Part D: Critical Questions and Links to Information Regarding Clinical and Regulatory Requirements for Implementing Methadone Maintenance Programs: Examples of Approaches

This section provides a sample of frequently asked questions about how methadone programs are regulated and operated in various countries. Answers to these questions can be found in a number of key resource documents that provide guidance in areas such as patient assessment, management of the facility and the clinical environment, safety issues and adverse events, staff credentialing, patient admission criteria, dosage guidelines, withdrawal and discharge requirements, provision of concurrent services, and support of community relations and education. Links also are provided to the regulations that guide the legal dispensing of opioid-controlled substances for maintenance or detoxification treatment. This information is provided to illustrate the impact of methadone maintenance therapy research on actual program regulation and implementation within the international community. The countries identified are provided as examples of how regulatory requirements are addressed in other countries.

Question 1: How are methadone programs approved or registered for operation?

Answer:

United States

Methadone maintenance programs must go through an accreditation process in order to operate. The Substance Abuse and Mental Health Services Administration (SAMHSA) (www.samhsa.gov/) is the lead agency responsible for Federal methadone treatment oversight and the accreditation of methadone programs. Through its Center for Substance Abuse Treatment (http://dpt.samhsa.gov/), SAMHSA has guidelines for program accreditation (http://dpt.samhsa.gov/pdf/001218accred.pdf) that address each critical legal, clinical, safety, and program management area related to the treatment of patients using methadone maintenance therapy.

All accredited methadone programs operate under the authority of the Drug Enforcement Agency (DEA) regulations that govern the dispensing of controlled substances. The DEA regulations (www.deadiversion.usdoj.gov/pubs/manuals/narcotic/narcotic.pdf) stipulate requirements for the type of registration required, qualifications for physicians who dispense methadone, and rules for physician record-keeping.

Canada

In Canada, treatment practitioners and the hospitals providing methadone treatment must be registered to dispense methadone and are exempt from the control regulations set forth in the Controlled Drug and Substances Act (http://laws.justice.gc.ca/en/C-38.8/C.R.C.-c.1041/211220.html#rid-211242).

Australia

In Australia, methadone programs are approved by the Director-General of Health and treatment practitioners must complete and pass a Methadone Prescriber's Accreditation Course before they are allowed to dispense methadone (http://opiateaddictionrx.info/pdfs/methadone_clinicalpractice_guidelines.pdf).

New Zealand

The Minister of Health has designated the Director of Mental Health as the authority to determine what organization can be specified as a methadone treatment service (www.moh.govt.nz/moh.nsf/49ba80c00757b8804c256673001d47d0/43c7fe2ae5863e39cc256cf30002b8a

d/$FILE/Opioid%20Substitution%20Treatment.pdf). In addition, New Zealand will only approve practitioners who agree to establish and maintain a direct relationship with the local treatment services provider. Local programs are required to provide a letter of support for the practitioner to dispense methadone and to work collaboratively as a team (www.moh.govt.nz/moh.nsf/49ba80c00757b8804c256673001d47d0/43c7fe2ae5863e39cc256cf30002b8ad/$FILE/Opioid%20Substitution%20Treatment.pdf).

Question 2: What forms of methadone are acceptable for treatment?

Answer:

United States

Methadone is provided in various forms, including diskettes, tablets, oral solution, liquid concentrate, and powder. In the United States, methadone used in medically assisted treatment is almost always administered orally in liquid form. Parenteral administration is prohibited in opioid treatment programs. Parenteral abuse of methadone is not widespread, and people rarely inject the methadone dispensed in U.S. programs because it is mixed with substances (e.g., flavored drinks) that make injection unattractive (www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.section.82775; www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.section.82907).

England

Oral methadone solution is the form of choice in England, and the standard dose contains 1 mg of methadone in 1 ml of liquid. Oral solution is preferred because of its clinically proven effectiveness, ability to alleviate oral withdrawal symptoms, potential for reducing risks associated with injection, and ability to be adjusted to an optimal level. Other forms of approved methadone include a concentrated mixture of oral solution (10 mg and 20 mg), methadone tablets (5 mg), and injectable ampules. Methadone tablets are seldom recommended due to their ability to be injected and their high street value. Injectable methadone is used only after careful patient assessment by an addiction specialist (http://opiateaddictionrx.info/pdfs/RCGP_UseOfMethadone.pdf).

Question 3: What are the guidelines for initial dosing?

Answer:

Australia

Determining the initial dosing of methadone is guided by a number of factors that include the severity of the patient's opioid dependence, drug use history, and the results of the medical examination and urine test. Prescribing the first dose of methadone requires consideration of whether the patient is using other central nervous system depressants and their hepatic functioning. Practitioners are directed not to exceed 40 mg for an initial dose, lowering the limit to 30 mg for patients at risk for overdose (http://opiateaddictionrx.info/pdfs/methadone_clinicalpractice_guidelines.pdf).

Canada

Patients are given a specific first dose of methadone, based on assessment outcomes, and observed for a period of time to determine reaction and toxicity. Guidelines require initial low doses (10-30 mg for first 3 days) for those at normal risk, and lower doses (10-20 mg) for those who have a higher risk for methadone toxicity, including those who use depressants, are alcohol dependent, are 60 years or older, or have respiratory problems (www.cpso.on.ca/publications/MethadoneGuideNov05.pdf).

United Kingdom

Concern for risk of overdose requires practitioners to start initial dosing between 10 and 30 mg daily. Patients using sedatives, including alcohol, are limited to 20 mg a day. The initial stabilization period lasts for 2 weeks, at which time the dose is increased by 5-10 mg (http://opiateaddictionrx.info/pdfs/RCGP_UseOfMethadone.pdf).

United States

The acceptable initial dose for methadone treatment is 30 mg daily, unless a reason for a higher dose can be evidenced, which could increase the initial dose to no more than 40 mg a day. Based on the judgment of the program physician and careful observation of the patient, dosing can go up to 60 mg a day prior to stabilization (http://dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf).