechanism to evaluate their own success. It is equally important to have checking mechanisms to see if the different professionals are doing their work appropriately, or whether individual patients admitted into treatment are suited for that particular type of treatment.

Monitoring and evaluating services and programmes are an essential part of a good practice. Most programmes should have some system of monitoring their activities: how many people are present, with what frequency, the quantity of OST medication prescribed, etc.

Assessment of service quality could be measured with more qualitative instruments such as through a ‘focus group’ or in-depth interviews with workers, clients, consumer groups, neighbours, community leaders, police, etc.

V. OPERATIONAL MODEL FOR OST SERVICE DELIVERY AND PLANNING

A. Minimal and Best Practice Recommendations for the Operationalisation of the Programme

Health authorities should ensure that treatment providers have sufficient skills and qualifications to use controlled substances appropriately. These requirements may include postgraduate training and certification, continuing education and licensing, as well as setting aside funding for monitoring and evaluation.

To maximize the safety and effectiveness of agonist maintenance treatment programmes, policies and regulations should encourage flexible, individualized dosing structures, with low starting doses and high maintenance doses, and with no restrictions placed on dose levels and the duration of treatment.

Psychosocial support should be available to all opioid dependent patients in association with pharmacological treatment. At a minimum, this should include assessment of psychosocial needs, supportive counselling as well as links to existing family and community services.

Treatment plans should take a long-term perspective. On-site psychosocial and psychiatric treatment should be provided for patients with psychiatric comorbidity.

OST dispensing sites, methods and equipment necessary to set up the facilities

International Recommendation: In specialized clinical settings, an on-site pharmacy or dispensary can enable observation of patients at the time of each dosing. This observation means that clinic staff can more thoroughly assess patients whom they would normally observe less frequently.

Before dispensing OST medications, dispensing staff should establish the identity of the patient and:

- Confirm this with the name on the prescription
- Confirm that the patient is not intoxicated
- Check that the prescription is valid and that the current day is a dosing day (for alternate days or three-times-a-week buprenorphine prescriptions)
- Confirm the dose on the prescription.

It is vital that OST medications are not dispensed to sedated or intoxicated individuals because this may lead to over-sedation. Dispensing staff should be skilled in the assessment of the degree of sedation and confident in refusing doses to intoxicated patients. Intoxicated or sedated patients should be asked to return when the intoxication or sedation has abated.

CR: Recommendation for OST sites

In *Heliopolis Psychiatric (Airport) Hospital* there is a nice outpatient clinic in front of the inpatient units. At the end of the corridor, there is enough room to organise an outpatient clinic for OST with all necessary premises, including a nice waiting room where group work or educational trainings for patients can be organised, a room for dispensing OST medication, a room for individual psychosocial therapy or for examining patients, a toilet for urine testing, etc. There is enough room behind the house for possible extra room(s). Special secure room should be prepared for a safe intended for storing OST medication; this can also be done in some other facilities within the hospital.

In *Ain Shams University Medical School* the premises might be part of the existing outpatient clinic. The staff suggested that the timetable for dispensing OST medication should be separated from the timetable when other non-drug using patients are treated. As the premises are in the cellar, the security issues might be problematic, so we recommend that special security staff is present during the OST clinic opening hours.

Criteria for client admission and retention into the OST programme

International Recommendation: Agonist maintenance treatment is indicated for all patients who are opioid dependent, able to give informed consent, and for who there are no specific contraindications. Pharmacological treatment of opioid dependence should be widely accessible for everybody in need thereof and meet the inclusion criteria.

To achieve optimal coverage and treatment outcomes, treatment of opioid dependence should be provided free of charge, or covered by the public healthcare insurance.

Due to the lack of financial/human resources, some OST treatment programmes only accept heroin drug dependent people when suffering from comorbid, physical illnesses, such as HIV/AIDS or tuberculosis; this is not an internationally recommended practice. At the other end of the scale, there are low-threshold programmes which would welcome anybody with a proven addiction to opioids who wishes to enter a treatment programme.

The criteria for entering OST treatment differ widely between programmes and countries. These inclusion criteria differ according to the type of treatment (maintenance or detoxification), the length of time a patient is expected to be in treatment, availability of treatment places, minimum age, length of opioid addiction, physical and mental health, personal motivation of the patient, etc. In areas where there are no waiting lists programmes, they can adopt looser criteria than in places where there is a larger demand than supply of treatment possibilities. In general, the best situation is where everyone who is opioid dependent and in need of treatment can enter OST treatment after appropriate assessment and treatment induction. It is recommended that the availability of treatment places is taken into account when adopting admission criteria in Egypt.

High threshold programmes adopt strict criteria

Guidelines for Moroccan OST programme, 2008 (low threshold)	
	<ul style="list-style-type: none"> • A minimum of five years of opioid addiction
Psychological:	<ul style="list-style-type: none"> • A strong desire or compulsion to take the substance • Difficulty in controlling behaviour regarding the onset, termination or levels of use
Physiological:	<ul style="list-style-type: none"> • Characteristic withdrawal syndrome for the substance if not taken • Evidence of tolerance and need for an increased dose to achieve the effect
Social:	<ul style="list-style-type: none"> • Progressive neglect of alternative interests/pleasures and an increased time span necessary to obtain, take or recover from substance. • Persisting with substance use despite the negative, harmful consequences (EU).

Low-threshold programmes adapt free access to OST in community-based and primary care systems; the OST medications are given for PWID only if the person is a justified opioid user according to the International Classification of Diseases (ICD) or the Diagnostic and Statistical Manual of Mental Disorders (DSM).

The advantages of such models are high accessibility to a wide number of patients in need of treatment.

OST Inclusion criteria for Slovenia, according to EU criteria, where there is a combination of low and high threshold of OST programmes (the coverage is over 50 per cent of opioid users in OST)	
	<ul style="list-style-type: none"> • Opioid dependence by international diagnostic criteria • Informed consent • Age over 15 years for buprenorphine and over 16 years for methadone • Residence in the region where a drug prevention and treatment centre is located • Family doctor • Health insurance (free of charge for the citizens of Slovenia)
CR for admission criteria for OST operational research in Egypt	
	<ul style="list-style-type: none"> • Heroin or Tramadol addiction by one of the international diagnostic criteria for opioid dependence • Minimum of one to three years of opioid addiction • A minimum age of 21 • History of failed treatment attempt(s) • Strong motivation to enter treatment.

These criteria should be adapted after evaluation and when more treatment slots are available.

Groups and Settings

The majority of people who are prescribed methadone worldwide are men between 25 and 40 years old. While they do not form a homogenous group with the same needs, there are groups with more specific needs:

- Pregnant women
- Opioid users with small children
- Young people
- PLWHA
- People with viral hepatitis
- People with mental health problems
- Poly-drug users
- PWID and are living in custodial settings (prisons, jails...) or under police arrest.

These groups should be given a priority over the general opioid dependent population. This, however, should not entail compulsory HIV-antibody testing of patients. Recommendations should be adopted by clinical staff, according to the client's needs for each OST treatment centre.

a) Women

Data on the relative efficacy of gender-specific services for women is lacking. To retain women, services may need to provide either individual or female-only group counselling, provide care for people with small children, for example, provide childcare facilities, and take measures to guard female patients against sexual harassment by male staff and patients. Opioid dependent women not involved in treatment should be encouraged to start the maintenance OST programme with methadone or buprenorphine.¹⁸

b) Pregnancy

Pregnancy testing should be offered to all women. Pregnant women who are involved in maintenance OST programme should be encouraged not to quit it during pregnancy. Methadone maintenance should be used in pregnancy in preference to buprenorphine. Although there is less evidence about the safety of buprenorphine, it might also be offered.¹⁹

As already mentioned, attracting and maintaining pregnant women in treatment services, preferably with their partner, is of vital importance. It is advisable to give pregnant women priority over others in entering methadone treatment due to the health risks associated with substance abuse for both the mother and the fetus, such as premature labour, multiple drug-use that can damage the fetus, poor nutrition, infection through unsafe injecting, etc. The long-term outcome of women who enter OST programmes during pregnancy is better in terms of their pregnancy, childbirth and infant development, irrespective of the continuous illicit drug use. Women attending treatment services usually have better antenatal care and better general health than drug-using women not in treatment, even if they are still using illicit drugs.²⁰

c) Neonates of opioid dependent women

Over 60 per cent of neonates born to opioid dependent mothers have symptoms of neonatal abstinence syndrome (NAS) that tend to occur 24-74 hours after delivery and include the following: high-pitched cry, rapid breathing, hungry but ineffective sucking and excessive wakefulness. Hypertonicity and convulsions could also occur. The intensity of NAS does not

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Loretta Finnegan, "Women, Pregnancy and Methadone", *Heroin Addiction and Related Clinical Problems*, vol. 2, No. 1 (June 2000).

correlate with the dose of the methadone or other opioids used by pregnant women.²¹ NAS can “easily” be treated by expert neonatologist and there is a lot of evidence that babies born to opioid dependent mothers maintained on methadone or buprenorphine experienced no harmful consequences later in their life.

d) Breastfeeding

Breastfeeding is encouraged not only because of its general advantages but also because some methadone may pass to the baby in very low doses and this may in turn help reduce any withdrawal symptoms of the baby. In case of HCV infection, the benefits of breastfeeding should be considered according to the mother’s viral load.²² Contraindications to breastfeeding: if the mother has HIV/AIDS, if she uses high doses of benzodiazepines or if she continues with the illicit drug consumption.

Assessment

The clinician has to conduct a personal interview with the patient, carry out a physical, mental state examination and do a urinalysis to assess whether the patient is taking opioids and to establish the presence and severity of opioid dependence. The final decision for the type of treatment should be taken on the basis of the needs of the individual patient and the options available for the clinician. To ensure a successful treatment programme, the clinician or assessor is required to give the patient information on the full range of treatment options. It should be ensured that the patient is provided with the most appropriate treatment for their current outline of best clinical practice needs.

Further, when starting OST medication or treatment with any other psychoactive medication (and it is the same for any treatment), the clinician should give detailed information about the treatment, about the possible side effects of the medication and the potential social consequences (such as long-term dependency and increased tolerance).

Urinalysis can be helpful in confirming opioid use, however, this should be considered with care. With some PWID it may encourage the use of opioids prior to an assessment. Furthermore, it can only confirm opioid use, but it does not provide any information about the extent of use or dependence. Its main usefulness may be in determining the use of other substances presently being used by the applicant.²³

²¹ Council of Europe, Pompidou Group, *Pregnancy and Drug Misuse*.

²² Ibid.

²³ Richard Mattick and Wayne Hall, *Methadone Maintenance Treatment and other Opioid Replacement Therapies* (Amsterdam, Harwood Academic Publishers, 1998).

a) Recommendation (Minimum standard):

A detailed individual assessment should be conducted including:

- History (past treatment experiences, medical and psychiatric history, living conditions, legal issues, occupational situation, and social and cultural factors that may influence substance use);
- Clinical examination (assessment of intoxication/ withdrawal, injection marks);
- Investigations (such as urine drug screen, tests for HIV, Hepatitis C Virus, Hepatitis B Virus, TB and liver functions).

Treatment Plan and Goal (duration and dosage)

a) Recommendation (Best Practice)

- Screening for psychiatric and somatic comorbidity should form part of the initial assessment.
- The choice of treatment for an individual should be based on a detailed assessment of the treatment needs, the appropriateness of the treatment to meet these needs (assessment of appropriateness should be evidence-based), patient acceptance and treatment availability.
- Treatment plans should take a long-term perspective.
- Opioid detoxification should be planned only in conjunction with ongoing treatment.²⁴

²⁴ Ibid.

Table 5
Steps in Methadone Treatment

<ul style="list-style-type: none"> • Individual enrolls into the programme
Welcomed by one member of the staff:
<ul style="list-style-type: none"> • Administrative intake of personal details • Checks if the individual meets intake criteria (if applicable)
Medical intake by doctor
Assessment of opioid dependence through:
<ul style="list-style-type: none"> • Personal interview • Medical assessment • Urinalysis
Treatment plan (maintenance, detoxification):
<ul style="list-style-type: none"> • Induction and calculation of the starting dose; if withdrawal symptoms reoccur, an additional dose will be given • The patient kept under supervision for a few hours to check if the initial dose is correct • The patient is given detailed information on the treatment and risks of using other drugs • Psychosocial intake by a social worker/counsellor • Assessment of problems to be addressed • Liaison with relevant services • In case of comorbidity, liaison with relevant medical services • Stabilization period to establish the right dose which may take up to six weeks.
Maintenance or detoxification regimen
<ul style="list-style-type: none"> • Regular review to set new goals (depending on type of treatment)

Source: (Methadone Guidelines 2000)

Ideally, all patients should be tested at initial assessment for recent drug use. Urine drug testing should be available for use at initial assessment when a recent history of opioid use cannot be verified by other means (e.g. Evidence of opioid withdrawal or intoxication).²⁵

²⁵ Ibid.

VII. RECOMMENDATIONS FOR COMPREHENSIVE HOLISTIC TREATMENT

Psychosocial services should be made available to all patients, although those who do not take up the offer should not be denied effective pharmacological treatment. This intervention should be carried out within a therapeutic context at an individual, family or group level. Psychosocial interventions may include structured, professionally administered interventions (for example, cognitive behaviour therapy or insight oriented psychotherapy) or non-professional interventions (e.g. Self-help groups and non-pharmacological interventions from traditional healers).

A. Recommendation (Minimum Standard)

Psychosocial support in association with pharmacological treatments of opioid dependence should be available to all opioid dependent patients. At a minimum, this should include assessment of psychosocial needs, supportive counselling and links to existing family and community services.

B. Recommendation (Best Practice)

A variety of structured psychosocial interventions should be available, according to the needs of the patients. Such interventions may include - but are not limited to – different forms of counselling and/or psychotherapy, along with social assistance such as housing, employment, education, welfare and legal aid.

CR: Counselling: may help the patient address their drug dependence. This may be done by the prescriber. OST programme should be integrated into the patient's holistic care. Linkages to psychiatric services or NGO counsellors should be made available as well.

A hotline for referral to drug counselling services can be a possible way for enhancing the efficiency of this aspect of care services.

On-site psychosocial and psychiatric treatment should be provided for clients with psychiatric comorbidity.²⁶

Naloxone should be available for treating opioid overdose.

It is strongly recommended that the OST “Operational research” is implemented not only in the health care systems, but also in coordination with other governmental services (police, justice system,...). It is also advised that civil society-based outreach and drop in centres together with NGOs and families cooperate to enhance the motivation of drug users in order for them to comply with the OST programme and other treatment services.

²⁶ Ibid.

VI. PLANNING AND INVENTORY MANAGEMENT OF OST MEDICATIONS FOCUSING ON THE SAFE PURCHASE, TRANSFER AND STORAGE OF CONTROLLED SUBSTANCES

A. Project Management

- Strengthening the management and leadership of the programme by institutionalizing a unit entrusted with the mission and task of the programme monitoring and evaluation.
- Establishing a training schedule on harm reduction interventions as well as OST through on-the-job trainings, or trainings at resource centres such as Network of Associations for Harm Reduction (NAHR) (FHI360).
- Establishing an information system that will help monitor and evaluate the programme.
- Advocacy to sustain a social and political OST programme commitment.
- Intervention around the legislative framework with counterparts.
- Mobilization of financial resources.

International Recommendation: Up-to-date medical records should be kept for all patients. These should include, at a minimum, the history, clinical examination, investigations, diagnosis, health and social status, treatment plans and their revisions, referrals, evidence of consent, prescribed drugs and other interventions received.

Confidentiality of patient records should be ensured. Healthcare providers involved in the treatment of an individual should have access to patient data in accordance with national regulations, as should patients themselves.²⁷

Healthcare providers or other personnel involved in patient treatment should not share information about patients with police and other law enforcement authorities without patient approval, unless required by law. Patients treated with opioid agonists should be identifiable by the treating staff.

B. Dispensing OST

Recommendations on adapting current national treatment protocols to include OST

International Recommendation: To maximize the safety and effectiveness of agonist maintenance treatment programmes, policies and regulations should encourage flexible

²⁷ Ibid.

dosing structures, with low starting doses and high maintenance doses, without placing restrictions on dose levels and the duration of treatment.²⁸

Level of supervised dosing methadone:

Only the high intensity supervision: involves no takeaway doses on a regular basis. This is the default level of supervision that should be adopted at the start of OST treatment.

Treatment considerations

Methadone is available in several forms – either injectable, as an oral solution or a tablet. The oral solution form is recommended for the treatment of opioid dependence because its administration is more easily supervised; also, take-home medication is less likely to be injected when it is sufficiently diluted when administered.

The main methadone anti-diversion strategy employed is dose dilution. Supervised doses should be diluted before administration. Diluting the dose to 200ml reduces the incidence of injection of takeaway doses.

Supervised methadone dosing first involves dispensing methadone liquid into a clean cup, then consuming the liquid under the direct observation of a nurse, pharmacist or doctor. Talking to patients after they have consumed their methadone is generally adequate to ensure that the dose has been taken.

C. Managing Dose Diversion

All OST medications are susceptible to diversion for illicit or unsanctioned use. The non-prescribed use of pharmacotherapy has been associated with incidents of serious harm, including death, which have all involved the treated patient, their associates or other third parties, including children. Practitioners prescribing pharmacotherapy, administering supervised doses, have a responsibility to consider the risks of diversion and should adopt practices that minimise diversion.

Patients should indicate that they have received a dose in some way, for example by signing a dosing card. If a patient attempts to spit out a dose or to leave the dispensary before the dose has dissolved, the prescribing doctor should be informed.

The risks of diversion and illicit injection should be discussed with the teams of OST providers. Possible strategies to manage diversion should be established for each case. Collaborative approach between treatment prescribers, pharmacists and other allied healthcare professionals is important, with each having a key role in a patient's treatment with OST. Good communication between all parties is essential to maximize the benefits of OST.

²⁸ Ibid.

D. Review of Patient's Progress

Assessment for suitability for unsupervised doses requires that the patient sees the prescriber on a regular basis. To avoid the risk of duplicated dosing, clear instructions in writing to both pharmacists about their respective finishing and starting dates should be provided. The patient's dosing patterns should be confirmed with the current hospital pharmacist before the prescription is issued from a new hospital.

E. Discharge

Involuntary discharge from treatment is justified to ensure the safety of staff and/or other patients, but noncompliance with programme rules alone should not generally be a reason for involuntary discharge. Before involuntary discharge, reasonable measures to improve the situation should be taken, including re-evaluation of the treatment approach used. Staff should be cautious when excluding patients seeking opioid agonist maintenance treatment, since such patients often have poor clinical outcomes if they do not receive treatment.

International Recommendation: OST is indicated for all patients who are opioid dependent and are able to give informed consent, and for whom there are no specific contraindications. Given the long-term nature of the treatment and the potential for toxicity in the first two weeks, a high degree of certainty of the diagnosis is required before recommending opioid agonist maintenance treatment. If the diagnosis cannot be confirmed by observation of opioid withdrawal, injection sites or confirmation of previous treatment, then treatment should be started with care and close monitoring; in this situation, lack of intoxication from opioid agonists will provide direct evidence of opioid tolerance. Staff should be cautious when excluding patients seeking opioid agonist maintenance treatment, because such patients often have poor clinical outcomes if they do not receive treatment.²⁹

F. Linking the OST Programme to Other Services

It's necessary to actively link OST programme to other HIV and addiction treatment services through an active referral system, and ensure the availability and use of other preventive measures including new needles, syringes and condoms.

International Recommendation :

Voluntary testing for HIV, viral hepatitis, TB and other common infectious diseases should be available as part of an individual assessment, accompanied by pre- and post-testing counselling.

Where there are significant numbers of opioid dependent patients with either HIV, viral hepatitis or TB, treatment of opioid dependence should be integrated with medical services for these conditions.

For patients with TB, viral hepatitis or HIV and opioid dependence, opioid agonists should be administered in conjunction with medical treatment. There is no need to wait for

²⁹ Ibid.

abstinence from opioids to commence either anti-TB medication, treatment for viral hepatitis or antiretroviral medication.

Opioid-dependent patients with TB, viral hepatitis or HIV should have equitable access to treatment for TB, viral hepatitis, HIV and opioid dependence. --> Linkage with National TB programme.³⁰

CR: Coordination with other services (medical, social, community based organisations ...) aims to:

- Develop cooperation between OST, AIDS and TB/infectious diseases services available through NAP, by devising adequate protocols and/or increasing the accessibility of treatment in one place (one shop service)
- Activate referral mechanism from OST sites to community based organisations outreach project and VCTs run by NGOs such as FHI360 projects
- Link with national hepatitis programmes that offer hepatitis B vaccination to all opioid-dependent patients
- Develop mutual educative events/trainings on comprehensive treatment of OST and infectious diseases

The system OST patient referral to services (such as HIV infection, viral hepatitis and TB) should be done through existing services for drug users, and if possible, all interventions should be done in OST services. This idea was strongly supported by Dr. Walid Kamal, NAP Manager, MOHP. Recommendations on the treatment of opioid dependent patients with HIV, viral hepatitis and TB should be included in the treatment protocols.

Table 6

Methods to assess patient stability

<i>Clinical records /Patient history</i>	<i>Clinical Examination</i>	<i>Urine Toxicology</i>	<i>Discussion with Other health Professionals</i>
Attendance at medical/case manager reviews	•		
Missed doses			•
Provision of Urine Drug Screens (UDS)		•	
Heroin and other opioid use	•	•	•/-
Benzodiazepine use (particularly alprazolam)	•	•	•/-
Alcohol use	•	•	•/ -
Stimulant use	•	•	•/-
Mental state assessment	•	•	
Medical comorbidity	•	•	
Stable accommodation	•		•/-
Evidence of recent injecting sites		•	
Intoxicated presentations at pharmacy or	•		•

³⁰ Ibid.

medical clinic overdoses			
Concerns abuse/diversion	•		•/-

Resource: *Policy for maintenance pharmacotherapy for opioid dependence, 2013* <http://www.health.vic.gov.au/dpcs/pharm.htm>)

VII. MONITORING AND EVALUATION PLAN

A. Evaluation of the OST “Operational Research”

OST, particularly methadone has been the subject of rich and varied evaluative research undertaken since the 1950s, and continue to be updated till this day in many countries. Despite the recognition that OST has benefits all over the world and its undeniable success, it is always important to convince the merits of other experiences and display results achieved in each new country that implements them.

