Providing integrated services at health care facilities for people who use drugs in Ukraine

Guidelines

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Альянс

Міжнародний Альянс з ВІЛ/СНІД в Україні

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These guidelines were prepared with funding from the United States Agency for International Development (USAID) under a grant to World Health Organization, Award No GHA-G-00-09-00003, Amendment #5.

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

Originally issued in Ukrainian by the Ukrainian Institute on Public Health Policy under the title "Упровадження інтегрованих послуг для осіб із наркотичною залежністю в закладах охорони здоров'я" in 2011. Permission has been granted to the WHO Regional Office for Europe to issue this translation in English by the Ukrainian Institute on Public Health Policy.

Abstract

This document provides background information and practical recommendations for establishing Integrated Care Centres at health care facilities in Ukraine; it takes the local context into account (availability of human and financial resources, infrastructure development etc). It provides a range of approaches to organizing health and social services for people who inject drugs and offers step-by-step directions for implementing services. All the approaches proposed here are in line with current national legislation and are already being used in practice at some health care facilities in Ukraine. Thus, this document can be used as a practical guide to integrating key services into health care facilities in order to improve the accessibility of health care services for people who inject drugs.

This document is primarily intended for health care managers and administrators interested in implementing relevant health and social services for people who inject drugs. The approaches presented have broad applicability and can also be used when working with various most-at-risk groups at a range of health care facilities.

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Acknowledgements

The authors would like to express their gratitude to all specialists involved in developing these guidelines and to all professionals who participated in meetings and seminars on integrated care, and shared their experience and expertise in this area.

Development and publishing of these guidelines was made possible by financial support from the United States Agency on International Development, and expert assistance from World Health Organization professionals.

Abbreviations

AFB	Acid fast bacilli
AIDS	Acquired immunodeficiency syndrome
ALT	Alanine aminotransferase
anti-HBcor	Antibodies against hepatitis B core antigen
anti-HCV	Antibodies against hepatitis C
AP	Alkaline phosphatise
ART	Antiretroviral therapy
ARV	Antiretroviral
ASI	Addiction severity index
AST	Aspartate aminotransferase
BBV-TRAQ	Blood borne virus transmission risk assessment questionnaire
CBC	Complete blood count
CD4	Cluster of differentiation 4
CDL	Clinical and diagnostic laboratory
CM	Cabinet of Ministers
CME	Continuing medical education
CMV	Cytomegalovirus
CPR	C-reactive protein
DNA	Deoxyribonucleic acid
DOB	Date of birth
DOTS	Directly observed therapy strategy (for TB or HIV)
ECG	Electrocardiogram
ELISA	Enzyme-linked immunosorbent assay
FOS	Feldsher-obstetrical stations (primary care points)
GFATM	Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria
GI	Gastrointestinal
GGT	Gamma-glutamyltransferase
HA	Health administration

HBV	Hepatitis B virus
HBsAg	Surface antigen of the hepatitis B virus
HCF	Health Care Facility?
HCV	Hepatitis C virus
HDLP	High density lipoprotein
HIV	Human immunodeficiency virus
HTC	HIV testing and counselling
ICC	Integrated care centre (health care facility implementing integrated services)
ID	Identification
IM	Intramuscular
JSI	John Snow, Inc.
KhMAPE	Kharkiv Medical academy of postgraduate education
LDH	Lactate dehydrogenase
LDLP	Low density lipoprotein
MAC	Mycobacterium avium complex
MCC	Medical-consultative commission
MDT	Multidisciplinary team
MDR-TB	Multidrug-resistant tuberculosis
MIA	Ministry of Internal Affairs
MoH	Ministry of Health
MOE	Ministry of Economics
MOES	Ministry of Education and Science
MOJ	Ministry of Justice
NAMS	National academy of medical sciences
NGO	Nongovernmental organization
OI	Opportunistic infection
OST	Opioid substitution therapy
PCP	Pneumocystic pneumonia
PCR	Polymerase chain reaction
PI	Protease inhibitor
PLWH	People living with HIV

PMTCT	Prevention of mother to child transmission (HIV vertical transmission prevention)
PPD	Purified protein derivative
PTI	Prothrombin index
PWID	People/person who inject drugs
RNA	Ribonucleic acid
RT	Rapid test (for example, for HIV, hepatitis, STI, substances etc.)
RW	Reaction of Wassermann
STI	Sexually transmitted infection
TB	Tuberculosis
TU	Tubercilin unit
UIPHP	Ukrainian research institute on public health policy
USAID	United States' Agency for International Development
USSR	Union of Soviet Socialist Republics
VCT	Voluntary counselling and testing
VDRL	Venereal disease research laboratory
VL	Viral load
VLDLP	Very low density lipoprotein
VR	Verkhovna Rada (Parliament of Ukraine)
WHO	World Health Organization

Introduction

Defining the integrated approach to service delivery

An integrated approach to health service delivery is widely used in Europe and North America, particularly for people experiencing or at high risk of complex, chronic medical problems. Perhaps the most comprehensive definition of integrated care is provided by Kodner and Spreeuwenberg: “Integration is a coherent set of methods and models on the funding, administrative, organizational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors. The goal of these methods and models is to enhance quality of care and quality of life, consumer satisfaction and system efficiency for patients with complex, long-term problems cutting across multiple services, providers and settings. The result of such multipronged efforts to promote integration for the benefit of these special patient groups is called ‘integrated care’.”Problems associated with injecting drug use fully meet the criteria for implementing integrated care. First, injecting drug use is a chronic problem of dependence, social isolation and stigmatization of a vulnerable group—people who inject drugs (PWID). Second, drug use can lead to health consequences and complications such as human immunodeficiency virus (HIV) infection, hepatitis, and tuberculosis (TB). According to the latest data, HIV prevalence in the PWID community in Ukraine ranges from 10 to 55%, TB prevalence exceeds the average rate for the country 10–30 fold, and the hepatitis rate among PWID is 80%. The existing health care system provides services to this group through distinct vertically integrated specialized health facilities, and this approach has proven to be inefficient; opportunities are lost for timely diagnosis, prevention and treatment of the above-mentioned conditions and diseases. Increasing the efficiency of medical and social interventions for this vulnerable population can be achieved only through building integrated models and developing practical supportive legislation.

The basic principle of integrated care is based on comprehensive delivery of services at convenient “one-stop shop” locations that include gender-specific approaches. The spectrum of services provided can vary, but should address all health needs associated with HIV, TB and drug use. Patient-centred care and flexibility of services in responding to clients’ changing needs are also important strategic aspects of integrated care. The requisite involvement of a broad range of specialists and services requires an efficient mechanism for teamwork within a multidisciplinary team (MDT), as well as integration across specializations (cross-training)—as when a physician who has received the appropriate training is officially allowed to provide care in related medical disciplines, for example, provision of opioid substitution therapy (OST) by an infectious disease specialist or a TB specialist.

Considering the significant social and psychological issues faced by PWID, psychological case management should be an integral part of integrated care, and should include various types of patient counselling, training and education, access to harm reduction programs and involvement of peer counsellors. Integrated programs work well with the case management approach—a model of managing a patient based on an individualized approach to each person and his or her active participation in the treatment process.

Integrated care programs are predicated on equal access to the whole spectrum of services, and should be free of stigmatization and discrimination, and flexible and responsive to the needs and issues of patients – including program clients and their family and friends.

History of integrated care in Ukraine

The integrated care approach is not new to the Ukrainian health care system. Even during Soviet Union times, when the focus was on establishing a wide network of specialized health care facilities (HCFs) and expanding the number of medical specializations, it was clear that for some cases, particularly in the case of chronic diseases that affect people's quality of life and present a threat to public health, the traditional approach did not work; on the contrary, it created additional obstacles to care delivery. The key to overcoming the structural limitations of medical specialization lay in expanding the spectrum of health care services provided at specialized facilities. Thus, for example, to treat TB in patients with mental diseases or alcohol abuse problems, special in-patient wards for treating TB were created at mental and substance abuse/narcological clinics, and were appropriately staffed and equipped. In some psychiatric hospitals, special departments to treat medical illnesses and even separate infectious disease departments were established.

These integrated approaches were primarily adopted for in-patient care, and very little was done in the area of out-patient care. Thus, after discharge from the hospital, patients found it difficult to maintain continuity of care, and this influenced health outcomes, particularly because, in the case of chronic diseases, the duration of in-patient care was generally much shorter than out-patient care. Poor access to the range of necessary services has had an impact on the development of the HIV epidemic in Ukraine, especially because the onset of the epidemic corresponded with economic recession in Ukraine and a crisis of national health care system.

The state responded very quickly to the first registered HIV cases, and because the epidemic spread in the community of PWID, the state involved narcological services to carry out widespread HIV testing of all registered PWID. At the same time, a system of regional AIDS centres was created to address all major issues related to the epidemic, including diagnosis, primary prevention, and treatment. Integration of key medical and social services became the guiding principle of AIDS centres. Important components such as case management, TB screening, diagnosis of sexually transmitted infections (STIs), and gynaecological care were introduced in the majority of such facilities. However, due to limited access to antiretroviral therapy (ART), lack of efficient substance abuse treatment programs, and poor coordination with narcological services, access to HIV prevention and treatment services for PWID was not sufficient to curb the HIV epidemic in this vulnerable group.

The situation changed after substitution therapy with buprenorphine and later methadone was introduced in Ukraine, and after access to ART expanded. Large numbers of HIV-positive clients of substitution therapy programs gained access to HIV testing and treatment.

International and nongovernmental organizations (NGOs) working in the area of HIV have made important contributions to the development of an integrated approach in Ukraine. In 2005, with support from the Open Society Institute, a study tour was organized for physicians and NGO representatives to visit Yale University and learn about integrated care through substitution therapy programs. Following that visit, pilot projects started in Dnipropetrovsk, Mykolayiv, Odessa and Kyiv, and provided the basis for developing feasible integrated care models and case management approaches. These early projects demonstrated that full-fledged integration is possible, actively engaged state structures, and brought about structural changes in the health care system.

In 2006, projects for people with co-infections were launched with support from the International HIV/AIDS Alliance in Ukraine under the first round of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). In addition to designing a multidisciplinary model of recruiting and managing HIV-positive drug-users, one of the project's objectives was to establish cooperation with projects involved with ART case management, and to develop clear referral systems and jointly manage co-infected clients.

In November 2007,under Project SUNRISE—"Expanding access to substitution maintenance therapy for HIV-positive injecting drug users," supported by the United States' Agency for International Development (USAID), a partner meeting was held that defined the minimum criteria for service integration, including defining which medical and psychosocial services need to be integrated, how such services could be integrated within programs for PWID, and what kind of technical assistance would be required to implement integrated care projects. To define the minimal service package, PWID's basic medical and social needs were assessed. The meeting participants concluded that the key services were: comprehensive health assessment, OST, diagnosis and treatment of HIV, TB, and STIs, out-patient care and hepatitis B vaccination.

In the first half of 2008, participants of an integrated care working group, established and supported by the World Health Organization (WHO), developed a tool to assess the readiness of HCFs to provide comprehensive services to

patients with a dual or triple-diagnosis of injection drug use, HIV and/or TB. This document was the first to define the criteria and principles of integrated care. The minimum package of relevant criteria included diagnosis, treatment and preventive measures in the areas of HIV, TB and hepatitis.

Introduction of OST, in particular methadone, provided an impetus to integrated care implementation in Ukraine. In 2008, with support from the International HIV/AIDS Alliance in Ukraine, the first pilot projects started to provide integrated medical and psychosocial services in Kyiv, Odessa and Mykolayiv oblasts. In Dnipropetrovsk oblast, integrated care for PWID was provided under projects supported by the Clinton Foundation. These projects piloted different organizational models at tertiary hospitals, out-patient facilities, AIDS centres, substance abuse centres/ narcological dispensaries. Later, similar projects were initiated at TB clinics; this is a critical component of the model because TB is the most serious life-threatening co-morbidity and the leading cause of death among people living with HIV (PLWH), in particular PWID, in Ukraine.

The next stage of integrated care development was increasing the number of HCFs involved in implementation of the project, by establishing integrated care centres (ICCs) supported by the All-Ukrainian Network of People Living with HIV under Global Fund Round 6. The spectrum of services accessible to clients at the ICCs included primary health care, diagnosis and treatment of TB, reproductive health for women, prevention of mother-to-child transmission and health services for pregnant women. The focus of integrated care shifted to meet the basic needs of people with dual or triple diagnoses of injection drug use, HIV/AIDS and/or TB.

In the course of establishing integrated care centres, national and international experts conducted a series of studies and assessments.[1,2,3,4]The main conclusion of these studies was as follows: This approach successfully expands access to services critically important to PWID, and it can be used in a variety of HCFs. The vertically structured health care system does create barriers to provision of many services, but current legislation supports mechanisms that can overcome those barriers.

Today, the integrated care concept has gained support at the national level: Establishment of ICCs is one of the indicators in the National Program for 2009–2013[5], which provides for inclusion of 1,200 patients in such programs. Assessments conducted by national and international experts have shown that the current system of AIDS centres provides an optimal environment in which to develop integrated care programs, as AIDS centres have the relevant resources, staff and the legal authority to undertake this work. In addition, with minimal reorganization, some additional staff, and improvements to the referral system, ICCs can be established at narcological dispensaries—as they are currently the biggest providers of substitution therapy, as well as at other HCFs. The priority for such centres is provision of the largest possible number of services, such as diagnosis and treatment of HIV, substance use, and TB—all provided under one roof, or via a clear system of referral and case management.

An important integral component of such programs is case management, provided to patients through different governmental organizations and NGOs. Pilot projects have confirmed that NGOs are able to successfully provide case management services.

We are very hopeful that today, when health care reforms are pending, public health challenges will not be left unattended; in this context, development of integrated care will become one of the catalysts of health care restructuring, and will support maintaining and enhancing the joint efforts of NGOs, patient organizations and state organizations.

Goal and objectives of these guidelines

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[1]Dumchev K., Forostyanaya E. Assessment of accessibility of comprehensive health and social care services for injecting drug users(IDUs) in integrated care centers. WHO, 2009.
[2]M. Curtis. Building Integrated Care Services for Injection Drug Usersin Ukraine. WHO, 2010.
[3]R. Bruce, S. Boerboom. Report on pharmacological treatment of opioid dependence and integrated health care system: Ukraine. Report based on consultations 13-17 July 2009. Alliance, 2009.
[4]F.Altis. Assessment of integrated services provision in Ukraine. UIPHP, 2009.
[5]Law of Ukraine of 19.02.2009 № 1026-VI "On approval of the National programme for HIV prevention, treatment, care and support for HIV-infected and AIDS patients in 2009-2013"

Dissemination of novel prevention and treatment techniques, in particular implementation of integrated services for PWID, is provided for in the National Program for HIV prevention, treatment, care and support for HIV-infected and AIDS patients in 2009-2013 (Objective 6) [5]. The main goal of this guideline is to provide background information on and promote the establishment of ICCs.

The practical objective of these guidelines is to systematize approaches to organizing health and social services and describe step-by-step implementation procedures. All the approaches described here are supported by current legislation and are already being used in practice at some HCFs. Thus, these guidelines can be used as a practical guide to implementing services in order to make them accessible to patients at any HCF.

Issues of the practicality and efficiency of integrated approaches are generally well covered in other documents, and for this reason, these guidelines do not focus on these issues in detail. Similarly, the clinical aspects of care provision are addressed in specific protocols and recommendations, and these guidelines therefore refer to the relevant documents, but do not duplicate them.

References to laws and regulations are current as of the date of this guideline. Some of the sections below refer to draft laws, and it is anticipated that these will soon be formally adopted. When legislation is reviewed and new laws and regulations are adopted, some parts of this guideline will become outdated and will be updated in the next version.

Target audience

These guidelines are primarily designed for health managers and administrators interested in implementing relevant health and social services in the framework of care for PWID. However, the approaches presented are universal, and can also be applied when working with vulnerable groups at health facilities of any specialization.

Part I
Overarching issues

Principles of integrated care organization

Six principles make integrated care for PWID [2] more efficient than the traditional system of care provision.

1. *Providing a comprehensive package of services*

A comprehensive list of services relevant to PWID was first outlined in Ukraine in a special checklist[6]. The checklist includes diagnosis, treatment and prevention of: mental diseases and dependence, HIV, TB, hepatitis, STIs, reproductive and other diseases. The minimum package of services that must be accessible to PWID at ICCs was discussed during meetings and focus group discussions, but at the time this guideline was published, consensus had not been reached. This is related to the wide variation in services provided at different ICCs. The variation was so great that it was not possible to clearly differentiate between integrated and non-integrated care centres. For this reason, this guideline does not define the package of services; rather, the authors discuss implementation of each individual service regardless whether other services are provided or not. This allows the guideline to be used as a practical guide that provides detailed information about specific services that can be introduced at any stage of ICC evolution.

From the patients' perspective, implementing any relevant service is desirable as it will improve health outcomes. But integration of additional services frequently requires significant resources, and therefore new services must be justified by proving need. If the number of patients is small, introducing new services may not be cost effective. There no regulation in place that stipulates the minimum number of clients needed to justify introducing a new service into a health facility. This decision must be taken by the head of the HCF and be based on the actual number of patients and available resources.

It is worth noting that HCFs can provide only those health services for which they have a medical license. Should a HCF plan to provide other health services, it must first apply for a new license.

2. *Providing services at a "one-stop shop"*

Research indicates that providing all services at a "one-stop shop" is much more efficient than referring patients to other HCF services, even when all necessary agreements and mechanisms are in place. For this reason, this guideline first considers the "one-stop shop" option. In some cases, this option can be pursued by coordinating with medical professionals or mobile teams who provide services at an ICC. In cases where it is not possible to provide services on-site, those services can be offered through a structured referral system, as described below in a separate section of this guideline.

It is evident that a facility that is going to be turned into an ICC must be located in a place convenient for the target clients. Relevant infrastructure (space, equipment) will greatly facilitate additional service implementation.

3. *Multidisciplinary approach*

Case management by a group of specialists who meet regularly to coordinate their activities guarantees rational organization, timely response and greater efficiency of treatment.

It is important to remember that services need to be coordinated not only in terms of co-location, but also in terms of coordination: Providing services at the same location does not mean that services are integrated. Effective integration requires on-going coordination of all aspects of service provision, including scheduling, patient turnover, equipment supply, information exchange etc.

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[6]"Assessing feasibility of a HCF to provide integrated care". Assessment instrument developed by working group on integrated care for PWID, 2008.

4. Partnering with patients

Trust and mutual understanding between patients and health or social workers decreases the risk of treatment interruption associated with the side effects of medication, inadequate dosing or violation of program rules; supports greater achievement of therapeutic goals; and decreases the risk of burn-out among project personnel.

5. Applying harm reduction principles

The philosophy of harm reduction in public health means that medical or social services are designed to support patients' right to choose their own lifestyle. Extensive research has shown that this approach is efficient from an individual patient's perspective and for addressing the epidemic in general.

The principle of harm reduction is not compatible with such practices as forcing patients out of treatment programs due to drug use. This leads to a worsening of patients' medical conditions, and promotes the spread of infection, including resistant forms, in the general population.

6. Intersectoral cooperation

Cooperation between governmental and nongovernmental sectors in the organization and provision of services is both useful and necessary. Although NGOs may lack the infrastructural capacity to provide comprehensive care, these organizations are frequently able to attract technical support as well as funds that state facilities are not able to attract.

Referrals

If it is not possible or reasonable to provide a certain service at a HCF, that service should be provided through referral. Even when staff or lab resources are limited, some services can be provided at an ICC by involving specialists from other HCFs or by routine outreach with mobile teams (specially equipped vehicles).These mechanisms are described in the relevant sections, below.

In cases where referral is the only option, it is important to take special care when selecting a health facility to which to refer. Factors to consider include location/distance and capacity, i.e. staffing, laboratory and equipment. Some services may be accessible in the communities where clients live; often, it may be more convenient for clients to visit a HCF located close to the ICC. In such cases, patients can submit an application requesting to attend services at that HCF, thereby allowing convenient access to geographically proximate services.

When referring, it is useful to observe the following rules:

- there should be an official agreement with the facility to which referral is made;
- date and time of referral (visit notification) should be agreed upon with the specialist providing the service;
- whenever possible, patients should be accompanied to the HCF;
- service provision should be documented (such as test results, notes and other records provided by the service provider).

Well-designed referral mechanisms facilitate service provision; however, it is helpful to keep in mind that services will be much better utilized if they are provided onsite at the ICC.

Monitoring and evaluation

Monitoring is an essential part of integrated care programs. Monitoring is a process of collection and systematization of data on key program indicators. Its goal is to evaluate and adjust current activities, to ensure the rational use of resources and continuity of service provision, to achieve what is planned and to identify opportunities for development.

Information collection for health program monitoring should be based on the workflow system that is used at an ICC. The general principle of data flow organization at HCFs lies in using individual (medical chart, patient record) and aggregated (logs) documentation that serve as the basis for report generation. Depending on the type of data and health facility, either individual or aggregated information (for example, lab test results first are registered in a lab test log, and visit results – in a patient's medical record) is considered primary (meaning it is the deciding factor in case problems arise). This can lead to duplication of information, and sometimes to a loss of data. In the majority of

cases, neither individual nor aggregated documentation is suitable for quick processing and analysis of information, so calculating even simple values can take a lot of time.

To speed up data analysis and report generation, specially developed logs or forms can be used (in combination with electronic tables, or on their own) in order to quickly produce information about a particular patient group. In other countries, and also in Ukraine, more sophisticated electronic data processing systems are used (work stations, electronic patient records), making it possible to forego the majority of secondary documentation that is not mandated by current law. Such electronic data processing systems can generate reports based on chosen indicators and cross-sections, and print out standard forms with just a click of the mouse.

In integrated care programs, data collection and processing becomes more difficult because the vertical organization of health care in Ukraine requires that patients with co-morbidities be treated by several specialized HCFs at the same time (one illness per HCF). Each HCF keeps its own records, and there is no system to centralize data collection from all these HCFs. The key principle of integrated care is keeping all patient information in one place. For this reason, one of the priorities for ICCs is coordinating data collection from all the facilities providing referral services.

In general, the following area of routine monitoring at integrated care programs can be identified:

- patient admission and discharge;
- supply, dispensing and record-keeping of medications;
- provision of health services in the areas of diagnosis, treatment and prevention;
- provision of psychosocial rehabilitation services.

The specific list of indicators and reporting forms are determined by the administration of the HCF or by project sponsors. A model list of indicators is provided in table 1. Specific calculation techniques for indicators are explained in project publications and trainings, and this guideline does not describe them.

Table 1. Standard monitoring indicators for integrated care programs, and sources of information

Individual documentation	Primary data	Aggregated documentation	Examples of standard indicators (monitoring indicators)
Out-patient record	Passport data (sex, DOB)	Patient admission and discharge log	Mean age of patients
			Number of women (%)
	Date of initiating/ stopping treatment (participating in program)	Patient admission and discharge log	Number of clients at a certain time
			Number (%) of patients discharged by reason
			Rate of patients retention in program for a certain period
	Age of initiating substance use	-	Average period of substance use
	Date and result of lab test or other test (HBV, HCV, TB, HIV, pregnancy, substance use)	Lab test log, test-kits record log	Number of tests used
			Number (and percent) of people tested
			Number (and percent) of clients with a positive test result (HIV+, history of TB, HCV etc.)
			Number (and percentage) of clients requiring treatment
	Date treatment was prescribed and dosage	-	Average, max., min. dosage (for substitution therapy medications)
			Number (and percentage) of clients on therapy

	Date and outcome of counselling session	Counselling log	Number (and percentage) of clients reached with a certain type of counselling service
			Number of counselling sessions
Medication record	Date and quantity of a drug dispensed	Drug consumption (record-keeping) log	Quantity of drug received and consumed
			Amount of drugs remaining at a certain time
			Number (and percentage) of timely visits to receive drugs
Psychosocial management (case management) record	Date and outcome of counselling	Case management log, counselling log	Number (and percentage) of people reached with certain type of counselling
			Number of counselling sessions
	Information about employment	-	Number (and percentage) of clients employed

Evaluation is a systematic process to ascertain program efficiency. Usually, this process is not part of the daily activities of a HCF; however, undertaking evaluation as often as possible can be a very useful exercise to improve the efficiency of program activities.

Targeted evaluation should use validated instruments, such as the Addiction Severity Index (ASI), or the Blood Borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ) etc. These instruments should be used by experienced interviewers. Most of the time, programs do not have the opportunity to conduct systematic evaluations using validated instruments. However, some of the data collected during routine monitoring can help programs to evaluate their efficiency and reach their therapeutic goals.

The following indicators can be used to determine whether or not the program is efficient:

- number of clients (percentage)who underwent all tests and medical examinations in the proper timeframe;
- number of clients who became employed or renewed their employment papers during a certain period of time;
- number of new cases of HIV and hepatitis (seroconversions) among program clients;
- number of patients (percentage) withCD4 < 350 who are on ART, etc.

Conclusions about program efficiency should be based on a comprehensive assessment; however, individual indicators can also reveal program weaknesses and identify areas for improvement.

Structure of the document

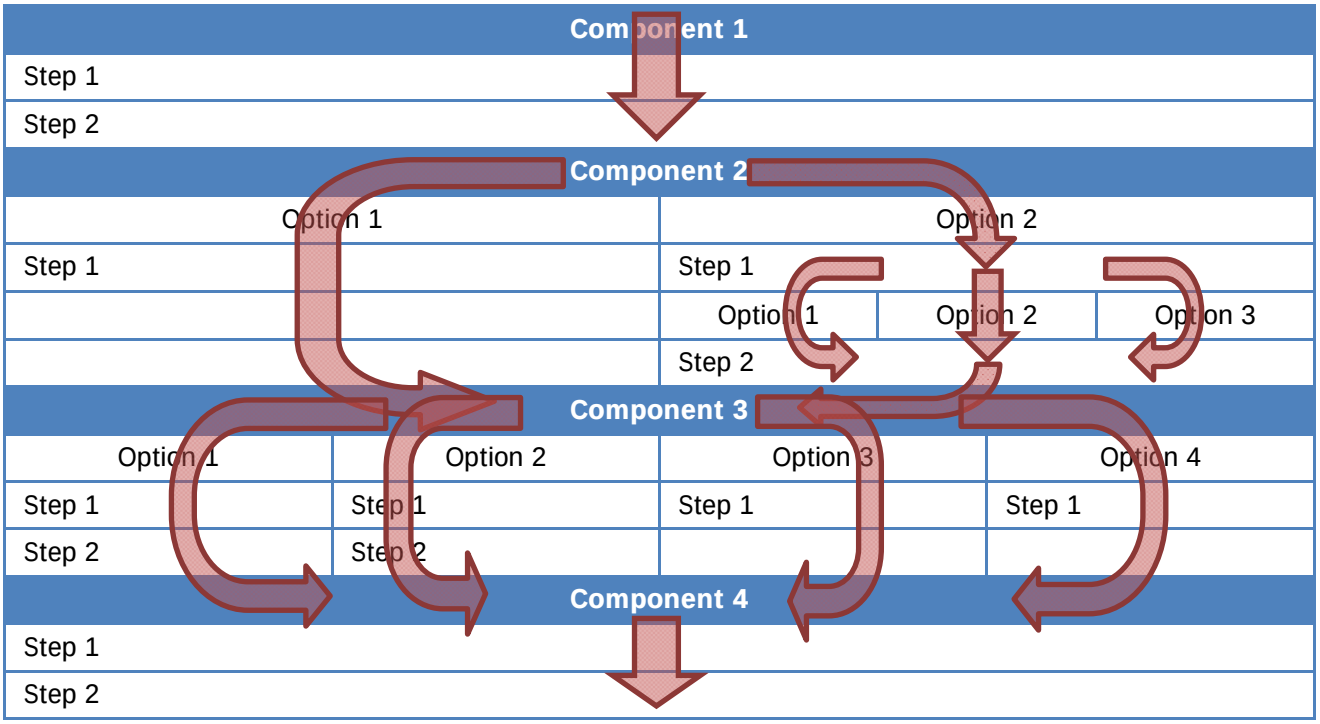
All services consist of certain structural elements or ***components***. Some components are indispensable to the service, while others are not. There may also be several different ways to implement components.

Services share many structural components. For example, counselling by a physician is an integral component of diagnosing drug dependence, case management in ART, treatment of TB etc. The actual content of this component differs according to the service, but organizationally, this component is always an integral part of any service.

Components can have one or more implementation ***options***. The value of each component remains the same, regardless of the implementation option selected.

Each implementation option can further be divided into ***practical steps*** that must be followed for successful service delivery.

Fig. Structure of service description



Where components are shared by several services, and in order to avoid duplication, a general description of a service and a list of its structural components are presented in Part II. Detailed descriptions of component implementation are presented separately in Part III. Part II contains links to relevant component descriptions as hyperlinks (on page 16).

In the electronic version of this document, hyperlinks (underlined blue font in brackets) work by pressing the [Ctrl] button on a keyboard while clicking on a hyperlink. The [Back] mouse button (if available) or [Alt] + [←] combination on the keyboard will allow you to quickly go back to the previous section.

References to legislation are an important part of this document. Besides footnotes in the text, a complete list of legislative and other referenced documents is provided in the appendix. For easier reading of the text, when a document is referenced for the first time, its full name is provided in a footnote with its corresponding number in the appendix. In subsequent references to the same document, only its number is provided in square brackets, which also work as a hyperlink in the electronic version.

Part II
Services and their structural components

Service group 1. HIV/AIDS

HIV prevention, diagnosis and treatment services are among the most important components of integrated care for PWID. PWID remain the driving force of the HIV epidemic, and broad coverage with these services is a critical public health objective.

Service 1. HIV testing and counselling

Background. HIV counselling and testing is a key component of HIV/AIDS prevention, treatment and care programs. In addition to HIV diagnosis, this service also supports prevention, by providing information and improving awareness about routes and risks of infection.

Organizational and regulatory framework. The rights of citizens of Ukraine, other nationals and stateless persons in regards to HIV testing are laid out in the National Law[7].

There are three main approaches to HIV testing: Under the first approach, counselling and testing are initiated by an individual who wishes to know his or her HIV status. This approach is known as voluntary counselling and testing (VCT); this was previously the main testing method in Ukraine and is well described in the regulatory framework. The key document here is the Order on VCT improvement[8], which approves several other documents, including the VCT procedures[9]. The second approach to HIV testing is provider-initiated testing (provided patients agree to it), which can reach more people. This approach was introduced after VCT, and the regulatory framework for its use is yet to be approved[10]. The third approach is mandatory HIV testing for blood or tissue donors, and is not the topic of these guidelines.

Regardless of who initiates testing, pre- and post-test counselling are mandatory, hence the common name of this service is HIV testing and counselling (HTC).

According to the Law of Ukraine [7], HIV testing can be performed at all HCFs regardless of form of ownership, at social support services and at other organizations licensed for this activity. Two concepts—“testing to identify HIV” and “making an HIV diagnosis” need to be distinguished; the latter may include other assessments/testing and can be performed only at HCFs.

HTC at a HCF can be carried out either by staff or by professionals from partnering organizations. Staffing requirements of HCFs is governed by the current version of Ministry of Health of Ukraine Order11. If necessary, in

[7]Law of Ukraine of 23.12. 2010 № 2861-VI“On countering the spread of diseases caused by human immune deficiency virus, and legal and social protection of people living with HIV”.
[8]MoH Ukraine Order № 415 of 19.08. 2005 “On improvement of voluntary counseling and testing for HIV-infection”.
[9]“Procedure (protocol) of voluntary counseling and testing for HIV-infection” approved by MoH Ukraine Order № 415 of 19.08. 2005 “On improvement of voluntary counseling and testing for HIV-infection”.
[10]Guideline for health care workers on delivering HIV counseling and testing services (draft of the MoH Ukraine Order)
[11] MoH Ukraine Order № 33 of 23.02.2000 “On staffing norms and standard staffing of HCFs” with amendments in accordance with MoH Ukraine Order № 122 of 12.03. 2008

accordance with the protocol [9], experts from governmental organizations and NGOs can also conduct HTC. HTC can also be conducted at the facility/on site by engaging mobile out-patient clinics[12].

If the facility plans to offer other services related to HIV care (clinical monitoring, ART), it is important to establish a "*Dovira/Trust*" (*VCT)* office that will support the introduction of additional staff positions such as a doctor and midlevel and junior medical personnel, and will facilitate the provision of other services. According to regulations[13],VCT offices are set up by the local health administrations (HA) at AIDS centres or other HCFs. (The last version of the Order [11] available at the time this guideline was developed describes the staffing standards for VCT offices only at AIDS centres, city and district hospitals and polyclinics).

Content: HIV counselling and testing comprises pre-test counselling, conducted prior to the HIV test; testing—laboratory testing for the presence of HIV antibodies/antigens with the use of traditional ELISA or rapid tests (RTs); and post-test counselling, provided after obtaining of the test result. The content of counselling is outlined in the draft Order [10], Protocol [9] and appendix to it[14]. The HCF head is responsible for adherence to HTC principles including the required content and completeness of counselling by each specialist, and ensures and controls confidentiality before, during and after HTC, in accordance with the Law of Ukraine [7] and item 5.1.2 of the Protocol.

Component 1. Pre-test counselling

Pre-test counselling is the first step of HTC. It aims to create a friendly environment, provide information on the procedure and purpose of testing, information on next steps, and the like. Whether HIV testing was initiated by the patient or the provider, informed consent should be obtained from the patient in the course of pre-test counselling, by signing the relevant form, or the patient might refuse to undergo testing.

This component has two implementation options.

Component 2. Pre analytical step of HIV testing

As in any other laboratory testing, the pre-analytical step of HIV testing can be carried out in two ways.

Component 3. Analytical step of HIV testing

According to the Law of Ukraine [7], HIV testing can be carried out in institutions regardless of form of ownership, providing the institution has appropriately equipped specialized laboratories accredited according to the established procedure[15, 16]. It should be noted that at the time this guideline was developed, there were no procedures in place for accreditation of facilities providing diagnosis with RTs[17, 18].

Detailed requirements for methods of testing, supplies and operation of the laboratory are included in the Instruction [16] and in the Order [18].

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[12]"On approval of Standard regulations on specialized units "Mobile point of counseling and testing for HIV-infection and mobile ambulatory points for counseling and testing of HIV-infection and sexually transmitted infections (STI) and treatment of STIs" (draft of the MoH Ukraine Order).

[13]"Standard regulation on "Dovira" (VCT) office" approved by MoH Ukraine Order № 102 of 25.02.2008 "On operations of "Dovira" (VCT) offices".

[14]Appendix 1 "Specific features of counseling for different population groups" to item 12, section 4 "Procedure (Protocol) of voluntary counseling and testing for HIV-infection" approved by MoH Ukraine Order № 415 of 19.08.2005 "On improvement of voluntary counseling and testing for HIV-infection".

[15]"Procedure for accreditation of special laboratories for AIDS diagnosis " approved by Resolution of the Cabinet of Ministers of Ukraine of 18.12.1998 № 2026 "Issues of prevention and protection of population from HIV-infection and AIDS".

[16]MoH Ukraine Order of 22.02.2002 № 71 "On approval of Instruction on organization of laboratory diagnosis of HIV-infection".

[17]MoH Ukraine Order of 27.08.2009 № 639 "On approval of Provisional procedure of testing for HIV-infection with rapid tests, their use, storage and recording of results".

[18]MoH Ukraine Order of 21.12.2010 № 1141 "On approval of Procedure for detection of serological markers of HIV-infection and ensuring the quality of tests".

The analytical step of testing for HIV antibodies can be set up in the same manner as other laboratory tests.

Component 4. Post-test counselling

The HIV test result is given to the patient in the course of post-test counselling [7].

Since information on HIV test results—presence or absence of HIV-infection in the evaluated person, is strictly confidential, it can be provided only to the person concerned, and in cases stipulated by current law of Ukraine – to legal representatives of this person, HCFs, prosecutors, investigation authorities, enquiry hearings and the court.

This information must not be transferred to other public non-medical or nongovernmental institutions (both medical and non-medical), institutions, or civic associations. Hence, supportive post-test counselling (provision of additional services after the provision of test result) can be provided at other institutions only in cases when the patient proactively approaches that institution and expresses his/her personal desire to disclose the test result.

Post-test counselling can be organized in the same manner as pre-test counselling.

Component 5. Confirmative testing and registration

In the case of a negative test result of enzyme-linked immunosorbent assay (ELISA) or RT, the patient is issued a report (a primary record form № 503-4/0).If the test result is positive or ambiguous the sample should be referred for confirmatory testing [16, 18]. Confirmatory testing is conducted in the laboratories listed in the Ministry of Health (MoH) Order.
If the positive test result is confirmed, the patient is referred to the regional AIDS centre or other facility which ensures regular outpatient follow-up of HIV patients ("*Dovira*"/VCT office). In this setting, a registration card for an HIV patient (form№ 502-1/o) and other recording and reporting documents, approved by MoH Ukraine Order and State Statistics Committee of Ukraine, is completed[19].The institution that ensures regular outpatient follow-up conducts an in-depth assessment to determine the stage of HIV-infection and whether there is a need to prescribe ART.

Service 2. Consultation with an infectious diseases physician

Background. Consultation with an infection diseases physician is a relevant service for the majority of PWID, due to high rates of HIV, hepatitis and TB in this population.

Organizational and regulatory framework. The scope of medical care and its quality is regulated by state social standards and clinical protocols. State social standards of medical care provision to adults in out-patient facilities are approved by the MoH Order[20]and include standards in the "infectious diseases" field of specialization. The following clinical protocols are the most relevant for drug users and substitution therapy patients: ART[21], opportunistic infections (OIs)[22], palliative care, symptomatic and pathogenetic care for HIV/AIDS patients[23],

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[19] Order of MoH Ukraine and State committee of statistics of Ukraine of 24.12.2004 № 640/663 "On approval of forms of primary recording and reporting forms on HIV/AIDS and instructions for their completion".
[20]MoH Ukraine Order 28.12.2002 №507 "On approving norms of health care delivery and indicators of quality of health care".
[21]"Clinical protocol for antiretroviral therapy of HIV-infection for adults and adolescents", approved by MoH Ukraine Order 12.07.2010 № 551 "On approval of clinical protocol for antiretroviral therapy of HIV-infection for adults and adolescents".
[22]"Clinical protocol for diagnosis and treatment of opportunistic infections and general symptoms in adults and adolescents with HIV-infection" approved by MoH Ukraine Order 13.04.2007 № 182 " On approval of clinical protocols".
[23]"Clinical protocol for provision of palliative care; symptomatic and pathogenetic therapy for patients with HIV-infection/AIDS", approved by MoH Ukraine Order 03.07.2007 № 368 "On approval of clinical protocol for provision of palliative care; symptomatic and pathogenetic therapy for patients with HIV-infection/AIDS".

HIV/TB co-infection[24], and HIV/HCV (hepatitis C virus) co-infection[25]. Infectious disease physicians should also follow the guidelines approved by the Ministry of Health, in particular those on laboratory monitoring of HIV[26].

Infectious disease physicians, or other professionals with appropriate training, can provide consultation regarding HIV/AIDS. The physician can be on staff at the facility or an invited expert. Labour relations between the physician-consultant and the HCF which invites him/her are regulated, depending on the type of collaboration, by regulations described in detail in the relevant section.

Content. The content of consultation is primarily determined by the patient's needs. The infectious disease doctor makes the diagnosis (takes history, conducts exam and physical exam, prescribes laboratory and instrumental tests) and treats infectious diseases. The standards of clinical examination are described in the current ART clinical protocol [21].

The infectious disease doctor should adhere to standards and protocols in force at the time of service provision or patient treatment.

Component 1. Physician's role

From an organizational perspective, this component is the sole responsibility of the physician. Practical implementation steps are described in the appropriate section.

Service 3. HIV management

Background. To organize *HIV Management Services* for patients with HIV/AIDS is not an easy task. Decentralization of this service is extremely beneficial for the patient, significantly increasing access to and efficiency of diagnosis and treatment. At the time this guideline was developed, more than 200 centres based in non-specialized facilities provided clinical monitoring. The majority of components described below have been successfully implemented in existing ICCs. Hence, implementation of this difficult but extremely important service is a very feasible task.

Content. Regular outpatient follow-up of HIV/AIDS patients is a complex process of service provision focusing on the needs of the individual patient. Management starts at the time of HIV diagnosis and is life-long. It includes ongoing monitoring of the patient's health, diagnosis, prevention and treatment of OIs and concurrent infections and diseases, monitoring of immune status and viral load (VL), preparation for ART and its administration, achievement, maintenance and control of treatment adherence, psychological and social support, and ensuring continuity and consistency of the full scope of care. The Law of Ukraine [7] envisages availability of all of the above components for HIV-positive patients.

In the context of integrated services for PWID, this guideline defines medical HIV management as a single service including all the mandatory aspects of HIV care—except ART administration, prevention and treatment of OIs and psychosocial support, all of which considered separate services. In other words, medical management includes all clinical interventions which an HIV-positive patient should receive before and during ART and treatment of OI.

Organizational and regulatory framework. In accordance with the Order on approval of monitoring forms[27], (currently being updated, however no changes are envisaged in the structure of regular outpatient follow-up

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[24]"Clinical protocol for provision of medical care for patients with coinfection of TB and HIV infection" approved by MoH Ukraine Order 28.05.2008 № 276 "On approval of clinical protocol for provision of medical care for patients with coinfection of TB and HIV".

[25] "Clinical protocol for diagnosis and treatment of viral hepatitis C in adults with HIV-infection" approved by MoH Ukraine Order of 30.12.2008 № 826 "On approval of clinical protocol for diagnosis and treatment of viral hepatitis C in adults with HIV-infection".

[26]"Guidelines for laboratory monitoring of HIV-infection and antiretroviral therapy" approved by MoH Ukraine Order of 12.12.2003 № 580 "On improvement of treatment for patients with HIV/AIDS".

[27]MoH Ukraine Order of 07.04.2008 № 187 "On approval of provision recording and reporting forms for monitoring treatment of HIV/AIDS and instructions on their completion".

records), outpatient recording of patients with HIV is conducted at HCFs under state and communal ownership, as well as in HIV prevention and treatment wards and offices (VTC offices included). The Order closely links records of persons with provision of diagnostic services, and gives facilities providing regular outpatient follow up the exclusive right to make referrals for immunological and virological testing. Hence, if a facility intends to provide disease management for people living with HIV, it is imperative to set up a VCT office.

If a facility is not able to set up a VCT office, the majority of service components can be initiated on-site in a different manner, provided that there is close collaboration with AIDS services that ensure monitoring and implementation of other regulations.

Component 1. Physician's role

A physician's work is the key component of HIV disease management. Only infectious disease doctors or specially trained internists can manage HIV patients. The organizational steps for the doctor's involvement are standardized.

The doctor evaluates the patient, conducts counselling, prescribes medications (ART for prophylaxis and treatment of other problems), ensures monitoring, works on enhancing the patient's adherence to all prescribed treatments, and provides referrals to specialists and for tests. At the same time, the doctor leads the MDT, is responsible for the training of team members, quality assurance, data control, and prevention of professional burn out, and provides general clinical and organizational leadership.

Besides access to the attending doctor responsible for the disease management (most often this is an infectious disease doctor), HIV patients often need consultations with other specialists, such as a TB specialist, neurologist, ophthalmologist, gynaecologist and the like. If there are no such specialists among the facility's staff (or they are not able to provide services to additional patients), the required specialist can be involved in one of the outlined ways according to the anticipated workload and the required frequency of consultations.

In this guideline, consultations with an addiction specialist (narcologist), psychiatrist, gynaecologist, and dermatologist/venereologist are described as separate services.

Component 2. Nurse's role

A nurse ensures ongoing communication between doctor and patient and evaluates patients, organizes repeat visits, provides psychological support, monitors adherence, counsels on risk behaviours and HIV prevention, provides home based care and palliative care, and controls the flow of medications (dispensing, storage and documentation).

If there are no midlevel staff who can perform the above functions, there are several options to engage them.

Component 3. MDT

Only doctors and midlevel professionals can provide the minimum required scope of medical HIV management. Creation of a MDT will significantly increase the quality of service provision and efficiency of treatment. General principles of MDT creation are the same for all types of services.

Component 4. Laboratory tests

One of the most extensive components of this service is laboratory testing. Types and frequency of laboratory tests for HIV patients and in the course of ART are listed in the relevant clinical protocol [21] and guidelines [26].

All the envisaged tests can be classified as follows:

1. *Mandatory clinical and biochemical tests:*
   - CBC (with haemoglobin, red blood, platelet, white blood differential, absolute white blood count);
   - blood chemistry (bilirubin and its fractions, ALT, AST, urea, creatinine, glucose, total protein and albumin); and
   - urinalysis.
2. *Additional clinical and biochemical tests:*
   - blood electrolytes (sodium, potassium) in case of suspected impaired electrolyte exchange;
   - blood LDH (for instance, if lactate acidosis is suspected);

- blood amylase and lipase (for suspected pancreatitis);
- C-reactive protein (CRP) as a non-specific marker of inflammation;
- indicators of lipid metabolism (cholesterol, triglycerides, HDLP, LDLP, VLDLP), since their monitoring is important in case of an ART regimen with protease inhibitors (PI).

3. *Tests for other infectious diseases:*
   - test for syphilis (RW)/ VDRL;
   - hepatitis B and C serology;
   - serological testing for IgG to toxoplasmosis;
   - testing of the *Cryptococcus* Ag-titer when the CD4 count is <200 µL-1, if available (this is important in the presence of disease symptoms due to the low specificity of clinical presentation of *Cryptococcus* disease*;* need not be performed in patients with asymptomatic HIV-infection);
   - antigenemia CMV (early pp65 antigen), when the CD4 count is < 100 µL-1, if available (allows for detection of early CMV infection; it also serves as marker of response to treatment of CMV infection);
   - smear for *Gonorrhoea* or *Chlamydia*, if clinically indicated.

4. *Laboratory monitoring of HIV course;*
   - to establish the level of immune deficiency and to control ART administration a CD4 lymphocyte count is conducted (immunological testing);
   - VL is recommended to determine the level of viral replication every 6 months for patients on ART or in pregnant women, to make decisions on ARVs prescription and mode of delivery.

To avoid technical discrepancies, ideally, testing techniques should be standardized and testing undertaken in the same laboratory.

From an organizational perspective, any laboratory test has three steps: preanalytical, analytical and postanalytical. Depending on the availability and capabilities of their own laboratory, facilities may chose different ways to complete each step (on-site or at a different lab); in all cases, collection of a sample to be sent to the laboratory should be conducted (preanalytical step). In accordance with item 1.5 of the standard provisions [13], any facility can collect blood, provided it has the appropriate facilities, but for HCFs that do not have their own ward or office for HIV prevention and treatment (VCT office), referral must be made and test result provided by the facility that provides regular outpatient follow-up [27].

Practical steps for the organization of preanalytical and analytical steps are the same for all laboratory tests. In the course of implementation of various types of testing, different types of preanalytical or analytical steps may be independently used; (for instance, the analytical step of clinical tests may be carried out at the facility, and immunological tests may be carried out by sending the samples to another HCF's laboratory).

Component 5. Instrumental tests

Besides laboratory tests, the clinical protocol [21] envisages the following mandatory instrumental tests (except testing for TB, which is a separate component):

- abdominal sonography (to assess lymph nodes, liver, billiary tree, pancreas, spleen) and kidneys;
- electrocardiogram (ECG) prior to initiation of ART (due to the increased risk of cardiovascular diseases in case of prescription of certain ARVs);
- endoscopy and radiographic exam can be prescribed if needed.

The proposed guideline describes practical steps for the organization of sonography and ECG services.

Component 6. Screening for TB

Timely screening for TB is one of the most important components of HIV management, because the presence of HIV increases the risk of developing pulmonary TB from 5-10%over a person's lifetime, and up to 5-10% within

one year. In PWID, this risk is additionally increased 10- 30 fold. Nowadays, TB is the main cause of death among people living with HIV – up to 70% of deaths in this population are caused by TB. For this reason, timely detection of active TB is one of the most important services for HIV patients.

Primary and mandatory TB diagnostic tests for persons with HIV include [21]:

- annual skin-allergic test (tuberculin) in the absence of clinical manifestations of TB;
- chest radiography at initial evaluation, and once a year afterwards; in the presence of respiratory symptoms or in case of recent TB exposure or if TB symptoms are found during the exam;
- sputum smear three times a year in the presence of pulmonary symptoms or in case of recent exposure to TB, or in case of detection of TB symptoms in the course of evaluation.

The attending doctor identifies TB symptoms, takes the patient's history, assesses the risk of TB development, prescribes tests (these functions are envisaged in component 1); according to protocol [24], TB diagnosis can be confirmed by a TB specialist only. TB case notification is done at a regional TB dispensary.

Tuberculin tests are used in the course of screening of persons with HIV/AIDS with the aim of TB prevention in case of detection of *Mycobacterium tuberculosis* infection. A Mantoux test is prescribed by the attending physician or consultant (infectious disease specialist or TB specialist). The test is performed and interpreted by a doctor or a trained nurse under the doctor's supervision[28]. To identify contraindications, on the day when the test is to be done, a doctor (or nurse) interviews and evaluates those to be tested. Contraindications, side effects and testing techniques are described in detail in instructions[29] [28] and procedures[30] (which supplement the instructions [29]).The mechanism for providing tuberculin diagnosis is described below. Tuberculin diagnostics are described in more detail in this guideline as a separate service.

Radiographic evaluation (X-ray or fluoroscopy) is not the definitive test in TB diagnosis; it only allows for suspicion of infection. Assessment is undertaken by the attending doctor in accordance with the relevant protocol, Cabinet of Ministers (CM)[31] resolution and instruction [32]. Options and organizational steps for radiographic examination are described below. Radiographic methods are also considered as a separate service and are described as such in this guideline.

Sputum smear microscopy allows detecting *M. Tuberculosis* and serves as the final confirmation of pulmonary TB diagnosis. However, it should be noted that the sensitivity of this test is not very high and it does not allow identification of extrapulmonary TB. The test is prescribed by a doctor in accordance with the clinical protocols[33] [21]. Pre-analytical steps and techniques (sputum sample collection) are described below. There are several ways to perform the analytical step, which are largely similar to those of other types of laboratory tests. Sputum smear microscopy is described in more detail in this guideline as a separate service.

Component 7. Record keeping and reporting

If the facility providing the medical monitoring services does not have a separate ward or office for HIV prevention and treatment (VCT office), communication should be established with the local AIDS service, which is responsible for follow up and monitoring of treatment. Effective mechanisms for two-way communication of information about the tests carried out and treatment prescribed should be established.

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[28]"Instruction on medical use of tuberculosis liquid purified allergen in standard dilution for intracutaneous use" approved by the Chief state sanitary doctor of Ukraine L. S. Nekrasova (1997).

[29]"Instruction on using tuberculin tests" approved by MoH Ukraine Order of 29.07.1996 № 233 "On approval of instructions concerning provision of medical and sanitary care for patients with tuberculosis".

[30]"Procedure of performing tuberculin diagnostics in Ukraine" (appendix to the draft of MoH Ukraine Order).

[31]Resolution of the CM of Ukraine of 15.02.2006 №143 "On approval of mandatory preventative check-up of certain categories of population for detection of tuberculosis".

[32] "Instruction on periodicity of radiographic evaluation of the chest organs for certain categories of the population of Ukraine" approved by MoH Ukraine Order of 17.05.2008 № 254 "On approval of Instruction on periodicity of radiographic evaluation of the chest organs for certain categories of the population of Ukraine".

[33]"Protocol for health care provision for patients with tuberculosis" approved by MoH Ukraine Order of 09.06.2006№ 384 "On approval of Protocol for health care provision for patients with tuberculosis".

At a facility with an approved ward or office for HIV prevention and treatment that independently maintains follow-up records, a registration card is completed for a person with HIV (form # 02-1/o), and other records and reports approved by the Ukrainian Ministry of Health and State committee of statistics [19] are maintained. The HIV/AIDS treatment monitoring system approved by the relevant Order [27] requires maintaining standard forms from the moment of registration, irrespective of whether or not a person is on ART.

Service 4. Antiretroviral therapy

Background. Decentralization of treatment is a priority objective of the National AIDS program. The Comprehensive plan to scale up access to HIV prevention, diagnosis, treatment and support, which is approved on an annual basis[34], envisages an increased number of facilities providing ART. Making this service more accessible to the target group significantly increases adherence to treatment, which in turn leads to greater effectiveness of treatment.

Organizational and regulatory framework. In this guideline, the set of diagnostic and consulting activities indicated for all HIV patients are described within an *HIV disease management service*. Prescription of ART does not change the list of these interventions (although in certain cases the frequency of exams may change), hence, in this guideline, *HIV disease management* is considered an obligatory prerequisite for ART provision; for this reason, the management components will not be repeated in the description of ART.

Currently there are no separate training programs (topical advanced training) on clinical management and ART, therefore, if a doctor has had special training and conducts clinical management, he/she also has the right to prescribe ART. However, at the moment, only very competent AIDS centres' physicians prescribe ART, and doctors from other ART sites manage patients at the later stages of the disease.

Content. From an organizational perspective, in addition to the components described within the "Clinical management of HIV" services, facilities providing ART should select a mechanism for supplying ARVs to ensure appropriate storage conditions for drugs and implementation of a system of quantification and inventory control, in addition to promoting adherence to treatment.

Clinical aspects of treatment must comply with the current Clinical protocols and standards[35] [21, 24].

Component 1. Supply of medications for ART

There are several options for supply of ART drugs. They are described in the relevant section.

Component 2. Documentation and record keeping

In addition to prescribing and dispensing drugs, personnel ensuring clinical monitoring are also responsible for documentation and record keeping. The facility should have staff members trained in record keeping in line with the ART monitoring system approved by the relevant Order [27]. (At the time this guideline was developed, this document was being updated).The Order envisages keeping logs of medications, of patients on regular outpatient follow-up, and of patients receiving ART, as well as generation of reports and completion of additional forms.

Component 3. Adherence promotion

In the course of ART treatment, adherence is critically important for effective suppression of HIV. To achieve successful treatment outcomes, the patient should take 90-95% of the prescribed dose; lower levels of dosing are associated with unfavourable treatment outcomes. Adherence promotion is an indispensible part of the prescribing physician's activities and those of the nurse dispensing ARV drugs; this is done at the time of counselling or

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[34]MoH Ukraine Order of 04.06.2010 № 461"On approval of Comprehensive plan for scaling up access of population to prevention of HIV-infection, diagnosis, treatment, care and support for people with HIV/AIDS in Ukraine in the quarter II –IV of the year 2010 - quarter I of the year 2011".

[35]"Standards of treatment of HIV-positive people who inject drugs" approved by MoH Ukraine Order of 19.08.2008 № 476 "On approval of standards of treatment of HIV-positive people who inject drugs".

dispensing of therapy. More advanced interventions in the area of adherence (training, interventions, and so on) are discussed in the section “Social and psychological support”.

Component 4. DOTS-ART (optional)

An additional intervention to increase adherence, which strengthens the effectiveness of therapy, is directly observed treatment strategy (DOTS). Implementation of this intervention is particularly appropriate in the case of daily patient visits to the facility, for instance, to receive substitution therapy. If a patient is receiving ART, which includes dosing several times a day, then the morning dose is dispensed on-site, and the remaining doses are taken by patients on their own. For this reason, DOTS-ART should be used only in the context of other activities geared to adherence strengthening.

Organization of directly observed dispensing of ART drugs includes several steps; it does not require significant additional resources.

Service 5. Social and psychological support and management

Background. The primary objective of psychosocial management for people living with HIV is to support adherence to treatment and access to evaluation. Activities for improving adherence, counselling on drug dependence, and assistance in addressing social problems, not only improve ART effectiveness, but also promote access to other services and improve quality of life.

Content. The methodology of psychosocial management and the content of interventions are covered in other manuals and relevant standards[36] [35]. An exhaustive list of social services for PLWH, PWID, people with co-infection and patients on OST, is included in the standards approved by the joint Order[37]. Activities related to adherence strengthening are described in detail in the protocol on ART [21]. The scope of social services relevant for PWID is significant and includes both primary and secondary prevention of HIV/AIDS in different populations, and provision of nonmedical care, psychological, social, legal, and material assistance to clients and their families.

Organizational and regulatory framework. In accordance with the Law of Ukraine[38], provision of social services is based on the principles of: 1) a targeted and individualized approach; 2) accessibility and openness; 3) voluntary consent/refusal of social services; 4) humaneness; 5) comprehensiveness; 6) maximum effectiveness of budgetary and non-budgetary funds for social services; 7) legality; 8) social justice; 9) ensuring confidentially for people accessing services, adherence to standards of quality, and adherence to ethical and legal norms.

Depending on the substance of the service, psychosocial management can be provided by a psychologist, lawyer, social worker, social teacher, health care worker, volunteer or counsellor (including peer counselling).

The standards [36] describe the qualification requirements for personnel; a person without relevant educational qualifications can work as a social worker provided they have participated in and/or graduated from a short-term course, passed testing by the service provider, and received an appropriate certificate.

Certain types of HCFs are able to establish staff positions for social workers. Currently there are no regulatory limitations concerning the types of social work that can be done by staff workers; the management of a facility can therefore establish their own guidelines for necessary services to be provided by appropriately trained staff, social workers or psychologists. If the facility cannot establish staff positions, on-site psychosocial management can be provided by the staff of partnership organizations.

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[36] “Standard of the minimal package of social services, aimed at prevention of HIV/STI and complications associated with injecting drug use” approved by Ministry of Ukraine for family, youth and sports Order of 18.12.2008 № 4941 “On approval and implementation of standards for the minimal package of social services in the area of HIV/AIDS for different categories of children, young adults and families”.

[37] Ministry of Ukraine for family, youth and sports, Ministry of labour and social policy, MoH Order of 13.09.2010 № 3123/275/770 “On approval of standards for provision of social services for the representatives of risk groups”.

[38] Law of Ukraine of 19.06.2003 № 966-IV “On social services”.

Component 1. Psychosocial case management

From an organizational perspective, the only component of this service is the organization of psychosocial work.

Service 6. Prophylaxis and treatment of opportunistic infections

Background. Prophylaxis and treatment of OIs is an indispensible component of the complex of services for HIV-positive PWID. Making this service more accessible to the target group significantly increases adherence to testing and timely collection of medications, which in turn increases treatment success.

Organizational and regulatory framework. In accordance with the protocol [22], prophylaxis, diagnosis and treatment of OIs constitute an important part of comprehensive HIV care provided by all levels of health care, and should be provided according to the capabilities and type of HCF. Presence of all components of management is not a mandatory prerequisite for provision of prophylaxis and treatment of OIs. However, it should be noted that offering comprehensive management of HIV is ideal in order to provide effective and complete care for patients with OIs.

Content. From an organizational perspective, in addition to the components described in the service framework "Medical management of HIV-infection", a facility conducting prophylaxis and treatment of OIs should establish a mechanism for supply of medications, arrange for proper storage and set up an inventory system.

Clinical aspects of treatment should be in line with effective clinical protocols [22]. Protocol focus on prophylaxis of infections such as PCP, TB, toxoplasmosis, MAC, Cryptococcus. The most frequently used drug for prophylaxis of OIs is cotrimoxazole. Treatment of OIs should not be grounds for stopping/interrupting other treatments (substitution therapy included).

Component 1. Supply of drugs for treatment of OIs

There are several ways to supply drugs for OI treatment.

Component 2. Physician's role

A doctor specifically trained in medical management of HIV-infection can conduct prophylaxis or treatment of OIs. Organizational steps for engaging the doctor are standardized.

Component 3. Diagnosis and monitoring of treatment response

Laboratory and instrumental findings inform the diagnosis of OIs. For all laboratory tests, practical steps for organizing preanalytical and analytical work are universal. In the course of carrying out different types of tests, variants of preanalytical or analytical steps can be used independently (for instance, the analytical step of clinical tests can be carried out at the facility, and immunological tests can be done by sending samples out to the laboratory of another HCF).

Practical steps for the organization of sonography, ECG and radiography are described in the relevant sections.

Service group 2. Tuberculosis

TB, an infectious disease caused by *Mycobacterium tuberculosis* is characterized by the formation of specific granulomas in different organs and tissues (specific TB inflammation) in combination with nonspecific reactions and varied clinical symptoms that depend on the form, stage, localization and extent of the disease.

The situation with TB in Ukraine is extremely complicated: Since it began in 1995, the TB epidemic has been progressing and becoming ever more threatening. Ten to eleven thousand patients die annually from the disease, i.e. over 30 people per day.

Injecting drug use, alcohol abuse, and imprisonment, increase the risk of HIV infection and development of TB. All patients who inject drugs or receive substitution therapy should have free access to TB diagnosis and treatment services. The importance of adequate access is due to the connection between TB and HIV epidemics as well as the following factors:

- Patients with HIV are at risk of contracting and developing active TB, which is one of the major causes of death among PLWH;
- HIV infection impacts the course of TB infection and the success of its treatment;
- Active TB influences the course of HIV infection and the success of ART;
- TB coincides with stage III or IV HIV infection, which requires prescription of ART.

Service 7. Consultation of a TB specialist

Background. Consultation with a TB specialist is mandatory for PWID due to their increased risk of acquiring TB as well as the high risk HIV/TB co-infection.

Regulatory framework. The scope of medical care and its quality are regulated by state social standards and clinical protocols. State social standards (norms) of medical care for adults in out-patient facilities are approved by MoH Order [20] and include norms laid out in *TB Specialization* and *Pulmonology*. When consulting PWID and patients receiving OST, the TB specialist should be guided by the following clinical protocols, standards and instructions: treatment of TB [33], DOTS[39], HIV/TB co-infection [24], drug resistant TB[40], instruction on TB classification[41], as well as by instructions and standards on the use of diagnostic tests (described in the relevant services).

TB consultation can be provided by TB specialists, pulmonologists, infectious disease physicians or other appropriately trained professionals. The physician can be either facility staff or an involved consultant. Labour relations between the physician consultant and the inviting HCF depend on the type of collaboration, and are governed by regulations that are described in detail in the relevant section.

Content. The content of a consultation is primarily determined by the patients' needs. The TB specialist diagnoses the patient (takes history, conducts assessment and physical exam, prescribes laboratory or instrumental tests), motivates the patient to attend timely assessments, informs the client about the routes of transmission, diagnostic methods, potential cure, and access to therapy, and guarantees treatment free of charge. Medical examination standards are described in the current protocol [33]. If a patient receives treatment (it is possible to conduct the maintenance phase and chemoprophylaxis in non-specialized institutions), the TB specialist consults on adherence, monitors efficiency of the therapy, and monitors and treats side effects.

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[39]"Protocol of implementation of DOTS strategy in Ukraine" approved by MoH Ukraine Order of 24.05.2006 № 318 "On approval of Protocol for implementation of DOTS strategy in Ukraine".

[40]"Standards for medical care provision to patients with drug resistant tuberculosis" approved by MoH Ukraine Order of 22.10.2008 № 600 "On approval of Standards for medical care provision to patients with drug resistant tuberculosis".

[41]"Instruction on clinical classification of tuberculosis and its use" approved by MoH Ukraine Order of 09.06.2006 № 385 "On approval of Instruction on health care provision to patients with tuberculosis".

Component 1. Physician's role

From an organizational perspective, the physician's work is the sole component of this service. Practical steps are described in the relevant section.

Service 8. Mantoux test

Background. The Mantoux test (tuberculin skin test) is a quick and inexpensive diagnostic method, that is used to identify people with TB disease, TB infection, and new cases of TB infection, as well as people at high risk of developing the disease. Tuberculin skin tests for adults are conducted for those exposed to active TB and persons at risk for TB (HIV patients, PWID), in order to provide TB chemoprophylaxis.

Regulatory and organizational framework. As a rule, diagnosis using the Mantoux test is provided in TB polyclinic offices, oblast AIDS centres and specialized TB facilities. To screen PWID for TB, and to achieve early diagnosis of persons with *M. tuberculosis* infection, tuberculin testing should be provided at all facilities offering services to this patient group. Indications for tuberculin testing for different patient categories are described in the Clinical Protocols [21, 24, 33].The technique of testing, side effects and contraindications are outlined in detail in Instructions [28, 29] and in the Procedure [30] to supplement the Instruction [29].

Content. The Mantoux test begins with a prescription from a physician (an attending physician or consultant–infectious disease specialist or TB specialist). The test is performed and interpreted by a physician or a specially trained nurse under physician's supervision [28]. Test results are interpreted in 72 hours; for this reason, it is important that the behaviours of active PWID be taken into consideration and adherence promotion conducted in order to ensure their timely return to the facility to have the test results assessed. The main differential/diagnostic criterion is the size of cellular infiltrate – the papule. The result can be negative, ambiguous, positive, or sharply positive (hyperergic). A positive test result is not the definitive criterion of TB disease, hence patients with positive Mantoux test results require additional assessment. After Mantoux test interpretation, it is important to arrange a consultation with a TB specialist, who will determine whether a patient had been exposed to TB and has clinical manifestations of the disease. The TB specialist also prescribes additional consultations and clinical/laboratory tests.

Component 1. Tuberculin supply and test performance

The main component of the service is provision of tuberculin, and staff training. Organizational issues and steps are described in a separate section.

Component 2. Nurse's role

Within the framework of provision of *Mantoux test* services, a nurse performs the test itself and assesses it. Practical steps for the organization of the nurse's work are described in the relevant section.

Service 9. Radiological exam

Background. A chest radiological exam is used both for TB screening and diagnosis, with fluoroscopy mainly used for screening, while other radiological methods (chest X-ray, X-ray tomography, CT) are used for diagnosis and differential diagnosis.

Organizational and regulatory framework. In accordance with the protocol, TB detection among adults is comprised of three steps: 1) taking history and recording symptoms; 2) chest X-ray; 3) triple sputum smear microscopy for acid fast bacilli (AFB). A radiological exam is prescribed only in the presence of symptoms (cough for over three weeks, body weight loss; fatigue; fever; night sweats; chest pain; loss of appetite; hemoptysis). If the patient belongs to a risk group (as with PWID), regular screening is prescribed on an annual basis even in the absence of symptoms. In accordance with the regulation [31], individuals observed at narcological, psychoneurological or TB facilities must undergo a mandatory radiological exam for TB detection.

In accordance with the protocol [33], TB detection through screening fluoroscopy among adults belonging to risk groups is conducted at any polyclinic department. Any specialist can prescribe a radiological exam for screening (in the absence of symptoms) or for differential diagnosis (in the presence of symptoms).

Content. A physician prescribes the radiological exam taking into account both indications and contraindications. It should be noted that fluoroscopy is merely a screening method, so if there are signs of TB disease on the film, a

chest X-ray should be prescribed. Radiological assessment is not a specific method to confirm a TB diagnosis, since similar abnormalities may be observed with other pulmonary problems; however, it is one of the key diagnostic tools. Every physician should to be able to evaluate X-ray film and identify suspicion of TB, but only a TB specialist can confirm the diagnosis, based on bacteriology.

Component 1. Conducting radiological exam

On-site radiological exams require very costly equipment. Other possible options for provision of this service are described in the relevant section.

Service 10. Sputum test

Background. A sputum test is included in the mandatory minimum diagnostic procedures for patients with suspected pulmonary TB. This test allows for preliminary diagnosis, detection of infectious patients, and assessment of the effectiveness of treatment for patients with TB. There are three major groups of testing methods: A sputum smear microscopy for acid-fast bacilli by the Ziehl-Neelsen method, bacteriology, and drug susceptibility testing.

In accordance with regulations [31], individuals observed in a narcological or psychoneurological facility that have a cough for three or more weeks must undergo mandatory assessment by sputum smear microscopy.

Organizational and regulatory framework. In accordance with the Order[42], Ziehl-Neelsen microscopy is a relatively simple diagnostic method that can be implemented in all laboratories in the general health care network (level I of TB diagnosis). The bacteriological method (culture) is more sensitive but requires a specially equipped laboratory and can be performed only in specialized facilities (level II of TB diagnosis). Drug susceptibility tests also require special equipment and conditions; they should be performed in specialized facilities (level III of TB diagnosis).

Sputum is collected in a specially equipped area[43]. Sputum collection areas and laboratories of all levels should comply with infection control standards[44].

Content. All patients with suspected TB should undergo a triple sputum smear microscopy for AFB. Isolation of a causative agent by culture on nutritional media is indicated when a patient's sputum microscopy shows no mycobacteria (in case of low bacterial concentration) or when there is a need to distinguish between *Mycobacterium tuberculosis* and other AFB. Presence of *Mycobacterium tuberculosis* in a patient's sputum is the only absolute confirmation of the diagnosis.

When choosing a treatment regime, it is important to determine susceptibility to anti-TB medications. A second bacteriological exam (culture) should be conducted in order to check treatment efficiency. Absence of mycobacteria in the tested sample is evidence that production of the causative agent has stopped.

Component 1. Sputum collection

From an organizational viewpoint, the first stage of this service is collection of sputum. Regardless of where laboratory testing will take place, it is appropriate to collect sputumon-site at the facility. Service delivery steps are described in the relevant section.

Component 2. Laboratory sputum tests

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[42]MoH Ukraine Order of 06.02.2006 №50 "On approval of Standard regulation on laboratories and points for diagnosis of tuberculosis and collection of sputum".

[43]"Standard regulations on sputum collection point based in the HCF" approved by MoH Ukraine Order of 06.02.2006 № 50 "On approval of Standard regulations on laboratories and points for diagnosis of tuberculosis and collection of sputum".

[44]"Standards of infection control of tuberculosis in HCFs, place of long-term stay of people and residence of patients with tuberculosis" approved by MoH Ukraine Order of 18.08.2010 №684 "On approval of Standards of infection control of tuberculosis in HCFs, place of long-term stay of people and residence of patients with tuberculosis".

The Laboratory stage of sputum testing can be organized in the same way as other types of laboratory tests. Sputum microscopy by Ziehl-Neelsen method is quite feasible in the laboratory of any HCF.

Should AFB be detected in at least one of the three sputum smears, a physician should fill out and send notification form № 089/o to the local TB institution[45]. This institution should conduct additional tests to confirm or rule out the diagnosis. It should register the patient for regular observation, by filling out the registers and forms approved by the Order[46] and protocol [33].

Service 11. TB treatment

Background. In accordance with the National Program[47], the creation of an effective TB treatment system should be based on the principles of DOTS strategy, i.e. bringing the treatment as close as possible to the patient and providing treatment under the direct observation of a health care worker. The main mechanism for decentralizing treatment is setting up DOTS offices. The regulation on DOTS offices[48]states that the main criterion for determining the location of a DOTS office is its proximity to TB patients. For this reason, it is important to establish outpatient TB treatment in facilities that provide regular services to those populations that are at higher risk of being infected with TB, for example in AIDS centres or at substitution therapy offices.

Organizational and regulatory framework. In accordance with current legislation, patients with infectious TB, including the socially disadvantaged, those with concurrent chronic alcohol abuse, drug or substance abuse, are subject to mandatory hospitalization at TB facilities and must undergo appropriate treatment[49]. For this reason, treatment of patients up to the point of cessation of bacterial production is possible only on an in-patient basis and in specialized facilities. TB can be treated outside the network of TB facilities only in the absence of bacterial production in patients in treatment categories III and IV (new cases and chronic TB disease) and at the maintenance stage for patients in categories I and II (severe cases and retreatment) [33]. MDR-TB is treated with extended regimens which include second line medications in an in-patient setting during the intensive phase and out-patient setting after discharge, similar to treatment for new cases [33].

In accordance with the ART protocol [21], treatment of TB in HIV patients is performed on the same basis as treatment for all TB patients.

The best way of providing out-patient TB treatment at HCFs that provide services to PWID and patients on substitution therapy is to establish DOTS-offices. DOTS-offices are set up by Order of the facility's manager in accordance with the decision of the local HA [48].

Content. TB treatment strategy depends on the specific diagnosis, drug resistance, and intolerance and side effects of antimycobacterial drugs. The choice of treatment regimen must be made by a competent TB specialist in accordance with protocols [33, 40]. Anti-TB therapy is only effective provided that the drug combination prescribed is in optimal doses and regularly administered. As a rule, after 2-3 weeks of an appropriate treatment regimen, the patient is no longer infectious.

Component 1. Physician's role

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[45]MoH Ukraine and State statistics committee of Ukraine Order № 112/139 "On approval of form for primary records N 089/o "Notification about a patient with newly diagnosed active tuberculosis or its relapse and Instructions on its completion".
[46]MoH Ukraine Order of 02.09.2009 № 657 "On approval of form for primary recording and reporting forms on tuberculosis and instructions on how to complete them".
[47]Order of the Cabinet of Ministers of Ukraine of 24.06.2006 № 354-р "On approval of the Concept of the National program to respond to tuberculosis in the years 2007-2011".
[48]"Regulation on the office for directly observed treatment of tuberculosis at the outpatient level" approved by MoH Ukraine Order of 07.12.2009 № 927 "On approval of Regulation on the office for directly observed treatment of patients with tuberculosis at the outpatient level".
[49]Law of Ukraine of 05.07.2001 № 2586-III "On control of tuberculosis disease". Latest version based on the Law of Ukraine of 11.06.2009 № 1276-VI.

One of the main components of efficient TB treatment is the work of a competent TB specialist who has special training and regular re-training on TB treatment, multi-resistant forms of the disease, principles of a multidisciplinary approach, and specific aspects of treatment for patients from risk groups. It is important that a TB specialist be a member of a MDT that coordinates provision of other services for a patient. This will allow for timely assessment of potential drug interactions.

It is especially important to teach medical workers to implement a DOTS strategy. Prior to DOTS strategy implementation, all participating medical workers should attend appropriate training.

The quality of specialist training is crucial, since poor training may result in TB drug resistance, and inappropriate patient management particularly in the choice of chemotherapy regime. The main reasons for drug resistance development include: 1) incorrect patient management related to inadequate training of TB specialists; 2) irregular supply of chemotherapeutical drugs; and 3) poor patient adherence to treatment.

In accordance with regulation [48], district TB specialists oversee the operation of DOTS- offices. Organizational steps for involvement and organization of physicians' work are standardized.

Component 2. Nurse's role

Within the framework of *TB treatment* services, a nurse fills the physician's prescriptions, exercises immediate control over drug administration, and keeps medication records and reports. A nurse can also provide initial counselling on adherence. Practical steps on the organization of nurses' work are described in the relevant section.

Component 3. Supply of anti TB medications

Special antimycobacterial drugs and some antibiotics that are effective against mycobacterium are used in TB treatment. There are several options to ensure supply of medications; the simplest approach is redistribution from TB facilities.

Component 4. Directly observed treatment

Directly observed dispensing of medication, and of drug taking by patients, is the basis of the DOTS strategy and ensures successful treatment. This achieves the highest level of adherence, especially among risk groups. According to the DOTS protocol [39], dispensing drugs to a patient, and then recording intake on a TB 01 form, is prohibited.

Organization of office work for observed dispensing of drugs is described in the relevant section.

Component 5. Monitoring of treatment success

In accordance with the Protocol [33], treatment outcomes should be monitored during provision of chemotherapy. Treatment of patients with newly diagnosed pulmonary TB is monitored by sputum smear and culture at the 2-3 month interval (upon completion of the intensive phase), at the 5 month interval, and at the end of treatment. If sputum smears are negative, the treatment should be continued according to the defined treatment regime. In the case of a positive sputum smear, treatment is considered to have failed. In this case, the patient's registration card should be discontinued and the treatment outcome should be recorded as unsatisfactory. In order to proceed with treatment, the case should be re-registered as treatment after failure, and the patient should receive a different treatment regime prescribed on the basis of the results of drug susceptibility tests.

Sputum smear testing involves sputum collection, which should be conducted on-site, while the laboratory step on page 74can be conducted either in the laboratory of the HCF or by sending the sample out to another facility's laboratory.

Treatment is considered successful if, upon completion of the full course of antimycobacterial therapy, clinical/radiographic stability has been achieved (absence of further positive dynamics of the residual foci, namely residual cavities when compared with the X-rays performed in the 3-6 month interval). An X-ray is performed at the same time as the sputum test. Plain radiography or tomography is performed at the beginning and at the end of the treatment. Practical steps for provision of radiological exams are described in the relevant section.

Component 6. Meeting regulatory requirements

In accordance with Order [45] and protocol [39], a medical record for a patient with TB infection (form TB 01) should be kept for each patient registered with the district TB register (form TB 03).The patient's record includes

detailed treatment data, treatment regime, doses, side effects of medications, examination data, etc. This record is completed at a TB dispensary (hospital, or TB office), where the initial (intensive) treatment phases is performed. Once the initial treatment phase is complete, the record is transferred to the out-patient facility (DOTS-office), where observed treatment is conducted and recorded along with the patient record or out-patient record (form TB 09). A district TB specialist should ensure that record information be transferred to the district TB register. Upon treatment completion, the record should be transferred to the district TB specialist who keeps it in the out-patient medical history files.

Component 7. Adherence promotion

Apart from direct control over drug dispensing, which is the main method to ensure adherence, additional activities on adherence improvement can be conducted. NGOs and public organizations may be involved in such activities which can include special counselling, social case management, and training interventions. Case management activities can be organized in several ways.

Service 12. TB chemoprophylaxis

Background. TB preventative treatment aims at reducing the number of new TB cases as well as the incidence of relapse. Primary TB develops both in cases of exposure to the source of infection and as a result of reactivation of latent TB infection. Relapses of the disease develop in people who have already had TB. Mono- or dual chemoprophylaxis reduces the risk of development of active TB.

Organizational and regulatory framework. The basis of TB chemoprophylaxis is described in the Law of Ukraine [49]. Chemoprophylaxis techniques are described in the protocol on TB treatment [33]; some aspects are also included in the ART protocol [21].

Content. Chemoprophylaxis is prescribed to patients with HIV infection in case of a positive Mantoux test or medical history of contact with a patient who has active TB. Patients without HIV receive chemoprophylaxis if they maintain contact with TB patients, especially if he or she belongs to socially disadvantaged populations or abuses drugs.

The organizational of chemoprophylaxis provision is similar to that of TB treatment.

Component 1. Physician's role

A TB specialist, or an infectious diseases physician under the supervision of a TB specialist, identifies indications, rules out active TB, prescribes preventative regimes and monitors treatment efficiency. In accordance with regulation [48], control over the operation of DOTS offices must be carried out by district TB specialists. The organizational steps of the physician's involvement and the organization of his/her work are standardized.

Isoniazid is recommended for preventative treatment. For chemoprophylaxis, a dose of 5mg/kg of isoniazid is usually prescribed for 6-9-12 months, providing that side effects are under control. In cases of resistance to isoniazid, it should be combined with rifampicin, or else two-component chemoprophylaxis regimens (isoniazid + pyrazinamide or isoniazid + ethambutol) should be used.

Component 2. Ruling out active TB

Before prescription of chemotherapy, the presence of active TB should be ruled out. Testing for active TB is performed in two steps using sputum smears: sputum collection and analysis, as well as X-ray diagnosis; the organization of this work is described in the relevant sections.

Component 3. Supply of medications

For chemoprophylaxis to be successful, there must be a continuous supply of medication. Special antimycobacterial drugs as well as some antibiotics active against mycobacteria are used for chemoprophylaxis of TB. For drug supply, several options may be used; the most practical approach is redistribution from anti TB facilities.

Component 4. DOTS

In accordance with the Law of Ukraine [49], TB chemoprophylaxis is carried out under the observation of a medical professional. This provides an opportunity for monitoring and observation of the patient's treatment, at the same time as prescribing the preventative regime. The organization of DOTS office operations is described in the relevant section.

Service group 3. Mental health

Mental health services are critical to ensure that PWID have access to other services and adequate adherence to evaluation and treatment regimens.

Service 13. Medical consultation on dependence

Background. Consultation on substance dependence is an extremely important service for PWID who require medical care. Active dependence is a barrier to obtaining important diagnostic and treatment services (for instance, HIV and TB treatment); it is therefore important to try to initiate narcological care as early as possible. It should also be noted that this is not an absolute pre-condition for access to treatment, and the absence of consultation or treatment for dependency should not be the basis for denying other types of care.

Organizational and regulatory framework. The scope of medical consultation on dependence and the quality of consultation are regulated by state social standards and clinical protocols. State social standards (norms) of health care provision for adults in ambulatory –polyclinic facilities are approved by Order [20] and include norms in the specialization of *Narcology*. The narcologist should also be guided by the Ministry of Health's approved Clinical Protocols[50]and guidelines, in particular, those on substitution therapy[51].

Consultation on dependence can be provided by doctors – narcologists or psychiatrists. The doctor can be on staff at the facility, or an invited consultant. Labour relations between the consultant-doctor and the inviting HCF depend on the type of collaboration and are governed by several regulations that are described in detail in the relevant section.

Content. The content of consultations is primarily determined by the patient's needs. A professional psychiatrist – narcologist should be able to diagnose dependence, other conditions which develop as a result of substance use (intoxication, overdose), and prescribe treatment for dependence, concurrent disorders and the like.

During consultation, the doctor should also provide the patient with information on HIV risks and ways to reduce them, and explain possible treatments and rehabilitation options.

Component 1. Physician's role

From an organizational perspective, involvement of a physician is the sole component of this service. Practical steps for providing this service are described in the relevant sectionна стNu0440 69.

Service 14. Psychiatric consultation

Background. Concurrent psychiatric disorders (depression, anxiety, personality disorders etc.) are the main cause of discontinuation of substitution therapy programs, as well as the cause of poor patient adherence to other treatments. PWID's access to diagnostic and consultative services for mental disorders is currently very low. Timely diagnosis and treatment of psychiatric problems significantly increases the success of substitution therapy and patients' adherence to other treatments.

Organizational and regulatory framework. A narcologist who is trained in psychiatry, or a psychiatrist in especially difficult cases, can diagnose and treat psychiatric disorders. The prescription of treatment regimens for certain mental states/disorders should be done by a psychiatrist.

The scope of medical consultation on mental disorders and the quality of such consultation is regulated by state social standards and clinical protocols. State social standards (norms) of health care provision for adults in ambulatory –polyclinic facilities are approved by Order [20] and include norms in the specialization of *Psychiatry*.

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[50]MoH Ukraine Order of 21.09.2009 № 681 "On approval of clinical protocols of medical care provision in the specialization "narcology".

[51]Guidelines "Substitution maintenance therapy in treating people with syndromes of dependence from opioids" approved by MoH Ukraine Order of 10.11.2008 № 645 "On approval of guideline "Substitution maintenance therapy in treating people with syndromes of dependence from opioids".

The psychiatrist should also be guided by the Ministry of Health approved diagnostic and treatment criteria[52]and clinical protocols[53].

All services related to the diagnosis and treatment of psychiatric disorders should be provided within the framework of the Law of Ukraine[54]. Psychiatric examination can be performed with the patient's consent or without consent, in case of potential threat to his or her own safety, the safety of others or if the patient is incapacitated, as well as with the consent of the patient's legal representatives.

Content. The content of the consultation is determined primarily by the patient's needs. The psychiatrist should be able to diagnose mental disorders, including those associated with dependence on substance and to prescribe treatment.

Component 1. Physician's role

From an organizational perspective, the sole component of this service is the involvement of the appropriate professional. Practical steps for providing this service are described in the relevant section.

Service 15. Diagnosis of dependence

Background. To receive OST the patient should have an official diagnosis of mental and behavioural disorder due to opioid use, with "dependence syndrome."

Organizational and regulatory framework. In accordance with item 12 of the Law of Ukraine[55], diagnosis of drug dependence for users of illegal substances (not prescribed by a doctor), is made by the medical-consultative commission (MCC). In accordance with item 1.2 of the instructions, illegal drug users or users of psychotropic substances are referred for medical assessment by internal affairs bodies to HCFs that provide narcological care; item 2.5 of the Instruction [56] also notes that diagnosis of "drug dependence" can be made only after assessment in a hospital. Thus, if law enforcement refers a person with established illegal drug use to a narcologist, this person should be evaluated in a hospital and diagnosis made by the commission.

Establishing the fact of illegal substance use does not fall within the competencies of health care workers; in accordance with the Order[57], in all other cases (for instance, in the case of self-referral),only a psychiatrist or narcologist can diagnose narcological disease in both out-patient and in-patient settings.

Content. When making a diagnosis, the doctor should use the diagnostic criteria of mental and behavioural disorders listed in the current clinical protocols [50]. The protocol is based on the International classification of diseases (ICD) –which is comprised of six criteria; the presence of three of them is a sign of dependence. A convenient questionnaire on dependence criteria can be found in appendix 1 of the guideline [51]. In ambiguous cases, laboratory tests for substance presence in urine or blood can be used.

Component 1. Physician's role

From an organizational perspective, the only component of this service is involvement of a physician. Practical steps for providing this service are described in the relevant section.

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[52]MoH Ukraine Order of 27.10.2000 № 271 "On approval of Criteria for diagnosis and treatment of mental and behavioral disorders".
[53]MoH Ukraine Order of 05.02.2007 № 59 "On approval of clinical protocols for care in the specialization "Psychiatry".
[54]Law of Ukraine of 22.02.2000 № 1489-III "On psychiatric care".
[55]Law of Ukraine of 15.02.1995 № 62/95-ВР "On measures for countering illegal circulation of narcotic substances, psychotropic substances and precursors and their abuse".
[56]"Instruction on the Procedure of identification and registration of persons illegally using narcotic substances or psychotropic substances" approved by the Order of MoH, MIA, General Prosecutor's Office, Ministry of Justice of Ukraine of 10.10.1997 №306/680/21/66/5.
[57]MoH USSR Order of 12.09.1988 №704 "On timing of regular outpatient follow-up of patients with alcohol abuse, drug abuse and substance abuse".

Component 2. Role of MCC (if applicable)

If law enforcement refers a person with illegal drug use to diagnosis for dependence, the MCC should be convened. The MCC can also be involved in complicated or ambiguous cases. Options for MCC involvement are described in the relevant section.

Component 3. Drug screen test (if applicable)

In ambiguous or controversial diagnostic cases, laboratory drug testing can be carried out. Chemical and toxicological tests most frequently used include chromatographic and immunological assays; the latter also include RTs. Samples of blood, saliva, or buccal wash can be used for these tests, and urine for RTs.

It should be noted that these tests are only auxiliary, and that the presence of substances or their metabolites in body fluids is not a criterion of dependence.

From an organizational perspective, all laboratory tests include preanalytical and analytical on page 74steps; the method of implementing these tests is described in the relevant sections.

Service 16. Opioid substitution therapy

Background. Opioid substitution therapy (OST) is one of the most effective treatments for dependence and for ensuring good adherence to other treatments. Active substance using patients rarely achieve an adequate level of adherence to treatment for such diseases as HIV, TB, hepatitis, or STI, without the active support of health care personnel. Once the physical and psychological status of an opioid dependent patient has stabilized, use of substituting drugs helps to ensure an adequate level of adherence in a significantly higher number of cases.

Organizational and regulatory framework. Provision of OST in Ukraine is done in accordance with the current Law [5, 7] and several Orders[58, 59] [35, 50, 51], however, at the time this guideline was developed, there was no document with a complete description of OST provision. There are no limitations concerning the type of facilities to provide OST for treatment of individuals with dependence.

Circulation of OST drugs, which are narcotics, is regulated by the Procedure of implementation[60] and Procedure for circulation[61]. Facilities providing OST should have a license giving them the right to engage in activities related to the circulation of narcotics and should update their license on a regular basis.

Prescription of OST can be provided only by an appropriately trained physician who, at the time of licensing, is included in the list of people authorized to work with narcotics and approved to prescribe OST to treat opioid dependence in case of confirmed diagnosis of drug dependence. Currently there are no limitations regarding the specialization of physicians who can prescribe OST.

Content. This service must be provided in accordance with the normative requirements concerning the circulation of drugs. Once these conditions have been fulfilled, prescription and dispensing of OST drugs and patient management must be carried out in accordance with current guidelines [50] and with the rules mentioned in the Procedure [60]. As a rule, the drug is prescribed in an out-patient setting, however, it can also be prescribed in a

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[58]MoH Ukraine Order of 13.04.2005 № 161"On development and improvement of substitution maintenance therapy for prevention of HIV/AIDS among drug users" with amendments in accordance with MoH Orders of 19.09.2005 № 481 and of 03.03.2006 № 102.

[59] MoH Ukraine Order of 20.12.2006 № 846 "On measures concerning organization of prevention of HIV/AIDS and substitution maintenance therapy for people who inject drugs".

[60]"Procedure for Implementing activities related to the circulation of narcotic substances, psychotropic substances and precursors, and control of their circulation" approved by the Resolution of Cabinet of Ministers Ukraine of 03.06.2009 № 589 "On approval of Procedure for Implementing activities related to the circulation of narcotic substances, psychotropic substances and precursors, and control of their circulation" with revisions per Resolution of CM Ukraine of 12.10.2010 № 929.

[61]"Order on the circulation of narcotic substances, psychotropic substances and precursors in HCFs of Ukraine" approved by MoH Ukraine Order of 21.01.2010 № 11"On approval of Order on the circulation of narcotic substances, psychotropic substances and precursors in HCFs of Ukraine".

hospital (day clinic). Special attention should be paid to psychosocial management of patients, as this is a prerequisite for rapid achievement of therapeutic goals.

Component 1. Preparation of premises

Availability of premises meeting the requirements[62] is a key factor for obtaining a license for drug circulation. These requirements concern the premises used both for storage and for use/dispensing of narcotics and psychoactive substances. Options for the preparation of premises are described in the relevant section, and require capital inputs for equipment. Generally speaking, the facilities furnish the premises at their own expense, however, in the case of OST, funds for equipping the premises have been provided by international donors, in particular the Global Fund round 6 grant.

Component 2. Licensing

Availability of premises meeting the relevant requirements is a firm condition for providing OST at a facility. In order to legally undertake activities in the area of drug circulation, the facility must obtain a license, or else the facility can rent the premises out to a licensed partnership facility. These options are described in more detail in the relevant section.

Component 3. OST drugs supply

There are several mechanisms for procuring drugs for OST. They are described in detail in the relevant section.

Component 4. Physician's role and drug prescription

Currently there are no legislative limitations regarding the specialization of a physician authorized to prescribe narcotics. Any doctor holding a higher education certificate in *Medicine*, irrespective of specialization, has the right to prescribe OST drugs after undergoing specific training. In addition to prescribing and adjusting the dose of substitution drugs, these doctors can counsel on adherence, diagnose and treat other diseases within the scope of their competency, and coordinate provision of other medical and psychosocial services. Options for preparation and organization of the physician's work are described in the relevant section.

In accordance with item 3.8 of the Order [60], a physician is authorized to prescribe narcotics for up to a three day period. Continued use of the drug for more than 3 days should be approved by the commission on the appropriateness of narcotics prescription. The commission is created by the Order of the facility manager, who must obtain the signature of each of its members. The commission includes the commission head and three members; the conclusion of the commission on the prescription of the drug is recorded on the approved form, which is approved by the facility head.

Component 5. The nurse's role

Drugs for OST are dispensed by a nurse in accordance with a doctor's prescription. In accordance with item 3.9 of the Order [60], oral narcotics should be taken by the patient in the presence of a health care worker (except in cases of dispensing the prescription and home-based care). In this case, the physician does not need to be present. The nurse can conduct initial counselling on adherence, assess the patient's status and refer him/her to the doctor if there are signs of disease or suspected drug or alcohol intoxication. The nurse is responsible for accounting related to narcotics and for keeping relevant logs and reports. Options for the organization of the nurse's work are described in the relevant section.

Component 6. MDT (optional)

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[62] "Requirements for sites and premises intended for implementation of activities on circulation of narcotic substances, psychotropic substances, precursors and storage of such substances removed from illegal circulation" approved by MIA Ukraine of 15.05.2009 № 216 "On approval of Requirements for sites and premises intended for implementation of activities on circulation of narcotic substances, psychotropic substances, precursors and storage of such substances removed from illegal circulation".

Only a doctor (approved by the commission on the appropriateness of prescription of narcotics) or midlevel health care worker can provide OST; however, creation of a MDT will significantly increase the quality of service provision and treatment effectiveness. The commission on the appropriateness of prescription of narcotics is not analogous to the MDT, since the commission is not intended to coordinate patient management. General principles of MDT formation are the same for all services.

Component 7. Psychosocial management

Psychosocial management for patients on OST plays an important role in accelerating social adaptation, resolution of family problems, employment, and improved access to other medical and social services. However, the primary objective of management is to support adherence to treatment and to retain patients in the program. The methodology of psychosocial management and counselling is outlined in standards and numerous manuals distributed by NGOs and is therefore not discussed in detail in this guideline.

From an organizational perspective, provision of psychosocial management is no different from that for other types of psychosocial services. Options and practical steps for this component of the service are described in the relevant section.

Component 8. Availability of naloxone

Naloxone should be available in substitution therapy offices. Opiate antagonist naloxone is used as an antidote in case of opioid overdose. Naloxone has an affinity for opiate receptors and displaces agonists bound to receptors. The half-life of naloxone is significantly lower than that of methadone, and for this reason, in the case of methadone overdose, the patient should be observed for no less than 12 hours, and sometimes – naloxone should be administered once again.

Naloxone is available in pharmacies and can be purchased by HCFs or patients with a prescription. The use of the drug should comply with instructions for cases of substance overdose, and in cases where the patient shows symptoms of overdose.

Component 9. Monitoring of treatment effectiveness (optional)

Facilities providing OST should monitor program activities in general and monitor the effectiveness of medical and psychosocial interventions in individual patients. OST program monitoring is described in guidelines [51] and is not discussed in detail in this guideline. Monitoring of individual patients can include illegal drug use and assessment of the patient's adherence to an individualized recovery plan.

The use of other substances can be controlled with RTs, using preanalytical and analytical on page 74steps. The use of RTs is similar to that of any other type of laboratory test.

Assessment of progress in individualized recovery plans [35] is done through regular meetings with a case manager (social worker, psychologist) and, in problematic cases, at the MDT meetings.

Component 10. Implementation of normative requirements

Provision of OST requires a huge amount of record keeping, and correct circulation of documents is key to uninterrupted operation of the program. For each patient, an out-patient medical record is completed (form № 025/o)[63] or, in some cases, an in-patient record (form №003/o)[64]. Prescription of drugs according to current procedures [60] is recorded in medical records and also in the prescription list of narcotics (form of annex 4), and from day 4, is approved by the commission on expediency (form of annex 5). This procedure [60] also requires keeping logs of narcotics in the wards (form of annex 6) and at nurses' stations (form of annex 7). Facilities receiving medications through centralized distribution should submit monthly reports on used and remaining drugs, as well as on the number of patients.

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[63]MoH Ukraine Order of 27.12.1999 № 302 "On approval of forms for recording statistical information used in polyclinics (ambulatories).

[64]MoH Ukraine Order of 26.07.1999 № 184 "On approval of forms for recording statistical information used in the in-patient departments of the HCFs".

Service 17. Detoxification

Background. Detoxification is a complex of medical and psychological interventions that help patients through acute withdrawal syndrome. Detoxification itself should be considered only the initial stage in the treatment of drug use and has low success without rehabilitation or long-term maintenance programs. As a rule, detoxification precedes programs aimed at the complete cessation of drug use. Since substitution therapy is the most effective method for treating dependence syndrome, detoxification is prescribed in those cases where OST is not available or if the patient insists on his/her willingness to completely quit opioid use. It should be noted, that after detoxification, the likelihood of relapse into illegal drug use is much higher than in the case of substitution therapy; hence, if there is an opportunity for long-term treatment, the patient should to be motivated to enter an OST program.

Content. Detoxification aimed at complete cessation of drug use is described in clinical protocols [50] and guidelines[65].

Detoxification also connotes the gradual tapering of the dose and discontinuation of OST, according to the patient's wish. In this case, detoxification is indicated only after stabilization of the patient's condition: complete and prolonged cessation of illegal drug use, improvement of physical and mental health, renewal of social status, etc. The detoxification method in OST programs is described in the guidelines [51].

Organizational framework. Detoxification can be provided on an in-patient or out-patient basis in narcological or psychiatric facilities; thus, the only organizational component of the service is referral to a specialized facility.

Service 18. Rehabilitation

Background. Rehabilitation—the complex of psychosocial interventions aimed at complete cessation of drug use—is a therapeutic alternative to OST for patients with opioid dependence. Currently rehabilitation is the main treatment method for patients with dependence on other substances.

Organizational framework. As a rule, rehabilitation is provided on an in-patient basis in separate isolated facilities, although it is also possible to conduct it on an out-patient basis. Complete integration of rehabilitation with OST programs is not necessary; however, access to rehabilitation services can be useful after planned detoxification, for patients with opioid dependence, as well as for PWID who abuse stimulants.

Content. The following rehabilitation programs are available in Ukraine:

- therapeutic communities;
- religious rehabilitation centres;
- centres operating according to the Minnesota model of rehabilitation;
- ambulatory centres using cognitive-behavioural therapy or the method of 'motivation increase';
- support groups of Narcotics Anonymous.

Rehabilitation protocols used in these programs are neither standardized nor approved. Decisions on transferring a patient to rehabilitation should be made jointly by the patient and doctor – narcologist or psychologist – after an examination of all possible alternatives.

In this case, the only organizational component of the service is referral to a rehabilitation centre.

[65]"Guideline on accelerated detoxification with injectable buprenorphin", KhMAPE.

Service group 4. Hepatitis

Provision of diagnostic, treatment and prevention services (vaccination against hepatitis B) is an indispensible component of the system of integrated services for PWID, especially those living with HIV. There is a high prevalence of hepatitis B virus (HBV) and HCV among HIV-positive PWID (estimated between 70 to 90% in the European Region). With scaling up of ART, which significantly increases the life expectancy of PLWH, liver diseases have become one of the primary causes of death among people living with HIV. HIV complicates the course of chronic HCV and accelerates its progression to liver cirrhosis and liver cancer. Viral hepatitis in turn exacerbates HIV infection, a situation which is further complicated by an increased risk of hepatotoxicity and the limited choice of medications available to treat HIV, OIs, comorbidities and other complications in the presence of chronic progressive liver disease.

Service 19. Consultation with an infectious disease physician

Background. A consultation on hepatitis with an infectious disease physician is an important service for the majority of PWID, due to the high prevalence of this problem and its adverse impact on the course of other diseases.

Regulatory framework. Labour relations between the consulting doctor and HCF depend on the type of collaboration and are governed by several regulations described in detail below. The scope and quality of medical care are regulated by state social standards and clinical protocols. State social standards (norms) of health care provision for adults in out-patient facilities are approved by MoH Order [20] and include norms in the specializations of *Infectious diseases* and *Gastroenterology*. In the area of infectious diseases, the following clinical protocols are relevant for PWID and substitution therapy patients: on chronic hepatitis[66] and HIV/HCV co-infection [25]. The list of standard diagnostic tests and the scope of treatment and diagnostic activities for gastroenterology patients are approved by a separate Order[67].Diagnosis and treatment of hepatitis are also described in the sectoral standards[68].

Content. The content of medical consultation is primarily determined by patients' needs. The infectious disease doctor makes the diagnosis (takes history, conducts assessment and physical exam, prescribes laboratory and instrumental tests) and treats infectious diseases. The doctor can also counsel on viral hepatitis, and motivate patients for screening and vaccination. The infectious disease physician must comply with the effective standards and protocols on a comprehensive approach to diagnosis and treatment.

Component 1. Physician's role

From an organizational perspective, the only component of this service is the doctor's work. Practical steps are described in the respective sections.

Service 20. Screening and diagnosis of viral hepatitis

Background. For the timely detection of viral hepatitis among PWID, screening should be conducted. This will allow for the appropriate adjustment of medical approaches and determination of the scope of preventative work needed.

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[66]"Clinical protocol for provision of medical care to patients with chronic hepatitis" approved by MoH Ukraine Order of 13.06.2005 № 271 "On approval of protocols for provision of medical care in the specialization "Gastroenterology".
[67] "Sets of diagnostic assessments and scope of activities on treatment and prevention in regular outpatient follow-up for patients with gastroenterological problems" approved by MoH Ukraine Order of 28.12.2009 № 1051 "On providing medical care for patients with gastroenterological problems".
[68]MoH Ukraine Order of 27.07.1998 № 226 "On approval of Provisional sectoral unified standards of medical technologies for diagnostic and treatment processes during in-patient care for adult population in HCFs of Ukraine and Provisional standards of the scope of diagnostic evaluations, treatment and criteria of quality for treating children".

Organizational and regulatory framework. Screening for viral hepatitis can be conducted in various settings in order to improve access for target groups. It can be conducted not only in a HCF but also in a mobile out-patient unit, as well as in NGOs servicing the target group.

Currently there are no limitations on the types of HCFs that can perform assessments for viral hepatitis diagnosis.

Testing for viral hepatitis is voluntary, and education is needed for patients to understand the importance of these tests.

Content. Screening for viral hepatitis involves testing for HCV antibodies (anti-HCV), antibodies for HBV (HBsAg) and HBV markers (anti-HBcor). The protocol on diagnosis and treatment of HCV [25] envisages testing for PWID 1-2 times a year, however, given the possibility of persistent risk behaviour, the tests can be done annually or, if needed, more often (in the presence of clinical symptoms).

To confirm viral hepatitis diagnosis, several laboratory (virological, immunological and biochemical) tests and sometimes, instrumental tests, need to be conducted. These will allow identification of the type of the virus, stage of the disease, treatment approach and prognosis. Clinical protocols [25, 69] describe the procedure of viral hepatitis diagnosis in detail. Diagnosis of chronic viral hepatitis is described in the standardized set of diagnostic tests [67] and the protocol [66].

Component 1. Screening

Screening for the presence of anti-HCV, HBsAg or anti-HBcor can be done by immunological testing in the laboratory or by RTs. Organization of these types of testing is similar to the organization of other types of tests and includes preanalytical and analytical steps.

Component 2. Clarification of diagnosis

The following methods are used for confirming a diagnosis: clinical (physical exam for hepatosplenomegaly; extrahepatic presentations, signs of liver cirrhosis, symptoms of liver insufficiency), virological (RNA HCV or HBV DNA with qualitative or quantitative polymerase chain reaction (PCR), identification of the viral genotype), biochemical (alaninaminotranspherase (ALT), gamma-glutamiltranspherase (GGT), alkaline phosphatase (AP), bilirubin, albumin, prothrombin index (PTI), etc.), instrumental (sonography) and histological (liver biopsy).

There are different options for organizing each of these tests, depending on the availability of laboratories, test kits and additional equipment. All laboratory tests have preanalytical and analytical steps. The method for conducting each test is independently selected i.e. some testing can be organized at the facility, others – through collaboration with another laboratory.

There are also several options for sonography. A sample for liver biopsy can be obtained at the facility through the steps described in the relevant section, or through referral. The laboratory stage of biopsy can be conducted using standard steps in laboratories staffed with personnel who have the appropriate qualifications and the necessary equipment for a pathology exam.

Service 21. Treatment of viral hepatitis

Background. Successful treatment of viral hepatitis is a very important factor for prolonging patients' lives and improving their quality of life. Treatment can also eliminate the negative impact of hepatitis on the course of HIV-infection.

Etiological treatment of viral hepatitis is extremely costly, however a few treatment courses are provided for patients funded by regional programs or international donors. If, in the future, funding becomes available from the national target program, this treatment may become available to more patients.

Organizational and regulatory framework. There is a need to confirm and refine the diagnosis before prescription of treatment; the mandatory prerequisite for providing this service is *Treatment of viral hepatitis* and the availability of service is outlined in *Screening and diagnosis of viral hepatitis*.

Doctors who have the appropriate training can treat viral hepatitis the tertiary care facilities. Treatment is conducted on an out-patient basis, however, in-patient treatment during the first week of therapy may be necessary in case of development of complications.

Content. Viral hepatitis treatment is described in clinical protocols [25, 66] and sectoral standards [68]. In accordance with these documents, contraindications such as pregnancy, alcohol abuse, decompensated liver cirrhosis and cardiac insufficiency should be ruled out before initiation of treatment. Treatment involves long-term prescription of antiviral medications (interferons and ribavirin). To address side effects and other symptoms, additional medications are also prescribed. For patients with liver cirrhosis, treatment is conducted in accordance with the relevant protocol[69].

Monitoring of treatment effectiveness is mandatory. Due to the long-term nature of therapy, it is important to work on increasing patient adherence to treatment.

Component 1. Physician's role

A physician with appropriate specialized training can prescribe treatment for viral hepatitis. This can be an infectious disease doctor, gastroenterologist or internist. The practical steps of the physician's work are described in the relevant section.

In addition to the doctor, who is directly responsible for treatment, consultations with other professionals – psychiatrist, narcologist, neurologist, cardiologist and the like, can be indicated for additional assessment of the patient and to rule out contraindications. If there are no such specialists in the facility (or they cannot serve additional patients), involvement of a consultant can be undertaken in one of the following ways.

Component 2. Nurse's role

When conducting *Treatment of viral hepatitis,* the nurse fulfils the doctor's prescriptions, obtains samples for diagnostic tests and can also provide primary counselling on adherence. The practical steps of the nurse's work are described in the relevant section.

Component 3. Additional tests before and after prescription of antiviral treatment

According to clinical protocols [25, 66], contraindications should be ruled out before prescription of antiviral medications. For this purpose ECG, mental status assessment, assessment of substance dependence, biochemical tests, evaluation of thyroid activity, pregnancy test and the like should be performed.

After initiation of therapy, assessment of virologic response by DNA or RNA testing is the basis for monitoring treatment success. Other types of tests may also be prescribed to control health status and detect treatment side effects. A liver biopsy is indicated only if sustained virologic response is not achieved, but should not be performed more than once in three years.

From an organizational perspective these and other laboratory tests have preanalytical and analytical steps, which can be undertaken in various ways.

Instrumental tests, such as ECG, sonography and liver biopsy, can be undertaken in different ways as described in the relevant sections.

Component 4. Supply of medications

For etiologic treatment of viral hepatitis, special antivirals are used. These medications are very expensive, however, there are several other options for treatment of patients. For pathogenetic and symptomatic treatment and neutralization of side effects, other classes of drugs are prescribed.

Component 5. Ensuring adherence

In the course of viral hepatitis treatment, patient adherence is an important condition of success. Initial work on enhancing treatment adherence is an indispensible part of the prescribing physician's work, and that of the nurse dispensing medication; this work is done in conjunction with counselling or dispensing of medications. More in-

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[69]"Clinical protocol of medical care provision for patients with liver cirrhosis", approved by MoH Ukraine Order of 13.06.2005 № 271 "On approval of protocols of medical care provision in the specialization "Gastroenterology".

depth activities on adherence can be provided through collaboration with NGOs following the same mechanisms as other types of psychosocial work.

Service 22. Vaccination against HBV

Background. In accordance with a preventive immunization calendar[70], vaccination against HBV is recommended for individuals at high risk of infection via sexual or parenteral transmission, including for PWID.

Organizational and regulatory framework. The basis for preventative vaccination, including vaccination against HBV, is described in detail in the relevant Regulation[71]. The document states that immunization is provided in the immunization offices of a HCF, as well as at in-patient settings, however, vaccination in the bandaging area and procedure rooms is forbidden. In accordance with certain Regulations[72], vaccination can be done in temporary offices or by mobile teams, including by a doctor, junior specialist and or registrar. Requirements for the organization of operations in temporary offices and mobile teams are comparatively simple.

The procedure for vaccination is determined by the HCF manager, who determines the responsibilities and roles of the health care workers participating in immunization. The scope of preventative vaccination is agreed with the local sanitary epidemiological stations twice a year. Vaccination is performed by health care workers who have received specific training, including on issues of urgent care in case of post-vaccinal reactions and complications.

Content. Acute or chronic HBV should be ruled out before vaccination. The use of vaccine should comply with instructions approved by the State sanitary doctor of Ukraine. Anti HBV vaccine is administered IM three times – the second shot one month after the first one, the third shot – six month after the first one. If the immune response is absent or inadequate, a single revaccination can be performed. To comply with the vaccination schedule, the necessary level of patient adherence should be ensured.

Component 1. Physician's role

A doctor's participation is a mandatory component of *Vaccination against HBV*. Only a physician is authorized to perform the medical assessment to identify indications and contraindications to vaccination. This can be a general physician, infectious diseases physician, gastroenterologist, internist or other trained professional.

The doctor can also consult on prevention of hepatitis and monitor post-vaccinal complications; (these tasks can also be performed by other medical and non-medical workers). Practical steps of the doctor's activities are described in the relevant section.

Component 2. Nurse's role

Within the service *Vaccination against HBV*, the nurse performs the vaccination, obtains samples for diagnostic tests and can provide initial counselling on adherence. The practical steps of the nurse's activities are described in the relevant section.

Vaccination should be done in offices that are appropriately equipped[73]. The operation of these offices should include documentation and reporting in accordance with the approved forms [72].

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[70]"Calendar of preventative immunization in Ukraine" approved by MoH Ukraine Order of 03.02.2006 № 48 "On procedure for conducting preventative immunization in Ukraine and quality control and circulation of immunobiological substances".

[71]"Regulation on organization and performance of preventative immunization" approved by MoH Ukraine of 03.02.2006 № 48 "On procedure for conducting preventative immunizations in Ukraine and control of quality and circulation of medical immune biological substances".

[72]"Exemplary regulation on immunization office" approved by MoH Ukraine of 31.12.2009 № 1095 "Issues of organization of work of Immunization offices".

[73]"Exemplary list of equipment of immunization offices", approved by MoH Ukraine Order of 31.12.2009 № 1095 "Issues of organization of work of immunization offices".

Component 3. Assessment for detection of indications, contraindications and monitoring of success

The presence of chronic or acute hepatitis B should be ruled out with the help of screening tests prior to vaccination. Six months after completion of vaccination, immune response should be tested to determine the level of anti-HBs Ag by ELISA.

To determine contraindications in PLWH, their immune status should be determined. Contraindications for vaccination are described in detail in the current List[74].

From the organizational perspective, these and other laboratory tests have preanalytical and analytical steps which can be undertaken in various ways.

Component 4. Supply of HBV vaccine

There are several options for procuring the hepatitis B vaccine. They are described in the relevant section.

Component 5. Monitoring of post-vaccinal complications

For 2 hours immediately after the injection, the patient should be observed by medical workers to monitor for post-vaccinal complications. For three days following the injection, a medical or non-medical worker from the partnership organization that ensures psychosocial management should conduct home visits.

Component 6. Ensuring adherence

The quality of immune response to vaccination depends on the timely administration of the second and third doses of vaccine. In order to increase the effectiveness of the service, work should be conducted to improve adherence. Initial counselling on adherence before completion of the vaccination schedule, and observance of the terms of its administration, is done by the doctor who prescribed the vaccination. In-depth activities on adherence can be conducted through collaboration with NGOs in the same way as other types of psychosocial work.

[74] "List of medical contraindications to performance of preventative immunization" approved by MoH Ukraine Order of 03.02.2006 № 48 "On procedure for conducting preventative immunizations in Ukraine and control of quality and circulation of medical immune biological substances".

Service group 5. Reproductive health

According to WHO guidelines, reproductive health is an indispensible part of overall health. In the context of scaling up services in OST, ART, and rehabilitation programs for PWID—all of which increase the level of social readaptation for this population, provision of sexual and reproductive health services for PWID is increasingly relevant. Including this component in the package of integrated services at HCFs will ensure better accessibility of these services for the target group. Services in reproductive health include counselling on reproductive planning, safe sexual behaviours, family planning; diagnosis and treatment of sexually transmitted diseases and disorders, diseases of the reproductive organs, infertility; and provision of supportive reproductive technologies.

Service 23. Medical consultation on reproductive health

Background. Counselling on reproductive health is a service that is in great demand among patients with dependence, who are initiating OST or are about to undergo rehabilitation. As the sexual functions of these individuals improve or are restored, issues of sexual health, family planning, STI prevention, etc. become relevant. Women in particular need this care; however, men also often require this type of counselling.

In women, restoration of reproductive functions in the absence of a menstrual cycle often results in unwanted pregnancy; hence counselling on contraception and family planning should be offered to all women without waiting for them to ask for it.

Regulatory framework. In accordance with the Order[75], outpatient obstetric-gynaecological care is provided not only in specialized facilities and wards, but also in gynaecologists' offices of the central *rayon* hospitals, general practice /family medicine clinics and examination rooms in polyclinics. This service can be provided either on a regular basis in a specialized office, or by an invited consultant. Labour relations between the consulting doctor and the HCF are governed by regulations described in detail below. It should be noted that obstetricians/gynaecologists, urologists, andrologists, internists, family doctors and other professionals can counsel on reproductive health topics within the scope of their competencies.

The scope of obstetric and gynaecological care and its quality are regulated by norms[76]and clinical protocols[77, 78, 79, 80]. Diagnosis and treatment of urological and sexual disorders is described in protocols, approved by the relevant Orders[81, 82, 83,84]. State social standards (norms) of care for adults in out-patient facilities are approved by MoH Order [20] and include norms in the specialization *Urology* and *Sexual Pathology*.

Content. The content of consultation is determined primarily by the patients' needs and can include diagnosis, treatment, prescription and counselling. According to the Order [75], the organization of out-patient gynaecological

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[75]MOH Ukraine Order of 28.12.2002 № 503 "On improvement of out-patient obstetric-gynecological care in Ukraine".
[76]"Norms of medical care provision to the female population in the specialization "Obstetrics/gynecology" in the setting of ambulatory-polyclinic HCFs" approved by MoH Ukraine Order of 28.12.2002 № 503 "On improving ambulatory obstetric/gynecological care in Ukraine".
[77] MoH Ukraine Order of 15.12.2003 № 582 "On approval of clinical protocols on obstetric and gynecological care".
[78]MOH Ukraine Order of 31.12.2004 № 676 "On approval of clinical protocols on obstetric and gynecological care".
[79]MOH Ukraine Order of 29.12.2005 № 782 "On approval of clinical protocols on obstetric and gynecological care".
[80] MoH Ukraine Order of 03.11.2008 № 624 "On amendments to MoH Ukraine Order of December 15, 2003 № 582 "On approval of clinical protocols on obstetric and gynecological care", MoH Order of 31.12.2004№ 676 "On approval of clinical protocols on obstetric and gynecological care".
[81]MOH Ukraine Order of 06.12.2004 № 604 "On approval of clinical protocols in the specialization "Urology".
[82] MoH Ukraine Order of 17.01.2005 № 23 "On approval of separate protocols on provision of medical care in the specialization "Urology".
[83] MoH Ukraine Order of 03.07.2006 № 431 "On approval of protocols for provision of medical care in the specialization "Sexopathology".
[84]MOH Ukraine Order of 15.06.2007 № 330 "On improvement of provision of urological care to the population of Ukraine".

care includes activities on prevention of gynaecological diseases, early detection and provision of treatment and rehabilitation. In these guidelines, the service *Medical consultation on reproductive health* is considered a purely medical consultation. Gynaecological or urological examination is described as a component of the service *Diagnosis in the area of reproductive health*.

Component 1. Physician's role

In the course of consultation, the doctor takes a medical history, conducts an assessment and physical examination, prescribes laboratory and instrumental tests and treatment for underlying diseases, and makes referrals as needed. Within the scope of his/her competency, the doctor counsels on family planning, prenatal care, sexual health, safe sex, etc. Counselling plays an important role in reproductive health services (diagnosis, treatment) and supports patients' motivation and adherence to timely diagnosis and appropriate treatment.

From an organizational perspective, the doctor's work is the main component of this service. Practical steps for undertaking this component are described in the relevant section. Given the broad range of issues in reproductive health, several professionals of different specializations should be involved in order to meet the needs of all clients.

Service 24. Diagnosis in the reproductive health area

Background. Women in populations that are vulnerable to HIV have poor access to gynaecological examination services. Regular health check-ups allow early diagnosis of diseases and timely treatment of reproductive health problems.

Organizational and regulatory framework. In accordance with item 1.1 of the Order [75], diagnostic interventions in reproductive health for women can be conducted at different levels of out-patient care: in walk-in clinics, feldsher-obstetrical stations (FOSs), general polyclinics, as well as in specialized facilities. Facilities having polyclinic divisions, can create a separate gynaecological office, staffed with a full-time personnel or part-time workers.

In accordance with the Order[85], sexological and andrological diagnosis and treatment can be done in departments of family medical–psychological counselling (which are established in city or *oblast* psychoneurological or psychiatric hospitals), andrology offices (which are created at polyclinics or hospitals that are adequately equipped) or through involvement of a medical consultant.

Diagnosis of reproductive disorders can be done by a doctor – obstetrician-gynaecologist, urologist, andrologist, surgeon, sexopathologists (sexual health specialist), family doctor and other professionals within the scope of their competencies.

Content. Diagnostic assessments can be scheduled (regular health check ups) or conducted "off schedule" in cases of patient self-referral or referral from another doctor. Health check-ups for women are recommended no less than once a year. The scope of evaluation and counselling within scheduled or unscheduled assessments in cases where patients report symptoms is determined by clinical protocols and norms [75–84]. The list of necessary tests depends on indications and can include a general exam and interview (that does not require special equipment and facilities), a specialized exam (gynaecological, urological or andrological exams) and assessment using laboratory and instrumental tests.

Component 1. Physician's role

In the course of a diagnostic assessment, the doctor takes a medical history and conducts a general physical exam, prescribes laboratory and instrumental tests and treatment of underlying diseases, and, if needed, makes referrals. The doctor, within his/her competency, counsels the patient on family planning, prenatal care, sexual health, safe sex, etc. Counselling plays an important role in reproductive health services (diagnosis, treatment) and supports patient motivation and improvement of adherence to timely diagnosis and treatment.

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[85]MOH Ukraine Order of 27.11.1992 № 171 "On improvement of sexological and andrologial care of population of Ukraine".

From an organizational perspective, the doctor's work is the main component of this service. The practical steps of carrying out this component are described in the relevant sectionна стNu0440 69. Given the broad range of issues in reproductive health, involvement of several professionals of different specializations is needed to meet the needs of all clients.

Component 2. Specialized exam

The following exams are conducted in the course of health check-ups: breast palpation, gynaecological cervical exam, obtaining of vaginal smears for Pap-smear and bacteriology, Shiller's test, bimanual exam, digital rectal exam [75]. This procedure is done by the doctor in a specially equipped office. Mobile ambulatory services can also be involved. Approaches to the diagnostic exam are described in a separate section.

Component 3. Laboratory tests

In the diagnosis of reproductive disorders, cytological and bacterioscopic tests are mainly used. Clinical, biochemical, and immunological blood tests and urinalysis can also be prescribed. RTs can be used for testing for pregnancy.

Each of the necessary evaluations can be organized in different ways depending on the availability of laboratory services, test assays and additional equipment. All laboratory tests have preanalytical and analytical steps. It should be noted that for each test, the implementation option is selected independent of other tests (some tests can be done at the facility, others – through collaboration with another laboratory).

Component 4. Instrumental tests

Sonography is a widely used instrumental test; the ways to organize it are described in a separate section. As a rule, most specialized tests (enhanced pelvic radiography, colposcopy, uretroscopy, etc.) should be referred to a specialized facility. For this reason, they are not described in detail in this guideline.

Service 25. Prenatal care

Background. Women who inject drugs and begin OST or rehabilitation may find that reproductive function is restored and they can get pregnant. Quite often, pregnancy occurs even before the regular menstrual cycle is established, and is unplanned; thus the importance of ongoing counselling on contraception and family planning. Neither drug use, nor HIV-status are indications for termination of pregnancy; these women can give birth to healthy babies. Moreover, according to intersectoral Order[86], it is forbidden to try to talk a pregnant woman into termination of pregnancy. Facilities providing services to female PWID should be prepared to provide care to their patients should they become pregnant.

Organizational and regulatory framework. In accordance with the current Order [75], the optimum number of prenatal visits for a pregnant woman is on average 10-12 times. In the absence of pathology, the purpose of these visits is laboratory or instrumental tests, medical exam and counselling. Currently prenatal care up until childbirth is provided by obstetric-gynaecological services, however, if a pregnant woman continues her regular visits to another HCF (AIDS centre, OST program, family medicine clinic), this facility can facilitate timely necessary assessments (on-site as well) and respond in case of complications. All interventions should be coordinated with the prenatal clinic at which the pregnant woman is registered and where her records are kept, and to which her test results should be submitted in a timely manner.

[86]Order of MoH, MOE, Ministry of Ukraine for families, youth and sports, State Penitentiary Department of Ukraine, Ministry of labour and social policy of Ukraine of 23.11.2007 №740/1030/4154/321/614a "On activities for organization of prevention of mother-to-child transmission of HIV, medical care and social case management of HIV-infected families and their children".

Currently, the normative framework on prenatal care addresses the responsibilities of ob-gyn services and provides a description of the family doctor's role[87], but does not define the role of other facilities. If pregnancy is determined at a non-specialized facility that can provide woman a more convenient schedule and on-site assessment, communication should be established with the prenatal clinic, the scope of responsibilities of each facility should be delineated and collaboration mechanisms set up. Completion of an individual pregnancy record, labour and delivery record (form № 111/o) and exchange card (form № 113/o) is the responsibility of the prenatal clinic doctor.

Content. All consultative and diagnostic interventions indicated in an uncomplicated pregnancy and in case of potential complications are described in the relevant protocols [75, 76]. The main components of this service are the physician's work and diagnostic tests.

It should be stressed that during pregnancy, it is very important to test for HIV as early as possible in order to provide appropriate interventions in a timely manner. Testing is done at registration and once more, in the case of a negative result, at 22-23 weeks of gestation. HIV testing is voluntary with pre-test and post counselling provided Service 1 *HIV testing and counselling*).

Should complications develop and specialized treatment be needed, referral should be made to obstetric/gynaecological facilities.

Component 1. Physicians' role

An obstetrician/gynaecologist, who can manage pregnancy and keep the appropriate records at the prenatal clinic plays a key role in providing prenatal care. The doctor conducts a physical exam, provides counselling, prescribes laboratory and instrumental tests, and makes referrals to other specialists for additional assessment. Some of these functions can be performed by doctors and consultants from non-specialized facilities that are visited by women on a regular basis. The necessary specialist can be involved in a number of different ways.

Similarly other professionals– narcologist, skin specialist, neurologist and the like, can be invited for consultation if needed.

Component 2. Specialized assessment

A general exam is followed by an obstetric exam, including pelvic measurements, vaginal exam including measuring the diagonal conjugate and calculation of the true conjugate. Gynaecological exam for a pregnant woman includes examination of the cervix with specula, and obtaining smears from vagina, cervical canal, and urethra for bacterioscopy [75]. This procedure is performed by a doctor during examination in a specially equipped room. Ways to organize a gynaecological exam are described in a separate section.

Women with uncomplicated pregnancies without any abnormalities in the cervix and vagina undergo an internal obstetric exam two times (at the time of registration and at 30 weeks of pregnancy).

Component 3. Laboratory tests

HIV and pregnancy laboratory tests are an integral part of this service. Types and frequency of these exams are listed in the appropriate specialization protocols [21] and norms [76].

For all laboratory tests, the organization of preanalytical and analytical steps is universal. For various types of tests, different options for preanalytical and analytical steps can be used (for instance, the analytical step of clinical exam can be carried out at the facility, and the immunological tests can be done by sending the sample out to another facility's lab).

Component 4. Instrumental tests

[87]Appendix 17 "Specific features of the family doctor's role in provision of obstetric-gynecological care" to "Guidelines on organization of ambulatory obstetric-gynecological care" approved by MoH Ukraine Order of 28.12.2002 № 503 "On improvement of ambulatory obstetric-gynecological care in Ukraine".

In addition to laboratory tests, clinical protocols [76] include mandatory instrumental tests such as BP and sonography. Other tests are done if indicated. Practical steps for carrying out sonography and ECG are described in the relevant sections. In the case of suspected pulmonary TB, a chest X-ray should be prescribed.

Service 26. Prevention of mother to child transmission

Background. Prevention of mother-to-child/vertical transmission (PMTCT) – is a set of treatment, prevention, social and psychological interventions aimed at reducing the likelihood of prenatal, intranatal and postnatal mother-to-child transmission of HIV. If done appropriately, PMTCT allows reducing the potential vertical transmission rate to 2%.

Organizational and regulatory framework. As stated in the intersectoral Order [86], comprehensive implementation of PMTCT requires the involvement of many specialists from different facilities. The clinical aspects of PMTCT are described in the clinical protocol[88].

There are four potential scenarios for PMTCT: 1) pregnant women who by their immunological status do not need ART; 2) pregnant women with indications for ART identified in the course of pregnancy; 3) pregnant women who initiated ART before pregnancy; 4) pregnant women whose HIV-status was detected just before childbirth or during labour and delivery. In the latter case, care is provided in obstetric institutions in accordance with the approved protocols, hence it is not discussed in this guideline. In the former three cases, care includes prescription, switching or continuation of an ART regimen in accordance with the current protocol [88].

In these cases, a woman receives her ARVs in the prenatal clinic or in the regional AIDS centre, or in the facility where she had been receiving them before pregnancy. In order to start providing PMTCT at a non-specialized facility, a comprehensive ART site needs to be established as well as collaboration with a prenatal clinic and an AIDS centre doctor, to coordinate diagnostic and counselling interventions.

If the HCF can provide ART on-site, then the non-specialized facility which provides other services for female PWID with HIV can facilitate timely assessments, receiving of ARVs as well as conducting counselling and training.

In all cases, special attention should be paid to activities for promoting adherence. In the case of daily visits to the facility, DOTS can be implemented.

Content. In terms of structure, *Prevention of mother-to child transmission (vertical transmission prevention*) is a synthesis of three other services: *HIV disease management*, *Antiretroviral therapy* and *Prenatal care* (services 3, 4, and 25 respectively). A detailed description of the content of these services can be found in the relevant sections of this guideline.

Component 1. Physicians' role

An infectious disease physician authorized to carry out HIV management and prescribe ART plays the central role in PMTCT provision. This doctor performs a physical exam, provides counselling, prescribes laboratory and instrumental tests, prescribes ART and conducts monitoring of the treatment. He/she also conducts the initial counselling on adherence, and provides referrals to other specialists for additional evaluation. The infectious disease physician should work in close collaboration with the AIDS centre obstetric/gynaecological and prenatal clinic doctor who provides prenatal care. If these doctors are not available at the facility (or they cannot provide services to additional patients), involvement of an appropriate specialist can be undertaken in one of the prescribed ways.

In a similar manner, other specialists– narcologist, psychiatrist, dermatologist/venereologist, neurologist and the like, can be invited for consultation if needed.

Component 2.Nurse's role

[88]MoH Ukraine Order of 14.11.2007 № 716 "On approval of clinical protocol on obstetric care "Prevention of mother-to-child transmission of HIV".

A nurse links the doctor and the patient, organizes patient assessments, makes repeat appointments, provides psychological support, monitors adherence, counsels on reproductive health and risk behaviour, provides home-based care, palliative care, and ensures control of medications (dispensing, storage and documentation).

If mid-level medical personnel are not available to fulfil all these functions, there are several options of involving additional personnelна стNu0440 69.

Component 3. MDT (optional)

At the minimum (prescription and dispensing of ARVs), PMTCT can be implemented by one doctor and one midlevel health care professional. However, creation of a MDT will allow significant improvement in the quality of the service and effectiveness of treatment. Besides an infectious diseases physician and a nurse, it is important to include an obstetrician/gynaecologist, paediatrician, narcologist and a social worker. General principles of MDT formation are the same for all services.

Component 4. Supply of ARVs

There are several options for procuring ARV medications. They are described in the relevant section.

Component 5. Laboratory tests

Laboratory testing for HIV and for pregnancy is an indispensible component of this service. Types and frequency of testing are set out in special protocols [21] and norms [76].

Practical approaches for carrying out preanalytical and analytical steps are the same for all laboratory testing. In the course of undertaking various types of tests, different types of preanalytical and analytical steps can be used independently (for instance, the analytical step of clinical tests is implemented at the facility site and immunological tests are done by sending samples out to another facility's lab).

Component 6. Instrumental tests

Besides laboratory tests, the clinical protocols [21, 76] call for mandatory instrumental tests. Practical steps for performing sonography and ECG are described in the relevant sections. If pulmonary TB is suspected, a chest X-ray should be prescribed.