But it would be unnecessary and costly to reproduce imaginative evaluative wealth of large multicentre studies and link it with the implementation of OST in Egypt. It is advisable for this new treatment to demonstrate the effectiveness of some simple and easy to document criteria. It is also important to demonstrate the safety of these treatments. Finally, it is always interesting to develop a brief survey by or focus group discussion between active heroin users who do not use these treatments, either because they reject the principle; or otherwise to identify barriers and obstacles that may persist. Ultimately, the results of this evaluation should be used to improve programme quality.

It is proposed to carry out a 'before and after' comparative assessment, based on preliminary information to be collected at the time of patient enrolment in the programme. This information will be compared to the result of a second batch to be collected twelve months after the patient entry into the programme. The collection of information should be made by practitioners themselves. It will therefore concentrate on the essential evaluative efforts and sensitive issues to avoid unnecessarily burdening practitioners.

Suggested monitoring and evaluation plan to determine targets in terms of coverage

International Recommendation : There should be a safety monitoring system of the treatment service, including the extent of medication diversion.

CR: There should be intermittent or ongoing evaluation of both the process and outcomes of the treatment provided through NTF on OST and ANGA close supervision.

Indicators that should be monitored and evaluated

- Retention rates in the programme after one year
- Treatment followed by patients (actual number of days of treatment); Patients' adherence to treatment
- Reasons for drop out and possible re-entry
- Illicit drug use during treatment (measured by self-report questionnaires and correlated analyses of urine collections)
- Evolution of risky behaviour (self-administered questionnaires on practices, injection, injection frequency, reuse and sharing of equipment)
- Improving the health status of patients (WHO questionnaires - SF12)

- Feelings and feedback of patients in response to treatment (satisfaction and dissatisfaction causes, side effects)
- The incidence and causes of death (including death from overdose)
- The incidence of criminal events (number of days in jail over the year)
- Social inclusion
- HIV, Hepatitis B and C prevalence among patients admitted and the existence of possible seroconversion
- The proportion of patients starting antiretroviral treatment

Duration of assessment

It seems reasonable to fix the duration of one year as a beginning of an OST programme with the evaluation of individual treatments. Given the time necessary to include patients, it is expected a total minimum period of two years to complete the assessment of patients. Patients will be followed for six months after their completion of one year on treatment to conclude the first analysis. Implementation is scheduled for 2015 and the first results of the evaluation will therefore be expected in late 2017.

B. Advocacy Plan

- Develop case studies of MENA countries with OST (Iran, Morocco, Lebanon)
- Translate key OST policy and technical publications to Arabic for dissemination
- Develop advocacy briefs for key audience (MOI, Religious leaders, psychiatrists, etc.)

To educate the community:

- To update curricula of psychiatry, and for medical students and postgraduate physician residents in psychiatry and toxicology to include evidence-based information on OST.
- To provide an opportunity for all physician residents in psychiatry to develop practical skills in the diagnosis of opioid dependence, in the administration of initial and maintenance doses of OST medication, such as methadone, and in organising the multi-disciplinary care, including management of HIV, HCV and TB.
- To develop/update an on-the-job as well as an in-depth continuous educational training course on dependence treatment (including OST) for practising psychiatrists, infectious disease doctors, nurses, psychologists and social workers, and other interested medical specialists as well.

C. Capacity Building

UNODC, MOHP and national partners will ensure staff training (managers and professionals), including exchange visits with other countries in the MENA region (Morocco, Lebanon) and EU countries (Slovenia), along with the training sessions in Cairo. In addition, an expert psychiatrist should be hired to supervise the first phase of OST programmes.

UNODC will contribute to the trainings on drug dependence treatment, through treatment materials and other training tools in close partnership with MOHP.

D. Major Challenges

Epidemiology

Based on the 2010 BBSS, Egypt is facing a concentrated HIV epidemic among PWID, with prevalence rates of 6.8 per cent in Cairo and 6.5 per cent in Alexandria.

The political commitment

GSMHAT is acting as the national body leading awareness about drug dependence as a disease and the principles of drug abuse treatment. This entity acts also as a manager of mental health hospital implementation across the governorates.

The National Fund for Drug Control and Addiction Treatment, together with university councils, the National Council for Drug Control and Treatment and GSMHAT elaborate and implement national strategies for overcoming and treating addiction.

Opioid Substitution Therapy and the Anti-Narcotics General Administration of Ministry of Interior

The interview with MOI representatives (General Montasser Abou Zeid, former ANGA Director, as well as Brigadier Nabil Hassan and Colonel Emad Gheith,) indicated that different sectors of MOI were not well informed of the importance of OST especially in crime reduction, but their attitude towards OST was extremely positive. They showed interest in learning more about OST and were very open to possible co-operation. They understood that OST could reduce the number of criminal offenses, the illegal drug market and drug trafficking as well as the number of incarcerated drug users.

Current service and accessibility:

Drug abuse services in Egypt are stretched over several governorates. GSMHAT is offering 90 per cent of mental health services in Egypt.

Due to the inpatient facility's distribution, patients and their families face difficulties in reaching the services as they might need to take more than one method of transportation to get to the hospital.

OST programmes are not officially available in Egypt. Medications like methadone and buprenorphine/buprenorphine + naloxon are still not being utilized. Despite the increasing numbers of patients contracting blood transmitted diseases through needle sharing, the model of harm reduction is still not used in Egypt due to legislative issues.

General human resources of all hospitals

The current national data show a total of 332 psychiatrists, 358 physicians (other specialties), 1,860 nurses and 356 of both psychologists and social workers. Each hospital will dedicate adequate human resources, according to the size (beds and outpatient clinics) of its existing drug abuse services.

The drug dependence treatment finance

About 2 per cent of the health budget in Egypt is dedicated to mental health, but no clear data about the size of spending on drug dependence services is available.