Component 7. Record keeping and reporting

Facilities that maintain records of regular outpatient follow-up for patients with HIV, must complete a registration card for a person with HIV (form № 502-1/o) and other records and reports approved by the Ministry of Health of Ukraine and the State committee of statistics of Ukraine [19]. The system for HIV/AIDS treatment monitoring approved by the relevant Order [27], specifies using standard forms from the time of registration, irrespective of whether or not the patient is on ART.

Findings of the obstetric/gynaecological exam and testing are recorded on form № 111/o *Individual prenatal and childbirth record* [63] and form № 113/o *Referral record to the maternity hospital, hospital delivery ward*[89].

Component 8. Provision of infant formula

To prevent infection of an infant during breastfeeding, the regional AIDS centre dispenses milk formula for newborns. The formula is dispensed directly to parents (guardians) on condition that a child is registered for regular observation. Provision of milk formula is funded through local budgets in accordance with regulation[90] and Order [86].

Component 9. Promotion of adherence

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[89]MoH Ukraine Order of 13.02.2006 № 67 "On approval of primary recording forms in facilities providing prenatal, intranatal and postnatal medical care to women, and instructions concerning their completion".
[90]Regulation of the Cabinet of Ministers of Ukraine of 08.02.1994 № 66 "On additional social guarantees for families with low income having sick children and children of one and two years of age".

Besides counselling provided by a doctor and nurse during the visit, there is room for additional interventions to promote adherence; NGOs and civic organizations can provide specific counselling, case management, and training interventions. Case management activities can be organized in a number of different ways.

Service group 6. Sexually transmitted infections

Diagnosis and treatment of STIs and counselling on safe sex at a HCF providing integrated services for PWID are both components in the system of reproductive health services and also separate services in their own right. The importance of including these services in the system of integrated care is evident in view of a significant increase in the percentage of people who acquire HIV through sexual transmission, the increasing incidence of STIs in Ukraine, and the increased vulnerability to sexually transmitted HIV in the presence of other STIs.

Service 27. Consultation with a dermatologist/venereologist

Background. Consultation with a dermatologist/venereologist on STIs, as well as on skin problems is an important service for PWID due to the high prevalence of these problems in Ukraine and their impact on HIV transmission.

Regulatory framework. The scope and quality of medical care are regulated by state social standards and clinical protocols. State social standards (norms) of health care for the adult population in ambulatory-polyclinic facilities are approved by health ministry Order [20] and comprise standards for the specialization *Dermatology/venereology*. The doctor should be guided by clinical protocols[91], standards and methods[92], as well as by separate health ministry Orders[93,94].

In addition to dermatologists/venerologists, obstetricians/gynaecologists, urologists, internists and family doctors also have the right to carry out diagnosis and treatment of certain STIs. Labour relations between the consultant physician and the HCF depend on the type of collaboration and are governed by several regulations that are described in detail in the section related to involvement of doctors.

Content. The content of the consultation is determined primarily by patient needs and can include diagnosis, treatment and counselling. For patients from vulnerable populations, it is recommended that counselling be conducted no less than once a year.

Component 1. Physician's role

The dermatologist/venereologist makes a diagnosis (takes history, conducts assessment and physical exam, prescribes laboratory and instrumental tests) and treats relevant diseases. The doctor can also conduct counselling on safe sex, the need to notify sex partners, motivation for diagnosis and treatment, and use of condoms. Counselling plays an important role in services on STI (diagnosis, treatment) and ensures the development of patient motivation and adherence.

From an organizational perspective, the main component of this service is the physician's work. Practical steps for carrying out this component are described in the relevant section.

Component 2. Diagnostic exam (if applicable)

It is important that the dermatologist/venereologist conduct counselling at the time of diagnostic examination. Medical exams can identify suspicion of STI in a patient and support selection of appropriate diagnostic measures; the exam should be based on the patient's description of symptoms. During the exam, the doctor evaluates the genitourinary system and can obtain samples for bacteriological or cytological tests. The medical exam is not a mandatory component of this service (i.e. counselling can be conducted without examination).

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[91]MoH Ukraine Order of 08.05.2009 № 312"On approval of clinical protocols on provision of medical care to patients with dermatological/venereological diseases".
[92]"Methods of diagnosis, treatment and prevention of sexually transmitted infections" approved by MoH Ukraine Order of 07.06.2004 № 286 "On improvement of dermatological/venereological care for the population of Ukraine".
[93] MoH Ukraine Order of 30.12.1992 № 207 "On organization of dermatological/venereological care for the population of Ukraine".
[94]MoH Ukraine Order of 07.06.2004 № 286 "On improvement of dermatological/venereological care for the population of Ukraine".

Ways to provide the diagnostic exam are described in a separate section.

Service 28. STI diagnosis

Background. STI diagnosis should be provided according to the clients' needs, ensuring the most convenient and smooth access. For drug dependent individuals, diagnosis can take place at needle exchange points, community centres or facilities offering OST programs. This approach will support achieving an adequate level of coverage of the target group.

Organizational and regulatory framework. Diagnostic approaches for STI service provision are approved by the regulatory Orders of the Ministry of Health in dermatology/venereology [93, 94]. There are also specific documents related to specific diseases[95, 96, 97]or patient groups[98,99].

Screening for STIs can be carried out in various settings to make this service more accessible to clients—not only at HCFs, but also at mobile clinics and NGOs providing services to the target group. Currently there are no limitations on the types of HCFs that can perform testing for STIs, however only a dermatologist/venereologist can confirm the final diagnosis. In accordance with Order [93], if a venereal disease (syphilis, gonorrhoea) or contagious skin disease is diagnosed, the patient is registered in the doctor's register using his/her passport data; a case notification form is completed (form № 089y or № 058), and is sent to the regional dermatological dispensary.

STI testing (except testing for syphilis in an in-patient setting) is voluntary; education should be provided to allow patients to understand the importance of these tests.

Content. In accordance with the Order [94], screening is conducted for all in-patients, and once a year for those who seek care at all types of HCFs. Diagnostic tests are performed according to clinical indications for symptomatic patients in order to identify etiology and refine diagnosis. Diagnostic tests are also performed for asymptomatic individuals, who seek care for reasons not related to STIs.

Component 1. Physician's role

To diagnose STIs, the doctor takes the history, the patient's description of symptoms, assesses the patient's status according to diagnostic criteria and prescribes laboratory tests. Any specialist can prescribe testing for STIs.

From an organizational perspective, the main component of the service is the physician's work. Practical steps for carrying out this component are described in the relevant section.

Component 2. Diagnostic exam (if applicable)

For some bacteriological tests for STIs, samples from the genitals should be obtained. This procedure is carried out by a doctor in a specially equipped office or in a mobile clinic. Ways to organize the diagnostic exam procedure are described in a separate section.

Component 3. Laboratory tests

For STI diagnosis, microscopic, culture, immunological, cytological, biochemical and other types of laboratory tests are used. For the majority of common STIs there are also RTs using immunofiltration and imunochromatography.

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[95] MoH Ukraine Order of 29.12.1992 № 204 "On organization of laboratory diagnostics for syphilis in Ukraine".
[96]MavrovG. I. et al. Protocols of laboratory diagnostics for infections caused by Neisseria Gonorrhoeae. Dermatology and Venereology 2007; 1 (35).
[97]MoH Ukraine Order of 12.06.1996 № 163 "On approval of Instruction on diagnosis and treatment of gonorrhea and syphilis".
[98]Mavrov G.I., Nagorniy O. E. Diagnostics of sexually transmitted infections in groups of the population vulnerable to HIV-infection. Institute of dermatology and venereology of NAMS, Ukraine, Institute of Urology of NAMS Ukraine.
[99]"Models of organization for provision of services in diagnosis and treatment of STIs in representatives of vulnerable groups of the population" (guidelines), approved by MoH Ukraine, Committee on countering HIV-/AIDS and other socially dangerous diseases, Ukrainian AIDS center, 2009.

For rapid testing, blood or serum (in the case of syphilis), smear or urine (in case of gonorrhoea, Chlamydia) are used.

Each of the necessary tests can be carried out in various ways depending on the availability of laboratory facilities, test kits and additional equipment. All laboratory tests have preanalytical and analytical steps. For each of the tests, the method for carrying out the test is chosen irrespective of other tests (thus some tests can be done at the facility site, others – through collaboration with another laboratory).

Service 29. Treatment of STIs

Background. Effective and timely treatment of STIs is extremely important for the improvement of the patient's life and decreased likelihood of sexual transmission of HIV. In Ukraine, medications are provided for members of risk groups. Medications are funded by international donors, however, significant efforts are required to establish collaboration between different facilities in order to make these drugs available to patients. Making this service more accessible for the target group will significantly increase coverage and assure timely treatment leading to improvement of epidemiological situation both in STIs and HIV.

Organizational and regulatory framework. STI treatment is performed by physicians with appropriate training – dermatologists/venerologists, gynaecologists, urologists, internists, family doctors who treat STIs; however, in case of diagnosed syphilis or gonorrhoea, consultation of a dermatologist/venereologist is mandatory.

STI treatment regimens are described in detail in clinical protocols [91], Order [94], instruction [97] and guidelines[100]. The following types for STI treatment can be distinguished [99]: preventative (for people with sexual or household contact with an STI patient), syndromal (based on clinical findings and risk assessment), semisyndromal (based on rapid-test results) and etiological (based on the results of confirmatory laboratory tests). In accordance with recent recommendations [100], given the potential for multiple infections and impossibility of obtaining results from all laboratory tests in one day/during one visit, the use of syndromal and preventative approaches is optimal for vulnerable populations.

In the majority of cases, treatment does not require prolonged use of medications (in several regimens the medication is administration once), and is conducted on an out-patient basis or in a day-treatment facility. In some cases, the patient need not be referred to the dermatological/venereological dispensary for in-patient treatment [91].

Content. Before prescribing treatment, the doctor should determine indications and contraindications. Taking into account the low likelihood of a repeat visit by patient from vulnerable groups, diagnosis and treatment should be attempted in one visit. During this one visit, the opportunity should be taken to conduct patient education and counselling, and provide condoms.

Component 1.Physician's role

STI treatment can be prescribed by a doctor with appropriate specialized training, however, in the majority of cases, it is important to ensure consultation with an experienced dermatologist. Practical steps for involving this doctor are described in the relevant section.

The doctor takes the history, patient's description of symptoms, assesses the patient's condition in accordance with diagnostic criteria, makes a clinical diagnosis, keeps the necessary records, prescribes treatment and, if needed, adjusts treatment.

Component 2. The nurse's role

Within the service *Treatment of STIs*, the nurse administers the doctor's prescriptions and conducts initial counselling on adherence to treatment. Practical steps of the nurse's work are described in the relevant section.

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[100] "Specific features of treating sexually transmitted infections in groups of the population vulnerable to infection with human immune deficiency virus (guidelines)" approved by MoH Ukraine and Institute of dermatology and venereology of NAMS Ukraine, 2009.

Component 3. Supply of medications

Various classes of antibiotics are used to treat STIs. There are several options for providing treatment to patients.

Service group 7. General health

Service 30. Consultation of another specialist

Background. After initiation of OST or rehabilitation, one of the first challenges faced by patients is their health status. Patients no longer feel the analgesic action of a drug, and symptoms of comorbidities which they never noticed before, begin to manifest. These problems may be various in nature, however, the most common are pulmonary diseases (bronchitis, pneumonia), vascular problems (thrombophlebitis, trophic ulcers), neurological disorders, and oral cavity diseases. Moreover, if the patients start TB or HIV treatment, they are faced with the side effects of medications on other organs and systems.

Consultation with a specialist– internist, neurologist, surgeon, vascular surgeon and the like, is an extremely important service for PWID and OST patients.

Organizational and regulatory framework. The scope of medical care and its quality is regulated by state social standards and clinical protocols. State social standards (norms) of health care services for adults in ambulatory-polyclinic facilities are approved by MoH Order [20] and include norms in the specializations of *Neurology*, *Pulmonology*, *Cardiology*, *Internal medicine*, *Surgery*, etc. Each doctor in his/her respective discipline should be guided by MoH approved guidelines and clinical protocols.

Labour relations between the doctor consultant and the inviting HCF depend on the type of collaboration and are governed by several regulations, which are described in detail in the section on doctors' involvement.

Content. The content of consultation is determined primarily by the patients' needs and can include diagnosis, treatment and counselling. Diagnostic methods for this service can include interview, history taking, assessment and physical exam. The doctor can also prescribe additional tests; the feasibility of providing these tests at the HCF is considered under the framework of service 31 (*Diagnosis of comorbidities*). Special treatments are also considered separately (under the framework of service 32 *Outpatient treatment of comorbidities*).

Component 1. Physician's role

From an organizational perspective, the only component of the service is the physician's work. Practical steps for implementation are described in the relevant section.

Service 31. Diagnosis of comorbidities

Background. Comorbidities among PWID and OST patients are an important consideration, which can prevent further participation in treatment programs. For diagnosis of these diseases, patients require easy access to clinical and specialized methods of diagnosis.

Organizational and regulatory framework. Any specialist has the right to prescribe and interpret findings from clinical laboratory tests. Some specialized tests require the participation of specialists, however, all doctors should have the skills to evaluate basic tests such as chest X-ray and ECG.

The optimal way to provide the most frequently required tests, is to perform them at on-site. The majority of secondary and higher level HCFs have laboratory facilities to ensure performance of the necessary tests.

Content. Methods of diagnosis, besides clinical (interview, medical history, exam and physical exam), that are conducted under the framework of service 31 (*Consultation with another specialist*) can include general, biochemical, immunological, bacteriological, cytological and other types of laboratory tests. The most common instrumental tests include imaging methods (chest X-ray, X-ray of bones, CT, methods with radiographic enhancement and the like), sonography, and ECG.

Component 1. Laboratory tests

Each one of the necessary tests can be carried out in a number ways, depending on the availability of laboratory facilities, test assays and additional equipment. All laboratory tests have preanalytical and analytical steps. The method for carrying out each test should be chosen irrespective of other tests (that is, several tests can be organized at the facility site, the rest – through collaboration with another laboratory).

Component 2. Instrumental tests

Facilities are most likely to be able to conduct the most common tests; this guideline discusses options for implementation of sonography, ECG and radiography. More specialized methods, as a rule, need to be referred to a specialized facility, and are therefore not discussed in detail in this guideline.

Service 32. Out-patient treatment of comorbidities

Background. Regular treatment of comorbidities on an out-patient basis at a facility that provides services to PWID, or to patients on OST, decreases the risk of treatment interruption and improves adherence.

Content. Pharmaceutical treatment of comorbidities in an out-patient setting can be prescribed by consulting physicians within service 30 (*Consultation by other specialists*). This service is considered separately, in order to focus on other out-patient treatment methods in non-specialized facilities—such as minor surgical interventions, wound management and bandaging, and some endoscopic procedures.

Organizational and regulatory framework. Implementation of treatment interventions is possible only in specially equipped offices. The majority of general facilities have a surgical department or surgical office with a surgical dressing area in the polyclinic. Surgical offices, dressing areas and other specialized offices should meet the requirements outlined in the sanitary rules and norms [101].

To conduct an intervention, a doctor with the appropriate qualification should be invited. This can be either facility staff or an invited consultant. Labour relations between the doctor-consultant and the inviting HCF depend on the type of collaboration and are governed by regulations described in detail in the section dedicated to involvement of doctors.

Component 1. Physician's role

From an organizational perspective, the primary component for providing specialized treatment interventions is the doctor's work. The doctor should have the necessary training and be aware of all aspects of care for people with drug dependence and HIV.

Practical implementation steps are described in the relevant section.

Component 2. The nurse's role (is applicable)

In the majority of treatment procedures, the participation of a nurse is required. Some procedures (for instance, dressing) can be performed by a nurse independently, following the doctor's prescription, and without his/her presence. Practical steps for organizing the nurse's work are described in the relevant section.

Component 3. Creating conditions for interventions

To provide this service at a facility, a mechanism for interaction between the division managing PWID or OST patients and the division which has the office required for the procedure, needs to be developed. It is important to ensure that patients have free access to services as needed.

If the facility does not have a room equipped for the necessary procedures, coordination with the closest facility having the necessary equipment should be established.

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[101] SanPiN 5179-90 "Sanitary rules of setting, equipping and running hospitals, maternity hospitals and in-patient departments" approved by the Chief State sanitary doctor of USSR, of June 29, 1990.

Service group 8. Psychosocial services

In accordance with the Law of Ukraine [38], social services are a set of legal, economic, psychological, educational, medical, rehabilitation and other activities, targeted at specific social groups or individuals living in difficult circumstances and in need of assistance.

The purpose of providing psychosocial services for PWID and OST patients is to improve the quality of their lives and support resocialization. These services should help patients to:

- decrease the rate of street drug use or to completely quit them;
- resolve issues associated with drug abuse (legal, social, family, etc.);
- decrease risk behaviours, in particular the risk of HIV, HBV, HCV infection and other blood born diseases and STIs;
- decrease the likelihood of relapse (resuming street drug abuse in the future);
- decrease criminal activity;
- stabilize emotional status; and
- facilitate access to health care for medical and other disorders.

Providing adequate psychosocial support is a catalyst for meeting the goals of all other services, due to associated higher levels of adherence to diagnosis and treatment.

Service 33. Social services

Background. Social work includes various activities provided by a person who has the necessary training, and is also readily accessible to patients. Provision of such services has different purposes, all of which are pertinent to clients.

Organizational framework. These services are provided by social workers, who have been trained in providing social services in the areas of OST, HIV and TB/HIV. Standards [36] describe the qualification requirements of personnel, but also note that a person without appropriate educational qualifications can work as a social worker provided they have undergone appropriate training or graduation from a short-term course, been tested by a service provider, and received a relevant certificate.

Provision of social services should be based on the principles outlined in the Law of Ukraine [38].

Content of services. A complete list of services for different target groups is provided in the relevant standards [37].For PWID and OST patients the most relevant are the following services:

- pre-test counselling for PWID related to their potential participation in an OST program and other programs for PWID, and provision of the necessary printed information on this topic;
- counselling on prevention of complications caused by substance use;
- accompanying the patient referred or transferred to other HCFs;
- motivating the client for evaluation and treatment by providing preliminary and follow-up consultations;
- identification of the client's economic problems, as well as assistance in accessing "internal resources" to address these issues.

Methods of psychosocial management and content of interventions are described in other guidelines and standards [35, 36], and are not considered in detail in this document.

Component 1. Provision of psychosocial work

From an organizational perspective, a social worker or psychologist should be involved in providing this service and the optimal conditions should be created to enable them to carry out their work. Options for implementation of these components are described in the relevant section.

Service 34. Case management

Background. In this guideline, case management is considered a separate service; it is a holistic approach used for improving and facilitating access of patients to all possible services. By provisionally subdividing factors hindering access to services into two categories – institutional (on the part of institution), and personal (on the part of the client), it becomes evident that effective integration of services removes only the barriers in the first category; it is case management that helps in resolving the second group of problems. Among such personal factors often encountered among PWID, are low awareness about available services, low motivation, presence of mental disorders, inadequately developed social skills and the like. Some PWID seriously care for their health and can undergo all the needed assessments and adhere to the doctor's prescriptions, however, the majority of PWID and OST patients require ongoing assistance and guidance.

Case management is a long-term individual intervention conducted by a trained worker with the purpose of timely and effective receipt of medical or social services by a client. This work is based on an existing administrative structure and the case manager's responsibilities do not include establishing linkages between facilities, invitation of consultants and other functions, the fulfilment of which is the responsibility of ICC manager.

In a sense, the case manager serves as a mediator between the client and all service providers; he/she needs to have all client information and be able to refer clients for assessment or consultation in a timely manner. The case manager's work can be compared with that of a guide on a mountain route, whose responsibilities include support, help, and obtaining information from the client, attending physician and counsellors. This professional should function as an advisor and supervisor, should have a good understanding of the client's needs and resources, including those about which the care recipient may not readily inform a stranger. The case manager should have the skills of empathic (sympathetic) listening and of establishing relations of trust (therapeutic alliance), be well informed on general issues of drug dependence and HIV/AIDS treatment, know the laws and be able to advocate for the clients' rights.

Organizational framework. Case management, as a separate approach, is currently not defined in any regulation. The main principles of this approach are outlined in guidelines[102], however there is no complete textbook or manual on case management in Ukraine to date. The most rational option is for social workers or psychologists to act as case managers, however, in practice, this role is often performed by the attending physician [1].

Content. In the case management process the following stages are identified;

- initial assessment; includes establishing contact with the client, history taking and analysis of information concerning needs, problems, strengths and weaknesses of the client;
- planning of care; this is the stage of decision-making, agreement with the client on the purpose and objectives of treatment and developing an action plan, selecting methods of work, review of resources and timeline, reaching agreement on services and expected outcomes;
- implementation of the plan; includes use by the client of his/her own knowledge, competence, and resources; and professional knowledge of the social worker and monitoring of the work;
- final evaluation; assessment of results in terms of meeting the goals, accomplishments, and readiness of the client to sustain the relationship with the case manager.

In long-term programs, case management can be provided on an ongoing basis throughout the entire term of the patient's treatment.

Component 1. Organization of psychosocial work

From an organizational perspective, this service requires the involvement of a social worker or a psychologist (or, if they are not available – of the attending physician). Implementation options are described in the relevant section.

Service 35. Legal consultation

[102] Social and psychological support for clients of substitution maintenance therapy programs. Guidelines.- UIRPHP.- Kyiv, 2008.

Background. Even after discontinuation of active drug use, many representatives of the target group continue to have problems with violations of the law. There are also cases of human rights violations on the part of law enforcement, medical and social institutions, because this individual belongs to a socially disadvantaged group. Prolonged drug use results in problems with identity documents, receipt of social support, parental rights, home ownership rights and the like. Assistance with these issues allows clients to stabilize their lives and have the time to address health problems.

Organizational framework. Consultation on legal issues and criminal cases is the responsibility of a professional lawyer, however, assistance regarding other issues can be provided by other workers with special knowledge, training and experience.

Content. Within the scope of their competencies, consultants can provide assistance on the following issues:

- accessing social services at state, municipal and nongovernmental institutions;
- generation and submission of complaints on actions or inaction of facilities, services or their staff that violate the clients' rights;
- preparing documents for employment, obtaining passport and other legal documents;
- receiving welfare assistance for disabled citizens from the Ukrainian Fund for social security;
- preparing documents to establish guardianship over legally incapacitated persons;
- getting certificates including those that confer rights for special privileges;
- obtaining social welfare and compensations as set by law (one-time assistance when a child is born; for childcare until the child reaches 3 years of age; for childcare for single mothers; state welfare for low income families; state social support for individuals not eligible to receive pension and disabled persons; state social support for care; support for burial);
- obtaining subsidies for reimbursement of utilities, purchasing of condensed gas, liquid and solid household fuel;
- receiving disability status.

If needed, the social worker should accompany the client to the relevant authorities' offices and assist in obtaining the necessary papers.

Component 1. Involvement of a consultant

From an organizational perspective, the only component of this service is involvement of a trained consultant on legal issues. The options for involving such a consultant are described in a separate section.

Service 36. Psychological consultations

Background. Quality support from a psychologist helps clients to stabilize their mental status, increases motivation for treatment and facilitates resolution of family and social problems.

Organizational framework. This service can be provided by a psychologist or a social worker on-site at any facility, provided the necessary conditions are in place. The content and format of counselling should be based on the principles laid out in the Law of Ukraine [38]. In his/her work, the psychologist should use standard methods that have proven effectiveness (for instance, cognitive-behavioural psychotherapy, motivational therapy and the like). The content of these methods is described in textbooks and guidelines.

Content. Psychological work at every stage should have the clear goal – cessation of illegal drug use, improvement of psychological status, adherence to specific treatment or other. Counselling can be provided in the format of individual, family or group work.

Individual work may include assessment of the psychological status of a client, developing an individual plan of recovery in conjunction with the social worker, review of the plan on a regular basis, working with emotional stimuli, development of coping skills in problematic situations without relapse to substance use, and the like.

Group work can be conducted in the format of trainings, the main goal of which is to develop clients' skills to resolve specific problems, master models of productive interaction, engage in conflict resolution, establish interaction, overcome psychological crisis, plan for the future, etc. Also topic-specific groups, devoted to discussion of specific problems with the purpose of their resolution, can be conducted; any clients experiencing the specific problem is a concern can be involved.

Another approach in psychological work is the creation and development of self-help groups among clients. In this case, the help of a qualified psychologist is needed only at the initial stage.

Component 1. Organization of psychosocial work

From an organizational perspective, a psychologist or social worker should be involved and appropriate working conditions created. Options for implementation are described in the relevant sectionна стNu0440 85.

Service 37. Information and educational services

Background. Provision of timely objective information on health issues, on availability of services at HCFs or at partnership organizations, on ways to resolve problems, and the like, promotes increased demand from clients for services and has a significant impact on prevention.

Organizational framework. Education should be provided on an ongoing basis by every professional at the facility who is working with the target group – volunteers, social workers, psychologists, nurses and doctors. Information can be passive (dissemination of printed materials, posters) or active – through individual or group counselling; these counselling sessions can be either client-initiated or facility-initiated. An appropriate information strategy requires coordination on the part of the facility or division manager. The optimal form of coordination is a MDT. At MDT sessions, all members can agree on the targeted coverage of certain clients and agree on specific issues.

Content. Educational activities can cover the following topics:

- list of services available at the facility and at partner organizations, with contact information for the responsible persons;
- the first signs of dangerous diseases (TB, HIV, hepatitis, STI, etc), methods of detection and treatment, importance of adherence to treatment regime;
- prevention of infectious diseases (TB, HIV, hepatitis, STI, etc.), skills of safe sexual behaviour;
- consequence of substance use and harm reduction; and
- other topics and information about partnership organizations.

The frequency of active information events should coincide with client needs, and not complicate life for clients.

Component 1. Organization of information activities

From an organizational perspective, implementation of this service is the responsibility of every facility worker, and this point should be emphasized at the time of personnel recruitment or invitation of consultants. Conducting active information events requires conditions similar to those needed for provision of other psychosocial services. Options and steps for implementation of this work are described in the relevant section.

Service 38. Peer support

Background and content. Stable patients, i.e. those who do not manifest any signs of withdrawal syndrome, psychotic disorders, or significant asocial behaviour, if willing, should be involved as peers in work with clients of therapeutic and preventative program. The objective of this work is to provide psychological support to therapeutic programs clients, to relieve their feelings of loneliness and isolation, to increase their self-esteem as well to provide information on the rules of behaviour in the treatment facility, on opportunities for obtaining medical and psychosocial services, and on less risky drug use.

Peer support is a popular concept that supports members of a certain group to work with other members of the same group in order to achieve behaviour modification. On the individual level, use of this method is aimed at changing the assumptions, beliefs or behaviour of a person.

This method is based on psychological and social theories, and on the belief that communication with certain members of a particular group and development of ways to resolve problems with the help of peers can promote more effective behaviour modification. In this case, people change, not due to availability of new evidence, but as a result of subjective judgments of people close to them and whom the trust.

Peer counsellors can establish effective and confidential relations since they have adequate knowledge of the target audience, and use understandable language and terminology, as well as non-verbal means of communication (for instance, gestures); this allows their clients to feel comfortable in the course of discussion of various issues, especially those related to sexual behaviour and HIV/AIDS.

Counsellors and their target audience are equal in terms of their individual and group status as representatives of a certain socio-cultural environment. For this reason, peer counsellors can provide good examples for behaviour modification.

The peer method expands participation of the target audience into planning, practical implementation and evaluation of the program. This method increases the level of consciousness of both “teacher”, and ‘pupil” through a horizontal, dialogue-based approach to education.

Component 1. Involvement and education of volunteers

From the organizational perspective, there is a need to select and train volunteer counsellors to provide peer counselling.

Selection of counsellors for peer support is very important for the success of the program. Mentors should be leaders, shaping views of the peers. It is important that they be acceptable to the target group members and suitable for education and further work.

All volunteers who agree to conduct such work should participate in training or instruction on issues relevant to the target group. These include issues of access to available services, prevention, diagnosis and treatment of infectious diseases, use of illegal drugs and harm reduction approaches, and the like. For volunteer training, it is best to involve NGOs that are experienced in work with PWID and understand the peer-based method.

Initially, effective counsellors can work on a volunteer basis, however, at a later point, it is desirable to pay for their support (by hiring them at 0.25–0.5 of a full-time position as social workers or involving them in work through partnership NGOs).

Service group 9. Harm reduction

Harm reduction is an approach that considers drug use from a realistic perspective and focuses on feasible objectives. This principle recognizes that some people will continue to use drugs; hence, drug use remains a continued phenomenon in our society. The priority in these programs is achievement of quick and realistic reduction of harm created by drugs, and reduction of the consequences of drug use both for PWID and for society at large.

Harm reduction strategies and integrated approaches to service provision have much in common. Both concepts aim at the prevention of HIV and other diseases, facilitate the access of PWID to quality health service, improve clients' health status and increase the level of social adaptation. Some of the main components of a harm reduction strategy are already included in the proposed guideline as independent services. These include consultations by medical specialists (services 2, 7, 13, 14, 19, 23, 27, 30), information and counselling on medical and social issues (services 33, 34, 36, 37), and access to HIV, TB, and STI testing (services 1, 9, 10, 28). For this reason, in this section dedicated to *Harm reduction* only one service is considered – dissemination of the means for HIV prevention. In this context, provision of clean syringes and provision of condoms to PWID and OST clients serve the same purpose, and these activities are therefore considered as one integral service.

Service 39. Distribution of means of prevention

Background. Distribution of syringes is a proven method for prevention of transmission of blood born infections among PWID. Although among OST patients the rate of drug use is not high, access to sterile injection paraphernalia plays important role in case of occasional substance use, and facilitates provision of this equipment to those members of the social network who continue active drug use.

Promotion of safe sex among PWID is important, both for prevention of viral transmission to other populations, and for prevention of sexual transmission among PWID themselves. Continuity and anonymity of access, and distribution of condoms for PWID free of charge, are the most important aspects for this service.

Syringes and condoms are available for purchase in the majority of pharmacies or stores, however, in reality, accessibility is low, due to their high cost, the inconvenience or remoteness of the places of sale, lack of anonymity and psychological features of the target group.

Organizational framework. Although provision of services for harm reduction is not forbidden at HCFs, there are currently no documents to regulate distribution of syringes and condoms at a HCF using its own funds, or the funds of local and state budgets. The only mechanism to provide this service is collaboration with NGOs or Centres for social service for families, children and youth, which can distribute condoms and clean syringes on a regular basis or according to an established schedule. Requirements regarding the quality of services for syringe exchange and condom distribution are outlined in the standards [36].

Content. Currently, the most widespread practice is dispensing of sterile injecting equipment and alcohol swabs (either via exchange for used syringes or without exchange), handing out condoms, provision of informational leaflets and brief counselling and information sessions on additional services. Clients should have access to medical services at a facility that is providing integrated services; separate case management and referral are not part of this service.

The main principles of this service are a friendly attitude towards clients, confidentiality, anonymity, orientation on immediate client needs, and timeliness of care.

Component 1. Provision and distribution of supplies

From an organizational perspective, a HCF should collaborate with organizations that provide harm reduction services in the region (it is desirable to sign a memorandum of understanding or an agreement), provide premises and set a work schedule. The partner organization is responsible for provision of supplies and syringes.

To offer the full scope of harm reduction services, HCF management should provide the other services that are part of this approach – counselling by medical specialists, testing for HIV and STI, assessment for TB, informational activities and social management.

Effective work of a MDT to coordinate service provision for each client and ensure cooperation between different service providers, is key to success.

Part III
Service implementation options and steps

This section contains a description of implementation steps for all structural components listed in the previous sections. Some components might use several implementation mechanisms; the head of each HCF must select the one that is most appropriate for each situation. All the described mechanisms pertain to service implementation at HCFs that serve PWID. If none of the proposed options is feasible, the service component should be implemented via structured referral. Principles of structured referral are described in a separate section.

Involving a physician

When serving PWID, there are several options for involving a physician.

Option 1. Introducing a new position to the staffing list of a HCF

Currently, the staffing regulations for HCFs are stipulated in the MoH Order [11], and the head of a HCF has no authority to expand the number of staff, even if extra funds are available. According to the above Order, the number of staff depends on the number of beds (for AIDS centres– on the population in the catchment area and number of patients). The number of beds must be approved by the executive body funding the HCF, in accordance with the catchment area and the needs. If a HCF justifies the need to expand its roles and functions, the local state administration (local government) can approve expanding the number of staff, in order to support and increase in the number of physicians.

Step 1. Issuing an Order or other official document by a territorial HA (Direction of the oblast state administration head or local government's Resolution, depending on political structure and which powers have been delegated to executive bodies in the region) about expanding the HCF's roles and functions (catchment area etc.).

Step 2. Incorporating changes into the statutory documents of a HCF to define expanding roles and functions (catchment area, objectives) of the HCF.

Step 3. Ensuring that any new positions adhere to the requirements of MoH Orders pertaining to HCF staffing [11], taking into consideration changes made to the HCF's statutory documents.

Step 4. Submitting an application to a higher authority regarding expanding the number of physicians on staff due to either 1) redistribution of positions within the predetermined number of positions in the catchment area (within the jurisdiction of the territorial HA), or; 2) increasing the number of specialized employees in the catchment area (within the jurisdiction of the local government to make this proposal to a higher authority, for example, the HA).

Item 3 of the Order [11], stipulates that when establishing structural divisions that are not covered by the Order, staffing patterns for these divisions should be approved by the health ministry of Ukraine. If a new subdivision is established with its own separate staffing pattern, approval from the health ministry of Ukraine is required as part of the HCF's application.

Option 2. Changing specialization within existing staff

In accordance with item 2 of the Order [11], when necessary, the head of a HCF can change staff positions in some divisions or introduce new positions that were not included in the standard officially approved staff contingent, using the budget of other divisions, so long as this expense remains within the limits of the current HCF payroll budget. Positions can be changed only within the same category (physicians, nurses, junior nurses) and according to positions that are stipulated under current staffing regulations (other positions can be introduced in cases where a new subdivision is established; option 1).

Changing a specialized position is done by order of the head of the HCF.

Option 3. Introducing (changing) a portion of a position for a part-time physician (physician combining jobs)
This is done as described in the previous option.

Option 4. Arranging a workplace for health care workers from a different HCF to work certain hours as per agreement between the two HCFs
In case a HCF has a large number of patients who require consultation with a physician from a different HCF, the two heads can agree on this physician spending part of his/her working hours at a partner HCF (time-sheets are filled out and payment is done at the main place of work). This option allows a physician to work according to his/her job description and with the same patients, but in a different location that is more convenient for these patients.

Such cooperation must be formalized in an agreement between the two HCFs. The HCF inviting a specialist must provide the necessary working conditions (space, equipment and instruments in accordance with the official equipment requirements form) during specified hours.

Option 5. Using an existing position (change in job description)
If a HCF already has the necessary specialist, his/her job description can be changed to allow him/her to provide additional services. Changing or expanding a job description must be approved by the head of the HCF, and has to be justified either in terms of a previously insufficient workload, or increasing catchment area, and include adequate additional payment within the confines of the HCF payroll[103]. The specifics of increased salaries should be agreed on with the specialist.

Option 6. Additional training of a physician from a different area of specialization (if permitted depending on his/her primary expertise)
If there is a physician at a HCF whose primary area of specialization permits him/her to undergo postgraduate training in a different but relevant specialization, he/she can be referred by the HCF to undergo specialized training and obtain a relevant certificate (for example, an internist might specialize in infectious diseases) or to take a continuing education course (for example, viral hepatitis for internists, gastroenterologists, family physicians etc.)[104].

Option 7. Consulting a physician from a different HCF
The head of a HCF or the deputy head may hire a consulting physician from a different HCF, based on the decision of a medical council. In this case, if the consultation time does not exceed 12 hours per month or 144 hours per year, the consulting physicians paid by the receiving HCF at an hourly rate that is jointly approved by both HCFs in a special Order [103]. Consultation services exceeding 12 hours a month are considered to be a part-time job, and according to current legislation, should be remunerated accordingly (option 3). Details about payments to consulting physicians are provided in Letters of the Ministry of Health[105, 106].

Option 8. Involving a consultant under civil legal contract
It is possible to engage specialists to work under a civil legal contract between a HCF and an individual, provided the HCF has funds to cover this expense. In contrast to an employment (labour) agreement, a civil legal contract

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[103] Order of MoH Ukraine and Ministry of labour and social policy of Ukraine of 05.10.2005 № 308/519 “On regulating wage conditions for employees of health care and social welfare institutions”.
[104] Order of MoH Ukraine of 22.07.1993 № 166 “On further improvement of the system for postgraduate education of physicians (pharmacists)".
[105]Letter of MoH Ukraine of 19.02.2009 №10.03.68/315 “On the procedure to formalize laboor relationship between a HCF and a physician involved in consultation activities".
[106] Letter of MoH Ukraine of 23.10.2008 №10.03.68/1698 “On payment to specialists involved in consultation activities”.

does not provide for social welfare or observance of other norms and regulations stipulated by the Labour code of Ukraine.

Also, this mechanism can be used indirectly through projects implemented by NGOs; in this case, it is useful to conclude a three-way agreement between the HCF where the services are provided, the NGO paying for the services, and the service provider.

Involving a nurse

Mechanisms to involve a nurse are no different from those used for physicians. The following options are relevant:

Option 1. Introducing a new position to add to the current staff of the HCF
Done similarly to option 1 for *Involving a physician*.

Option 2. Changing a specialization within the existing staff
Done similarly to option 2 for *Involving a physician*.

Option 3. Introducing (changing) a portion of a position for a part-time nurse (nurse combining jobs)
Done similarly to option 3 for *Involving a physician*.

Option 4. Arranging a workplace for a health care worker from a different HCF to work certain hours per agreement between two HCFs
Done similarly to option 4 for *Involving a physician*.

Option 5. Use of existing position (change in job description)
Done similarly to option 5 for *Involving a physician*.

Option 6. Involving a consultant under civil legal contract
Done similarly to option 8 for *Involving a physician*.

Psychologist and social worker involvement

Mechanisms for involving a psychologist and a social worker are somewhat different from those used for involving a physician or a nurse. The following options can be used.

Option 1. Introducing a position according to HCF staffing standards
According to the norms and standards stipulated by the Order [11], staff positions of a psychotherapist or/and psychologist can be introduced in psychiatric (mental) facilities, narcological facilities, appropriate departments at district or city hospitals, AIDS centres and hospices.

Positions of social workers can be introduced in psychiatric, narcological and hospice facilities, and oblast and city AIDS centres. Mental hospitals and relevant departments at city polyclinics or hospitals are permitted to have positions for a social care nurse.

If a VCT office is established at any HCF, a position for a psychologist or a social worker can be added.

Option 2. Arranging a workplace for a health care worker from a different HCF to work certain hours per agreement between the two HCFs
Done similarly to option 4 for *Involving a physician*.

Option 3. Involving a consultant under civil legal contract
Done similarly to option 8 for *Involving a physician*.

Establishing a multidisciplinary team

*Service component*3, 4, 16

The optimal management of patients with multiple diagnoses involves creating a MDT comprised of various specialists (physician, nurse, social worker, psychologist, peer counsellor etc.). In order to reach common goals, the team members jointly make decisions and discuss all strengths and weaknesses of treatment. Such teams have clearly defined roles and functions, and all members bear joint and individual responsibility for the treatment regime.

For many services, a MDT is a welcome staffing arrangement. However, the absence of a MDT should not be a barrier to provision of services by a physician or a nurse, even if these services are minimal compared to those that can be offered by a MDT.

Step 1. Specialists involvement

For a MDT providing services to PWID, it is reasonable to include an infectious disease doctor, narcologist, TB physician, neurologist, gynaecologist, dermatologist, eye specialist, internist, psychiatrist, surgeon, and urologist. Physicians of other specializations can be involved in a number of ways, either full-time or part-time, as necessary (на стNu0440 65).

NGOs collaborating with the HCF can actively participate in case management of PLWH and send their specialists to participate in the MDT –psychologists, social workers, counsellors.

Step 2. Regulation of activities

Current regulations do not have a clear definition of a MDT, or the procedure for its establishment and activities. The most widespread practice today is establishment of a MDT by order of the head of the HCF where patients access the majority of their services. The roles of employees of partner organizations and NGOs can also be included in the said order with a note “agreed with”. The Order should determine frequency and location for MDT meetings. The optimal frequency is no less than once every two weeks.

Step 3. Material and technical and regulatory basis

For efficient work, it is best for the MDT to have a designated room for meetings. Commission resolutions are formalized in meeting minutes.

Establishing a medical-consultative commission

*Service component*15

In this guideline, this component is considered as a single service: *Diagnosis of dependence*. According to the Law of Ukraine [55], assessment of dependence in persons whose illegal drug use has been officially confirmed must be done by the MCC; (if a person self-reported to a physician, the diagnosis can be made by this physician). There are two options for making such an assessment.

Option 1. Establishing the HCF Commission

Step 1. Approval of commission composition by a relevant Order

Current regulations do not have any requirements regarding the requisite composition of the MCC in order to make a diagnosis of dependence. However, one prerequisite is that it must include at least one narcologist. Commission composition must be approved by order of the head of the HCF, and commission members should be familiar with the document and sign it.

Step 2. Ensuring in-patient assessment

According to the Instruction [56], a diagnosis of substance use is made following an in-patient medical assessment. There are no requirements regarding the place and time of this assessment. For the purposes of making a diagnosis of substance use, patients can be admitted to any specialized hospital department and stay there for as long as is required for the MCC to conduct their assessment of dependence (in the majority of cases one day is sufficient).

Option 2. Referral to a substance use clinic for assessment

If a HCF cannot establish its own MCC, the only option is referral to a relevant specialized clinic. Every citizen has the right to undergo assessment at a substance use clinic, so no formal agreement is necessary in order to conduct the assessment. It is useful for the HCF to establish links and cooperative agreement to facilitate assessment. In all cases, rules for structural referral need to be observed.

Physician's role

*Service component*2, 3, 4, 6, 7, 11, 12, 13, 14, 15, 16, 19, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 32

A physician is a key component in many services. In the absence of this component, there are a number of options for initiating services:

Step 1. Involving a physician

If there is no physician with the requisite expertise on staff at the HCF, or the physician is unable to cover additional patients with consultations, several options can be explored (на стNu0440 65).

Step 2. Training a physician

In order to provide certain services, a physician should undergo special training or orientation. The following issues should be considered.

- ART is prescribed by physicians who specialize in infectious diseases or internal medicine, and have undergone training in ART. The right to prescribe ART is given to physicians who have undergone a complete course of postgraduate education on ART (principles of ART in adults or children, on-site monitoring of ART, and advanced course on ART in adults and children), and have a relevant document (for example, issued by the P.L. Shupik National academy for postgraduate education).
- Training of physicians in OST is provided under the Global Fund program by the Ukrainian institute of research in public health policy. Also, OST postgraduate courses are provided by the Chair of narcology at Kharkiv medical academy for postgraduate education, and narcologists can undergo relevant training there.

Step 3. Material-technical resources

HCF management must ensure adequate logistical support for the physician's activities, which include space, furniture, instruments and equipment.

All rooms at the HCF must conform with Sanitary rules and norms [101]. Some groups of patients require special conditions of work:

- Offices at HCFs providing care to patients with TB need to be equipped according to the official List[107].
- Out-patient treatment and diagnostic rooms of AIDS centres (offices of the infectious disease specialist, paediatrician, internists, neurologist, dermatologist/venereologist, endoscopy, substitution therapy) and VC offices need to be equipped according to the official List[108].

Nurse's role

*Service component*3, 4, 8, 11, 16, 21, 22, 26, 29, 32

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[107]Order of MoH Ukraine of 29.09.2009 № 694 "On approval of officially recommended equipment lists covering medical devices and medical products for structural divisions of HCFs providing care to people with TB depending on the level of care".

[108]Order of MoH Ukraine of 19.07.2010 № 590 "On approval of officially recommended equipment lists covering medical items for specialized HCFs and structural divisions of HCFs providing clinical and diagnostic assessment and care to people with HIV/AIDS".

A nurse is a key component in many services. In the absence of this component, there are several implementation options for initiating services:

Step 1. Involving a nurse

If there is no nurse with the necessary expertise on staff at a HCF, or the nurse cannot cover additional patients, several options can be explored (на стNu0440 67).

Step 2. Training a nurse

In order to provide certain services, a nurse should undergo special training or orientation:

- orientation on purified protein derivative (PPD) skin testing and sputum collection to assess TB status is done by oblast TB clinic specialists;
- training of nurses in OST is provided under the Global Fund program by the Ukrainian institute of research in public health policy.

Step 3. Material-technical resources

HCF management must ensure adequate logistical support for the nurse's activities, including instruments and equipment. When providing some services, a nurse may share an office with a physician, but sometimes he/she needs to have a separate office.

All the rooms at a HCF, including nurses' rooms, must conform with Sanitary rules and norms [101]. Some activities require specially equipped rooms:

- procedure rooms used for blood collection must be equipped according to the List[109];
- vaccination rooms must be equipped according to the exemplary List [73].

Pre-test, initial and supportive post-test counselling

*Service component*1

According to the Law of Ukraine [7], pre-test and post-test counselling, preparation and provision of test results can be done by any HCF that has the relevant license.

VCT procedures [9] do not specify requirements for pre-test and post-test counselling that differ from those of other tests.

The best approach is for the HCF to train its own personnel to provide both pre- and post-test counselling. AIDS centres, city and district hospitals that experience shortages of staff or resources can open a separate VCT office that will facilitate the addition of more staff and equipment in accordance with the Orders[110,111]and Standard regulations[112].

Option 1. On-site (including establishing a VCT office)

Step 1. Staffing

According to VCT procedural regulations [9], pre- and post-test counselling can be provided by various specialists: health care workers (physicians and nurses), psychologists, social workers, NGO representatives working in the area of HIV/AIDS (including peer counsellors who are PLWH or members of risk groups). The head of the HCF determines which specialist is to provide counselling, based on HCF staff capacity and training. There are several options for how to engage a physician, a nurse, a psychologist, and a social worker. The HCF head selects the most

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[109]"Equipment table covering medical items for treatment and diagnostic rooms of HCFs" approved by the Order of MoH Ukraine of 05.06.1998 № 153 "On approval of equipment tables covering medical items for structural divisions of HCFs".

[110] Order of MoH Ukraine of 25.02.2008 № 102 "On VCT offices operation".

[111] Appendices 3 and 52 to the Order of MoH Ukraine of 23.02.2000 № 33 "On staffing norms and standard staffing of HCFs" 11.

[112]Order of MoH Ukraine of 27.06.2006 № 421 "On approval of Standard regulations on a VCT office".

appropriate person for the task, according to each specific situation. The work is organized based on 12 visits per one specialist per shift.

The HCF head should appoint a person responsible for managing counselling and testing, monitoring, evaluation and supervision.

Step 2. Training of counsellors

Regardless of position or area of specialization, a counsellor must undergo special training in HTC in accordance with the topics and requisite number of academic hours[113]at training courses that can be offered:

- at educational institutions with qualified trainers and HTC curricula where health care workers, psychologists, or social workers are trained, provided HIV courses in which the curriculum includes the fundamentals of HTC (for example, the postgraduate CME course “Basics of voluntary HIV counselling and testing” offered by the Chair of Virology at P.L. Shupik National medical academy for postgraduate education);
- under international technical assistance projects operating on the basis of memoranda of understanding signed between governments, or between individual international and national organizations, or through international technical assistance projects with the Ukrainian Ministry of Health;
- through ongoing guidance and supervision of counsellors’ work by qualified specialists.

Step 3. Material-technical resources

HTC counselling can be conducted on-site or via mobile services (in a specially equipped vehicle). For on-site counselling, it is necessary to have a specially allocated office that meets the requirements of item 5.2 of the procedure [9] in terms of space, furniture, and lighting, to provide a comfortable counselling atmosphere. Offices used for counselling and testing should meet confidentiality requirements.

Step 4. Observing regulatory requirements

Confidentiality. Patients’ right to protection of their personal medical information is guaranteed by the Constitution of Ukraine, Laws of Ukraine [7] and by-laws. The head of the organization providing HTC must ensure confidentiality of counselling and safekeeping of records that contain information obtained during counselling.

All information about the patient must be stored in a place with limited access, and according to the directive of the head of the organization. This means that unauthorized persons (cleaning personnel, relatives of employees etc.) must not access patients’ personal information—which should be stored in a lock box. Other conditions are stipulated in the relevant Procedure [9].

Informed consent. A specialist who provides VCT must obtain the patient’s informed consent for testing[114] [10]. In case of anonymous testing a form should not be filled out.

Documents and records. The Procedure [9] provides for keeping a log for voluntary HIV testing and counselling (primary record form № 503/o), approved by the Order [8]. Another Order[115]also provides for HIV VCT report submission.

Step 5. Ensuring high quality counselling, supervision, monitoring and evaluation

The contents and procedures of pre- and post-test counselling are described in detail in the Law of Ukraine [7], Procedure [9] and guideline [10]. For this reason, they are not covered in this document.

Supervision must focus on improving counsellors’ knowledge and skills through guidance, methodological assistance and support, in order to guarantee high quality counselling services and management.

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[113]Appendix 2 “Training of VCT counselors, list of topics mandatory for the procedure of HIV voluntary counseling and testing (Protocol)” to “Procedure 8, 9 “Procedure of voluntary counseling and testing for HIV infection” approved by the Order of MoH Ukraine of 19.08.2005№ 415 “On improvement of voluntary counseling and testing for HIV infection”.

[114]Instruction on filling out primary record form N 503-1/o“Informed consent to HIV testing” approved by the Order of MoH Ukraine of 19.08.2005 № 415 “On improving voluntary HIV counseling and testing”.

[115]Order of MoH Ukraine of 11.05.2010 № 388 “On improving HIV diagnostic work-up".

Regional AIDS centres are responsible for ensuring monitoring, evaluation and supervision, and provision of HTC services in VCT offices, city AIDS centres and other HCFs, in accordance with VCT procedures [9]. Regional and district level supervisors are appointed in accordance with the Order of the MoH Ukraine[116]. Monitoring and evaluation is conducted by an authorized person according to qualitative and quantitative indicators approved by the head of the HCF. Decisions about improving counselling services are made on the basis of service evaluation outcomes.

Option 1. On-site at the HCF by specialists from a different organization

If a HCF cannot ensure pre-or post-test counselling provision by its own staff, specialists from other organizations providing HTC services can be involved.

This option means that the partner organization should have specially trained personnel. In this case, the partner facility is responsible for meeting all regulatory requirements, quality assurance, monitoring and record-keeping.

For the HCF, this entails choosing a partner organization, signing an agreement, providing necessary space and setting working hours.

Step 1. Partnering

Organizations able to provide pre- and post-test counselling services include: physicians' offices in family planning and reproductive health services; youth friendly clinics; and services for families, children and youth. HTC operations are regulated by the Procedure [9] and other regulatory acts[117, 118]. Cooperation between the State social service and HCFs is regulated by a separate Order[119]. Also, in many regions there are HIV-service NGOs that provide counselling services. If these NGOs implement projects to provide services to vulnerable groups, they may be interested in providing not only counselling but also provision of HIV test-kits or other items.

To formalize terms of cooperation and responsibilities of parties, a Cooperation agreement must be signed.

Step 2. Provision of space and defining working hours

HTC counselling can be on-site or mobile (in a specially equipped vehicle). For on-site counselling, it is necessary to have a specially allocated office that meets the requirements of item 5.2 of the procedure [9] in terms of space, furniture, and lighting, in order to provide a comfortable counselling atmosphere. Offices used for counselling and testing should meet confidentiality requirements.