The National Fund for Drug Control and Addiction Treatment is the funding body for the 24-hours hotline service. Drug dependent persons admitted to governmental hospitals via the hotline do not pay for their treatment as this is totally covered by the National Fund. Otherwise, drug dependent person's contribution to their treatment within the governmental hospitals varies between EGP 600 (the usual cost of treatment varies from about EGP 2,550 to EGP 3,000 per month according to the type and setting of service).

NGOs receive funding mainly from private donations. Because of drug dependence treatment legislation due to a GF round 11 cancellation, NAP is currently launching the process of applying for the Transitional Funding Mechanism with technical support provided by UNAIDS.

E. Recommendations

All representatives from the GSMHAT, National Council for Mental Health, ANGA, National Fund for Drug Control and Addiction Treatment, Prosecution, MOI, large governmental and private hospitals and NGOs, are genuinely committed to start OST pilot as operational research. Also, professionals working in the field of drug dependence treatment are enthusiastic to implement the OST programme and it is evident that patients need it. Since November 2013, UNODC has worked towards re-establishing the specialized NTF on OST. In the meeting held on 6 November 2013, "Harm Reduction Committee" "لجنة الحد من المخاطر", was recommended as a title for the OST task force.

To generate momentum and reach consensus on piloting OST in Egypt

- N TF on OST should act as the OST initiative secretariat in Egypt, led by GSMHAT, and feeding into the Strategy of the National Fund for Drug Control and Addiction Treatment.
- The Terms of Reference for this NTF is to be proposed by UNODC and has to respond to a consensus among partners.
- The Minister of Health is to request the nomination of focal points from each relevant department across MOHP, MOI, MOJ, MOH, and MOHE (covering university teaching hospitals, and other relevant departments such as CAPA).
- A round table should be held between participants for reviewing the Feasibility Study and Operational Plan, and also for more involvement in the initiative.

- The meeting schedule of NTF on OST should be managed by GSMHAT to ensure continuous contacts, regular meetings and follow-up, along with the reporting on progress to the Minister of Health through the Secretary-General.
- It is agreed that each nominated counterpart of the committee has the authority to make decisions on behalf of their department, ministry or organisation.

F. Threats

Main relevant threats are:

- Political challenges, elections, unrest and turnover;
- Risks in case of a negative view and perception by the media/community, depending on the stigma and low knowledge of the harm-related injected drug use. This can sometimes be a threat to, or lead to a failure of the pilot stage, according to the low level of awareness of indicators such as rapid patient enrolment in the programme, eligibility criteria, the (surrounding) misinterpretation of OST treatment and its effects.
- Lack of funding possibilities and sustainability of the Government.
- The risk of diversion is the case of non-control and insufficient monitoring throughout the whole programme.

This analysis has summarized the challenges to better services, taking into account the context of a relatively strong stigma and discrimination against people who use drugs, as it is the case in several Arab countries, along with the low public health profile, under-resourcing, the inefficient allocation of resources, a weak implementation of mental health plans and legalisations.

This project is part of an overall offer of care and treatment services for drug users in Egypt. The project has not been funded yet. Concrete fundraising efforts for this programme should be taken in parallel to the advocacy process; and negotiations with GFAMT and other donors were already in progress throughout 2014-2015.

G. Mission Constraints and Limitations

- Qualitative information was obtained in part by reading and analysing the documents made available to the mission, and from meetings with key persons as well as from site visits. On-the-spot observations of drug consumption, practices, as well as interviews with PWID were not possible given the short duration of the mission and the difficulty of accessing this hidden population.
- In addition, despite the mobilisation of UNODC team and the high commitment of the Mental Health office in MOHP, all pragmatic aspects have not been addressed and an additional mission for several days is suggested, in order to better understand the field realities and to achieve the goal of an appropriate local site design of an OST dispensation conception. The architectural review of the facilities is necessary, in a consensual approach with practitioners and administrators of each hospital.
- An important issue in the process is the storage of products in hospital pharmacies. This issue requires features such as safety and mandatory record keeping of specific

drugs by pharmacists. The local teams should be trained. This point could not be discussed with the local teams since it was not possible to reach all of the professionals during the hospital visits, except in the Airport hospital.

VIII. ANNEXES

Annex 1: Partners and Stakeholders Involved and Field Visits

Site visits:

Heliopolis Psychiatric (Airport) Hospital: Dr. Mahmoud El Gawish, Director and focus group discussion with doctors, counsellors, clients, social workers and lab technicians.

Ain Shams University Medical School: Visit to Psychiatric Centre, focus group discussions with the faculty members and visit to the facilities.

Behmen Psychiatric Hospital: Interview with the Hospital Director/expert and focus group discussions with addiction counsellors and social workers.

Contact meeting and Discussion with:

Representatives of Psychiatric Hospitals, GSMHAT and the Mental Health Council:

- Professor Dr. Hisham Ramy, GSMHAT Professor Dr. Amani Haroun El Rashid and fellow doctors, Ain Shams University Medical School, Faculty of Psychiatry/Addiction
- Dr. Tamer El Amroussy, GSMHAT Addiction Unit Director
- Dr. Manal Abed, GSMHAT Addiction Unit
- Dr. Khaled Siagy and fellow colleagues at the Mental Health Council

ANGA, MOI:

- General Montasser Abou Zeid, former Director
- Brigadier Nabil Hassan
- Colonel Emad Gheith

National Council for Drug Control and Treatment/National Fund for Drug Control and Addiction Treatment:

- Mr. Amr Osman, Director
- Prof. Dr. Inas El Gaafarawy National Center for Social and Criminological Research
- Prof. Dr. Laila Abdel Gawad, in charge of national drug hotline; National Centre for Social and Criminological Research
- Judge Wael Abou Eitta, Human Rights Department, MoJ.

Other Key National Partners from MOHP:

- Dr. Walid Kamal, NAP Manager
- Dr. Fadila Amer, Director, Central Agency for Pharmaceutical Affairs (CAPA)
- Ms. Samah Ragab, Technical Officer, CAPAMs. Rania Ashraf, Technical Office Deputy Director, CAPAMr. Rasha Abu Shadi, Head of Pharmaceutical Procurement Department, CAPA

Private Psychiatric Hospital and Addiction Facility:

- Dr. Nasser Loza, Director, Behmen hospital
- Dr. Mairose Doss, Head of Geriatrics, Behmen hospital.

Civil Society Organisations:

- FHI360, Network of Associations on Harm Reduction (NAHR) (representing eight community outreach NGO projects):
- Dr. Cherif Soliman, Country Director, FHI360
- Ms. Carla Khoury, Associate Technical Officer, FHI360
- Dr. Sherif ElKamhawi, Programme Officer, FHI360

Representatives of UN agencies:

- Dr. Hendrik Jan Bekedam, Representative, WHO Egypt Country Office
- Ms. Joumana Hermez, Technical Officer, AIDS and STD Unit, WHO EMRO
- Dr. Khaled Saeed, Technical Officer, Mental Health and Substance Use Unit, WHO EMRO
- Dr. Hala El Henawy, Technical Officer, WHO Egypt Country Office
- Dr. Ahmed Khamis, Country Coordinator, UNAIDS.

UNODC Regional Office for the Middle East and North Africa (ROMENA):

- Mr. Leif Villadsen, Former Regional Programme Coordinator
- Dr. Mohammad Tariq Sonnan, Regional HIV Adviser
- Ms. Karine Shalaby, former National HIV Officer
- Dr. Mohamed Hamad, National HIV Officer
- Dr. Talal Maarouf, Technical HIV Project Assistant
- Mr. Faisal Hegazy, Programme Officer
- Ms. Dina Fayad, Regional Research Officer

Annex 2: Technical Committee

- GSMHAT- Prof. Dr. Hisham Ramy
- ANGA - Colonel Emad Gheith
- National Fund for Drug Control and Addiction Treatment – Mr. Amr Othman
- National Council for Drug Control and Treatment –Prof. Dr. Inas El Gaafarawy
- MoJ (part of National Fund/ National Council): Judge Wael Abou Etta
- NAP – Dr. Walid Kamal
- CSOs - Network of Associations for Harm Reduction/FHI360
- WHO EMRO - Dr. Khaled Saeed
- WHO CO – Dr. Hala El Henawy
- UNODC – Dr. Tariq Sonnan, Dr. Mohamed Hamad and Mr. Faisal Hegazy

Members to be included at a later stage (Advocacy Committee)

- Religious leaders
- Customs agencies (MoI)
- Prisons settings
- National security
- More CSOs

Annex 3: Relevant Regulation and Laws on Substances Handling

As in all the Middle East and in almost all Arab countries in EMRO region, Egyptian chemical control legislations are not very easy to access, since these legislations are spread across many different agencies, ministries and regulatory bodies. According to government laws, regulations and policies, and authorities, the relevant context related to the purchase, transfer of and storage of controlled substances is as follows:

The Egyptian Environmental Affairs Agency, under the Ministry of State for Environmental Affairs, is the main body responsible for chemical control in the country. It administers environmental laws and regulations, formulates general policies for environment protection and promotion, and implements these in coordination with other authorities.

Law No. 4 for the Protection of the Environment of 1994 and the Executive Regulation of Law No. 4 (the Ministerial Decree No. 338 of 1995) provides the principal regulatory framework for handling hazardous substances, including permits, storage, transport, packaging and labelling. A number of additional regulations governing import, manufacturing, trade, and usage of chemicals have been issued under the jurisdiction of other ministries. Consequently the authorities introduced the **Egyptian Hazardous Substances Information and Management System (EHSIMS)**, an online initiative to facilitate the procedure for obtaining licenses for handling hazardous substances and provide consistency.

Egypt does not have an existing chemical substance inventory or a new chemical notification scheme, and a permit is required for the handling of hazardous substances. Law No. 4 prohibits anyone without a permit obtained from the competent authorities from handling hazardous substances and wastes, but requires anyone who produces or handles hazardous material, to take necessary precautions to ensure that no environmental damage occurs. Detailed information requirements and conditions for granting such permits are prescribed in the Executive Regulation (Decree No. 338). The decree specifies that a permit must be obtained from one of the competent authorities depending on the type of substance, such as the Ministry of Agriculture, Ministry of Industry (hazardous industrial substances and waste), Ministry of Health and Population (hazardous pharmaceutical, hospital and laboratory substances and waste, and domestic insecticides), Ministry of Environmental Affairs, Ministry of Petroleum, and MOI.

As Egypt's existing chemical control regulations are spread across a large number of agencies, EHSIMS was created to harmonize all into one central location. It was established with support from the Swiss Government in collaboration with other principal authorities involved in national chemical control matters. EHSIMS stated objectives are to 1) centralizes the hazardous materials permit application process, which entails working with six different ministries (i.e. Agriculture, Electricity, Health, Industry, Interior, and Petroleum); 2) serve as an internal communication network between these six ministries and the Egyptian Environmental Affairs Agency to facilitate intra-ministerial activities; 3) provide a central location for lists of hazardous substances as defined by the ministries; and 4) provide national guidelines for the safe storage, transport and packaging of hazardous substances, and a national labelling system. (Middle East, Global Emerging Regulations Issue Team Country Sheet the Cefic Global Emerging Regulations Issue Team, May 2011).

In addition, law No. 4 defines hazardous substances as substances that exhibit dangerous properties that are hazardous to human health or which adversely affect the environment.

Such properties include toxicity, exclusivity, flammability, and the exhibition of ionizing radiation. EHSIMS has published a Guideline on Potential Hazards providing information on the health risk of particular listed substances, including the type of danger i.e. Physical, chemical, or poisonous, and the effects of the substances on health. The Guideline focuses on 200 hazardous substances. It also provides a sample of ten substances with their individual classification and categorization.

Each substance is provided with 14 statements, including name of substance in Arabic and English, synonyms, characteristics (e.g., melting point, boiling point), and safety and hazard statements.

The Executive Regulation (Decree No. 338) sets out the general requirements for packaging and labelling of hazardous substances. The label of the container must include:

- Contents of container, active substances, and degree of concentration
- Total and net weight
- Name of producer, date of production and production number
- Nature of danger and toxicity
- First aid procedures to be taken in case of exposure
- Safe method of opening, emptying and using a container
- Safe storage method
- Dispose methods of empty containers

(Middle East, Global Emerging Regulations Issue, Team Country Sheet, the Cefic Global Emerging Regulations Issue Team, May 2011).

Annex 4: Companies that Provide Methadone

<i>Manufacturer/Distributor</i>	<i>Country/Address</i>
Boehringer Ingelheim Pharmaceuticals, Inc.	<p>United States Petersburg, VA-23805 2820 North Normandy Drive</p> <p>Postal Address: P.O. Box 1658 Tel.: +1 804 504 8809 Fax:+1-804-504-8637</p> <p>Contact: Mr Chris Vance e-mail:cvance@bichemicals.com</p> <p>http://us.boehringer-ingelheim.com/</p>
Dolder AG	<p>Switzerland CH-4004 Basel Immengasse 9</p> <p>Tel: +41 (0) 61 326 66 00 Fax: +41 (0) 61 326 62 04 pharma@dolder.com Marco Pickel</p> <p>Business Team Leader 'Pharma Sales': marco.pickel@dolder.com, Tel. +41 (0) 61-326 65 12 Christian Schulz</p> <p>Business Team Leader 'Pharma Business Development': christian.schulz@dolder.com, Tel. +41 (0)61-326 62 31</p> <p>http://www.dolder.com/en/</p>
Johnson Matthey Macfarlan Smith	<p>United Kingdom Edinburgh, 10 Wheatfield Rd.,</p> <p>Tel.: +44 0131 337 2434 Fax.: +44 0131 337 9813</p> <p>Email: msl@macsmith.com http://www.macsmith.com/</p>
Triquim S.A.	<p>Argentina Buenos Aires,</p> <p>Commercial Offices: AV. VélezSársfield 5855 Laboratories: Av. VélezSársfield 5928 Carapachay. Tel.: +54 11 4762 6405 Fax.: +54 11 4762 6405 triquim@lazar.com.ar http://www.lazarpharma.com/</p>

Harman Finochem Limited	<p>India Kalina, Santa Cruz (East) Mumbai-400098 107 A, Vinay Bhavya Complex 159a CST Road</p> <p>Te.: +91 22 265 28080 Fax.: +91 22 265 28285 E-mail: harmanfinochem@vsnl.com http://www.harmanfinochem.com/</p>
PharmascienceInc	<p>CANADA Montreal QC H4P 2T4 6111 Av Royalmount Suite 100</p> <p>Tel.: +1 514 340 9800 Fax: +1-514-342-7764 Contact: Mr. Khaled Farid kfarid@pharmascience.com www.pharmascience.com</p>
Pioneer Agro Industries (Pharmaceutical Division), Prop. Sanvin Laboratories Pvt. Ltd.	<p>India Mumbai-400071 Office address: 206, Eric House, 16th Road, Chembour,</p> <p>Tel.: +91 22 2521 70/ 72 - 75 Fax.: +91 22 2521 70 E-mail: sanvin@vsnl.com Contact: Dr. Sanjay Goel http://www.pioneeragro.co.in/</p>
Siegfried (USA), Inc	<p>United States Pennsville, NJ 08070 33 Industrial Park Road</p> <p>Tel.: +1 877 763 8630 E-mail: info@siegfried-usa.com Sales: milton.boyer@siegfried-usa.com R&D: richard.haldimann@siegfried.ch http://www.siegfried.ch</p>
Siegfried Ltd	<p>Switzerland 4800 Zofingen Untere Brühlstrasse 4</p> <p>Tel.: +41 62 746 1212 E-mail: info@siegfried.ch Sales: juerg.ammann@siegfried.ch R&D: regina.thiergardt@siegfried.ch http://www.siegfried.ch</p>

<p>Synerlab, Laboratoires SOPHATEX (Laboratoires Bouchara-Recordati)</p>	<p>France 28500 Vernouillet 21 rue du Pressoir Laboratoires Sophatex</p> <p>Tel: +33 (0) 2 37 62 76 76 Fax: +33 (0) 2 37 62 76 75</p> <p>France 92302 Levallois Perret Cedex 68, rue Marjolin Laboratoires Bouchara-Recordati</p> <p>Tel. +33 1 45191000 Fax +33 1 47560246 Contact: Mr. Thierry Kin t.kin@bouchara-recordati.fr http://www.Recordati.lt</p>
<p>Zentiva, a.s.</p>	<p>Slovak Republic 920 27 Hlohovec Nitrianska 100</p> <p>Tel: +421 33 736 1111 Fax: +421 33 736 0890 E-mail: info@zentiva.sk http://www.zentiva.sk/</p>
<p>Zentiva, a.s.</p>	<p>Czech Republic 102 37 Praha 10 U Kabelovny 130</p> <p>Tel: +420 267 241 111 Fax: +420 272 702 402 E-mail: zentiva@zentiva.cz http://www.zentiva.cz/</p>

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UNODC

United Nations Office on Drugs and Crime

For more information about UNODC's work related to HIV Prevention among PWID:

HIV/AIDS Section

UNODC P.O. Box 500, 1400 Vienna, Austria

Tel. (+43-1) 26060 4292

Email: fabienne.hariga@unodc.org

Online: <http://www.unodc.org/unodc/en/hiv-aids/new/index.html>



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