If a partner facility provides counselling and testing using a vehicle, it is necessary to designate a place for parking that is convenient for clients.

Whichever option is selected, it is necessary to work out the HTC schedule and inform potential clients about it.

Preanalytical step of lab testing

*Service component*1, 3, 4, 6, 15, 16, 20, 21, 22, 24, 25, 26, 28, 31

This component covers the initial step of diagnostic testing beginning with specimen collection and sending the specimen to the lab. For some types of testing, pre-analytical and analytical steps are regarded as one step (for example, when using RTs), but this guideline looks at them individually as they can be clearly differentiated in other types of testing.

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[116]Order of MoH Ukraine of 19.04.2006 № 236 "On implementation of Procedure for voluntary HIV counseling and testing (Protocol) at health care facilities".

[117]Order of MoH Ukraine of 14.11.2005 №604 "On improving provision of medical and social care to children and youth" .

[118]Order of MoH Ukraine of 04.08.2006 №539 "On setting up the operation of family planning and reproductive health Services in Ukraine".

[119]Order of MoH Ukraine and Ministry for family, youth and sports Ukraine of 17.11.2006 № 3925/760 "On approval of Procedure for collaboration between Centers of social services for families, children and youth and HCFs regarding various aspects of HIV/AIDS prevention".

Organization of the pre-analytical step is largely the same for all types of testing. Specific features of individual tests are presented in the relevant practical steps.

Option 1. On-site

Step 1. Staffing

Specimens should be collected by a nurse with appropriate qualifications. There are several options for involvement of a nurse (on page 67).

For HIV testing, a HCF head must appoint a person for blood collection and a person responsible for specimen preparation.

Step 2. Training of personnel

The majority of procedures do not have any specific requirements regarding personnel training; for this reason, any nurse can collect blood or other materials for testing.

To collect blood for HIV antibodies detection, CD4, or VL, a health care worker must undergo training at a regional AIDS centre.

Step 3. Provision of space

General requirements for procedure room equipment are described in Sanitary rules and norms, and for equipment of rooms at out-patient facilities – in exemplary Lists[120].

A VCT procedure room at a different HCF where HTC takes place, must be equipped in accordance with the Procedure [9] and individual Order [108].

For urinalysis, it is necessary to have a toilet and clean containers for urine collection.

Requirements for a room where HIV testing is done using RTs are described in the relevant MOH Order [17], which stipulates that such a room has to have a refrigerator and a clock.

Step 4. Supply of disposable items and equipment

Some tests (especially when lab work is done at a different HCF or after a certain period of time) require special equipment and devices. These include vacutainers (these are mandatory for PCR for hepatitis, CD4 count, VL measurement), centrifuge, transportation tubes, containers, refrigerators for freezing and storage of specimens, as required.

Disposable items include, among others, blood lancets, syringes, alcohol swabs, slides, tubes, urine collection containers, gynaecologic sets, brushes, universal probes, Folkman spoons, applicators etc. Depending on the test, disposable items can be purchased using the HCF's own budgetary or non-budgetary funds, donor organization funds, funds allocated for special-purpose projects, and in some cases—clients own funds.

In all cases, procedure rooms and rooms where testing is done must be equipped with containers and disinfectants for decontamination of instruments and/or test-kit components.

Step 5. Regulatory requirements and record-keeping

Specimen collection for some tests requires special record-keeping. Record forms, logs and relevant instructions are approved by MOH Orders.

Samples taken to test for HIV or to confirm HIV diagnosis must be registered in appropriate logs in accordance with the Order [18].

Samples for CD4 testing or VL must be accompanied by appropriate test requisition forms [27].

Step 6. Ensuring specimen quality

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[120] Order of MoH of Ukraine of 05.06.1998 № 153 "On approval of lists of medical items with which structural divisions of HCFs need to be equipped".

It is the responsibility of the HCF head to see that the criteria for specimen handling and transportation are met. Some tests have special collection requirements:

- viral hepatitis RNA detection by PCR[121];
- obtaining cervical cytology samples[122].

Option 2. On-site at an HCF, per agreement with a different facility

When a facility cannot use it own personnel for specimen collection, it is possible to involve specialists from other organizations for some tests. These specialists collect specimens at the HCF that engaged them to perform this work. This option is used, for example, for CD4 testing, when specialists from AIDS centres or VCT offices go out to other HCFs to collect blood. This option is also used when mobile labs are used to test for HIV, STIs and other infections.

When undertaking a pre-analytical step under this option, partner organizations should have specially trained personnel. The partner facility is responsible for meeting regulatory requirements, quality assurance, monitoring and record-keeping. The inviting HCF must choose a partner organization, sign an agreement, provide the necessary space and set working hours.

Step 1. Partnering

Depending on the type of test, the partner organization could be a regional AIDS centre, TB dispensary, HIV-service NGO etc.

To formalize terms of cooperation and responsibilities of parties, a Cooperation agreement should be signed.

Step 2. Provision of space and defining working hours

If specimens are collected at the HCF, the collection rooms must meet all the requirements stipulated in step 3 of Option 1. Disposable items are supplied in accordance with the agreement either by the inviting facility (step 4, option1) or by the partner facility.

If the partner facility uses a mobile lab for sample collection, it is necessary to designate a place for parking that is convenient for clients.

Analytical step in lab testing

*Service component*1, 3, 4, 6, 10, 11, 12, 15, 16, 20, 21, 22, 24, 25, 26, 28, 31

Regardless of testing type, there are 2 basic options for this step: using one's own lab or using another facility's lab (options 1, 2). Some tests can be performed at another facility without involvement of one's own lab (using RTs) or at one's own HCF by another HCF's employees, by for example, by using a mobile service (options 3, 4).

Some tests have certain specific requirements that should be taken into account when making a decision about whether to administering them.

- Testing to confirm HIV diagnosis, CD4 testing, and VL can currently only be done in those labs that are authorized by the MoH Order[123]; other organizations can access these tests through option2 only.

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[121]Appendix 7 "Procedure for biological material (blood) collection to detect HCV RNA by PCR" to item 2.6 of "Clinical protocol for hepatitis C virus diagnosis and treatment in adults with HIV" approved by the Order of MoH Ukraine of 30.12.2008 № 826 "On approval of clinical protocol for hepatitis C virus diagnosis and treatment in adults with HIV".
[122]"Clinical protocol "Benign and premalignant cervical lesions" approved by the Order of MoH Ukraine of 31.12.2004 № 676 "On approval of clinical protocols in obstetric and gynecological care".
[123]Order of MoH Ukraine of 16.09.2009 № 673 "On approval of lists of AIDS centers performing HIV and antiretrovial therapy laboratory monitoring, and confirmatory testing in Ukraine".

- Microbiological sputum testing for TB is done in accordance with MoH Order in laboratories of appropriate level or higher (sputum microscopy – level I, bacteriologic testing – level II, drug sensitivity – level III).

In view of the above requirements, the following options can be used when undertaking analytical step one.

Option 1. Using own laboratory

Step 1. Lab attestation/accreditation (material, technical basis and staffing)

Lab attestation is an official confirmation of a lab's preparedness to work in health care. Attestation and its formalization is done according to procedures stipulated by regulatory acts of the central executive authority in the area of metrology, as per the rules governing delegation of authority and attestation laid out in the state metrological system[124]. The entity appointed to perform attestation of laboratories, facilities and organizations is the main organization of the metrological service of the Ukrainian Ministry of Health, the National specialized paediatric hospital OHMATDIT[125, 126].

In addition, laboratories of state or communal HCFs testing for HIV must be accredited by the MoH [15]. The right to confirm HIV diagnosis, in case HIV serological markers are detected, is granted to those laboratories designated by the appropriate MoH Order.

The capacity of laboratories to perform testing is evaluated according to the following criteria.

- Lab must have measurement equipment, testing and accessory equipment, control samples (control serum, museum strains etc.), reagents, immunobiological preparations and measuring glassware that meet the regulatory requirements and are included in lab testing procedures and protocols. The requirements for equipment are detailed in approved official lists [120].
- Installation, operation and storage of instruments and equipment must be done in accordance with technical requirements to ensure consistent readiness for testing at the necessary level of precision.
- The operational capability of instruments, equipment and control samples must be officially confirmed (verification certificate, attestation certificate). Verification and/or attestation have to be conducted on a regular basis in accordance with standard requirements.
- A system of test results verification and quality control must be implemented.
- The laboratory must have a sufficient number of employees (lab physicians, lab technicians) who have relevant education and qualifications, and can ensure testing in the required areas. All specialists must have approved job descriptions with a continuing education component. Positions at a HCF laboratory are defined by relevant Appendices (depending on a type of HCF) and section 14 of appendix№ 26 to the MoH Order [11].
- Occupational safety, safety and anti-epidemic control manuals must be developed.
- Rooms must be se up in accordance with regulatory requirements pertaining to the conditions for testing (measurements), including safety, anti-epidemic control, health and environmental health safety requirements. General requirements for laboratory space and facilities are

[124] Order of The State committee for technical regulation and consumer policy of Ukraine of 29.03.2005 № 71 "On approval of Regulations for authority delegation and attestation in the state metrological system".

[125] Order of MoH Ukraine of 19.04.07 № 196 "On attestation of measurement laboratories at facilities, establishments and organizations".

[126] Booklet for CDL licensees "Information for licensees doing business in the medical field in specialized clinical biochemistry, clinical immunology, clinical laboratory diagnostics, laboratory immunology, bacteriology, virology" approved by the MoH Ukraine of 04.08.2009.

detailed in construction norms[127]. Rooms where infectious material is tested also need to comply with separate regulations[128].

- To test microorganisms, a permit corresponding to the level of their pathogenicity must be obtained.

The majority of district or higher level HCFs have equipment to conduct general clinical tests, but more specific tests require additional instruments. If additional equipment needs to be purchased, the following options can be used:

- purchase equipment using HCF funds (budgetary or non-budgetary);
- receipt under centralized supply systems from the health ministry/HA, provided the HCF has been selected to provide certain cervices to certain population groups;
- purchase through donors.

Step 2. Supply with test-kits and disposable items

Depending on the type of test, a HCF can obtain test-kits and disposable items through the centralized supply system (from health ministry or HA), from a donor organization, under a special-purpose project, or purchase them on its own (from budgetary or non-budgetary funds). In some cases, patients can buy disposable items at their own expense.

When purchasing supplies, it is important to remember that some test-kits are used for testing multiple samples, so they need to be purchased only if it is necessary to test many of patients within a short period of time.

All test-kits need to be stored at a specific temperature.

Step 3. Observing testing procedures

The main document that specifies the procedures for general clinical laboratory tests is the Instruction[129]approved by the health ministry of the USSR. There is a draft MoH Order[130]that will specify the criteria for lab test quality assurance, when adopted.

The main types of lab tests are specified in separate Orders or Instructions: PCR[131,132] and HIV diagnostic tests[133] [18]. Microbiologic labs and TB diagnostic stations of levels I–III must be in accordance with Standard regulations [42] and conduct testing according to the Instruction[134].

Step 4. Regulatory requirements and record-keeping

All tests done in HCF labs need to be registered in a laboratory log. Record-keeping and reporting for individual tests must comply with normative acts regulating these tests.

In the case of HIV testing, the Order [18] stipulates that it is necessary to keep a series of logs for blood specimen registration, testing protocols etc. The patient is provided a report of HIV antibody testing (primary record form № 503-5/0).

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[127]State Construction norms ДБН В.2.2-10-2001 “Buildings and structures – HCFs” approved by the State Committee for construction, architecture and housing policy Ukraine 04.01.2001.

[128]State sanitary rules ДСП 9.9.5.-080-02 “Regulation on lab set-up and work safety in microbiology laboratories (departments, divisions)” approved by MoH Ukraine and State sanitary and epidemiological service of Ukraine 28.01.2002.

[129]Instruction of MoH USSR of 14.05.1986№ 06-14/9 “Instruction on application of unified clinical laboratory testing procedures”.

[130]“On approval of provisional sectoral standards regarding clinical laboratory testing quality assurance” (draft MoH Order).

[131]Decision of the Chief State sanitary physician of Ukraine of 09.07.2003 № 24 “On approval of provisional guidance of MoH Ukraine “Polymerase chain reaction for detection of pathogens".

[132]“Laboratory management for testing biological specimens by polymerase chain reaction (guidelines)”, 2007, Kyiv.

[133]“Instruction about organization of work of HIV testing laboratories” approved by the Order of MoH Ukraine of 22.02.2002 № 71 “On approval of Instruction about organization of work in HIV testing laboratories”.

[134]“Instruction on bacteriologic testing for TB infection” approved by the Order of MoH Ukraine of 06.02.2002 № 45 “On approval of Instruction on bacteriologic testing for TB infection”.

In the case of AFB sputum tests, relevant logs are kept [33, 39]. Laboratory registration logs (bacterioscopic/microscopic tests) (form № ТБ 04/1) must be kept in all laboratories performing sputum smears to detect *M. tuberculosis*. Laboratory registration log (bacteriologic tests) (form № ТБ 04/2) must be kept in all laboratories performing sputum smears to culture for *M. tuberculosis*.

Monitoring and evaluation is performed by an appointed person based on qualitative and quantitative indicators and approved by the head of the HCF. A report based on evaluation indicators should be submitted to the regional AIDS centre. Based on the report, decisions are made about improvement of counselling services.

Option 2. Using the laboratory of another HCF

If a HCF does not have its own lab qualified and licensed to perform the required tests, it is possible to arrange for transportation of blood samples to an appropriate lab at another HCF. In this case, ensuring the supply of test-kits and disposable items is the responsibility of the HCF receiving the samples.

Step 1. Identifying a partner facility

When identifying a partner facility, it is important to consider the distance samples will need to be transported. Several options to cooperate with partner facilities in the laboratory area are possible:

- using the lab of a HCF that serves the catchment area population of a certain district (for patients living in a certain district);
- using a specialized lab (of a different facility, centralized etc.) designated by a higher authority (health ministry, territorial HA) to provide services free-of-charge (using budget allocated for maintaining this lab); laboratories that perform bacteriologic tests for TB(these tests can be performed only by labs of level II or III) for other facilities are designated by the Chief oblast/city TB specialist;
- using lab facilities of a different HCF on a contractual basis (for payment).

Whichever option is selected, it is useful to conclude a cooperative agreement or have a territorial HA issue an Order that defines the responsibilities and mechanisms of cooperation between the facilities.

Payment for services, if necessary, can be done using budgetary or non-budgetary funds, patients' own money etc. Lab services provided by state HCF at patients' own cost are regulated by the Resolution[135]. Regions may run projects to test different options for paying for testing and specimen transportation to the lab, for vulnerable groups. Partnership with such projects may help ensure patients' access to high-cost tests.

Step 2. Specimen transportation

Specimens must be transported by specially designated staff of the lab or client facility in a service vehicle. For certain tests it is mandatory to maintain temperature control. Bags with cooling agents, thermal containers or special vehicles can be used for this purpose.

For certain tests it is necessary to observe transportation requirements.

- For CD4 testing, material is transported by a health care worker or other worker without cooling it in containers.
- For PCR testing (for example, HCV RNA or HBV DNA), material and processed samples are transported frozen or in a special thermal container with cooling elements or in a thermos bottle with ice [25].
- For bacteriologic testing for STIs, material is transported in special containers (depending on the type of material) with temperature control [96].
- Cytology material is transported according to the requirements outlined in the relevant clinical protocol [122].

[135]Resolution of the Cabinet of Ministers Ukraine of 17.09.1996 № 1138 "On approval of the list of paid services provided by state HCFs and higher medical educational establishments", with revisions complying with the Resolution of CM Ukraine of 11.07.2002 № 989.

Step 3. Test results reporting

Test results can be mailed or e-mailed to the client's facility or delivered via its employees. Whichever option is chosen, confidentiality of medical information should be observed.

Option 3. Using rapid tests

For some types of testing, RTs are available. Their use is regulated by health ministry normative acts[136,137,138][17].

Step 1. Staffing

Current regulations do not stipulate detailed staffing or qualification requirements pertaining to personnel using RTs. Common practice is as follows: Pre-analytical (material collection) and analytical (application of material onto a test-kit) steps are performed by a nurse, and evaluation is done by a physician.

According to the Order [18], HIV testing with RTs can be performed by a health care worker who has been trained in a CME course, on-site at laboratories of regional AIDS centres or at special workshops to learn how to use RTs.

Step 2. Material and technical resources

Testing with RTs does not require a separate lab. It can be done at a testing office with appropriate conditions, including infectious control; containers and disinfectants need to be in place to decontaminate tests, instruments and work surfaces.

Step 3. Supply of test-kits and disposables

Depending on the type of test, a HCF can obtain test-kits and disposable items through centralized supply (from health ministry or HA), from a donor organization (currently donors provide HIV, hepatitis and STIs tests), under a special-purpose project, or the HCF can purchase these supplies on its own (using budgetary or non-budgetary funds). In some cases, patients can buy disposable items at their own expense.

All test-kits need to be stored at a special temperature.

Step 4. Documents and records

Reporting on RT results is done in accordance with normative acts regulating individual tests.

During HIV testing, a series of logs and reports are filled out; these forms are approved by relevant Orders[139, 140]. In the case of a positive result, a preliminary report is issued using form 503-3/o, approved by the Order [8]. Monitoring is performed by an authorized person, according to qualitative and quantitative indicators approved by the HCF head. Based on the outcomes of monitoring, decisions about ways to improve counselling services can be made.

Option 4. On-site testing per agreement with a different HCF

When a HCF does not have the capacity to conduct testing on-site or to refer the material to a different laboratory, the HCF can invite specialists from other organizations to the HCF to perform testing using their own test-kits. Usually, this is done for testing with RTs, including at mobile points [12].

To undertake the analytical step, the partner facility must have trained personnel with the relevant accreditation for this type of activity. It is the responsibility of the partner facility to meet regulatory requirements, ensure service quality, monitor and keep records.

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[136] Order of MoH Ukraine 09.06.2003 № 255 "On approval of guidelines on rapid test use for HIV antibodies detection in blood, records form N 498/o, and instructions to fill it out".

[137] Order of MoH Ukraine of23.09.2004 № 467 "On approval of guidelines on rapid blood test use for diagnosing infections, records form and instructions to fill it out".

[138] "Use of rapid tests to check for substance use in general medical practice (guidelines), MoH Ukraine and Ukrainian scientific and research institute of social, forensic psychiatry and narcology, Kyiv, 2006.

[139]Order of MoH Ukraine 06.06.2007 № 304 "On approval of primary record form for using rapid tests in health care facilities, and instructions to fill it out".

[140]Order of MoH Ukraine of 24.03.2006 № 158 "On approval of record form № 498-2/o "Immunochromatographic test report (CITO TEST)".

For the inviting HCF, this option entails selecting a partner organization, signing an agreement, providing necessary space and setting working hours.

Step 1. Partnering

Depending on the type of testing, a partner facility can be a regional AIDS centre, TB dispensary, HIV-service NGO etc.

To formalize terms of cooperation and the responsibilities of parties, a Cooperation agreement must be signed.

Step 2. Provision of space and setting working hours

If testing is performed at a HCF, the HCF must meet all the requirements stipulated in step 3 of option 1. Disposable items can supplied in accordance with the agreement, by any of the participating facilities.

If the partner facility uses a mobile point for sample collection, it is necessary to identify a place for parking that is convenient for clients.

Supply of ARVs

Service component 4,26

Currently, ARVs are purchased from state budget money and international donor money. Each delivery is distributed in accordance with the MoH Order[141]according to territorial units. Territorial HAs define the end recipients and the procedure for drug distribution among subordinate HCFs. To provide ARVs to HCF patients, the following options can be employed, depending on the projected need.

Option 1. Establishing an independent ART site

Currently, this mechanism is used to supply ARVs to VCT offices, maternity facilities, and infectious disease medical facilities.

Step 1. Preparation of HCF and its inclusion into the regional distribution scheme

In accordance with the Comprehensive plan [34], oblast HAs must issue Orders and submit information to the MoH about which HCFs are already providing ART or will be providing ART within the next year. In order for the HCF to be approved as an ART-providing site by the oblast HA, a special commission must perform a comprehensive evaluation of the HCF's preparedness to provide ART. The commission should include representatives of the oblast HA, oblast and city AIDS centres, and NGO representatives. The commission should include the following specialists: clinical infectious disease specialist, lab specialist, ART monitoring specialist, and health administrator. Evaluation of preparedness is conducted with a special instrument[142] that evaluates staff resources, material and technical resources, service provision methodologies etc. A report is generated using the results of the evaluation and is submitted to the oblast HA.

ARVs are supplied to HCFs through the oblast AIDS centre, in accordance with the mechanism stipulated in the HA Order or Letter.

Step 2. Material and technical resources

Drugs need to be kept in a HCF in accordance with the established procedure[143]. According to the Base standard[144], the space for ARVs storage should meet the following minimum requirements:

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[141]Order of MoH of 21.09.2010 № 795 "On distribution of antiretroviral drugs for treatment of HIV/AIDS and HIV prevention purchased from state budget funds for the year 2010".

[142]"Tool to Assess Site Program Readiness for Scaling Up Antiretroviral Therapy (ART) and Requirements for Further Training and Systems Development" adapted by the International HIV/AIDS Alliance from the original prepared by JSI/DELIVER, Version 1.1, September 2003.

[143]Order of MoH Ukraine of 16.12.2003 № 584 "On approval of Regulations on drugs storage and quality control at HCFs".

- – dry, ventilated, clean, with surfaces pained with paint (usually, oil) for the purpose of easy cleaning with disinfectants;
- – equipped with racks (cabinets), refrigerator (as necessary), thermometer and hygrometer;
- – sufficient level of protection against unauthorized entry (metal doors, window security bars, alarm system, as necessary), security, if alarm system is not in place – person on duty).

Only authorized personnel are allowed to enter the room where drugs are stored.

Step 3. Regulatory requirements and record-keeping

The inventory system for ARVs must be in compliance with the current Order on drug distribution. The Order[141]stipulates the procedure for submitting reports on receipt, consumption, residual quantities, inventory acts (forms approved in the Comprehensive plan [34]) and Write-Off Acts, (approved by the individual Order[145]), as well as on failure to use drugs.

Option 2. Delivery of drugs to patients at a different facility

If a patient is on treatment at a different HCF and is not able to pick up his/her drugs at the HCF where he/she usually gets the ARVs, personnel of the ART site or HCF where the patient currently resides can deliver ARVs to the patient. There can be no transfer of drugs from one HCF's balance to another's; ARVs record-keeping and reporting is performed by ART-site staff. This mechanism can be used to deliver drugs to facilities for PWID.

Supplying drugs for opportunistic infection treatment and prevention

Service component 6

Currently, drugs to treat and prevent OIs are purchased centrally from the state budget and international donor funds. Each delivery is distributed in accordance with MoH Order, according to geographic region, in the same way as ARVs. Territorial HAs define end recipients and the procedures for drug distribution among subordinate HCFs. Some of these drugs are available through pharmacy networks; they can be purchased either by HCFs or by patients.

To provide OI drugs to HCF patients the following options can be employed.

Option 1. Centralized supply

Step 1. Including HCFs into a regional distribution scheme

According to the Comprehensive plan [34],oblast HAs control distribution and use of OI prevention and treatment drugs. The drugs are supplied to the HCFs through the oblast AIDS centre in accordance with the mechanism stipulated by the HA Order or Letter.

Step 2. Material and technical resources

Drugs must be stored at a HCF in accordance with the established procedure [143].

Step 3. Regulatory requirements and record-keeping

The inventory system for OIs must comply with the current Order on drug distribution. The Order on distribution[146] requires reporting on the amount of drugs: The Comprehensive plan [34] approves report forms regarding the

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[144]"Base standard for implementation (scale-up) of antiretroviral therapy for people with HIV/AIDS in the region" approved by the MoH Order of 15.04.2008 № 205 "On approval of the Comprehensive plan to expand access of the population to HIV/AIDS prevention, treatment, diagnosis, care and support for people with HIV/AIDS in Ukraine in 2008".

[145]Order of MoH Ukraine of 26.03.2003 №136 "On procedures to show material assets in a centralized supply activities record".

[146]Order of MoH Ukraine of 08.04.2009 № 222 "On distribution of drugs for treatment of opportunistic infections and other comorbidities in people with HIV and AIDS purchased in 2009 under the HIV/AIDS component of the project "TB and HIV/AIDS Control in Ukraine".

number of people who underwent prevention and treatment, as well as drug receipt, consumption and residual quantities.

Option 2. Purchase at patients' own expense
As long as some drugs are available through pharmacies, in cases where there is no centralized supply, patients can buy them at their own expense. Not all patients have sufficient funds to buy these drugs themselves.

Option 3. Purchase from HCF's non-budgetary funds
Some drugs for treatment and prevention of OIs can be purchased from HCF non-budgetary funds.

Option 4. Purchase from donor funds
Projects to provide services to vulnerable groups (NGOs activities) may be implemented in regions; one of these projects' activities is payment for different drugs and their delivery to clients to strengthen adherence.

Supply with TB treatment and prevention drugs

*Service component*11, 12

Currently, drugs for treatment and prevention of TB are purchased centrally from state budget money. Each delivery is distributed in accordance with MoH Orders, according to geographic region; regional HAs subsequently define end recipients and procedures for drug distribution among subordinate HCFs. Some of these drugs are available through pharmacy networks.

To provide TB drugs to HCF patients the following options can be employed.

Option 1. Centralized supply

Step 4. Supply from oblast TB clinics

In accordance with MoH Orders on TB drugs distribution[147], oblast HAs exercise control over distribution and use of OI prevention and treatment drugs. The drugs are supplied to the HCFs according to mechanisms stipulated by the HA Order or Letter. The standard procedure provides for drug to be supplied by oblast TB clinics to district divisions, and from there – to DOTS therapy sites, FOSs, and other sites where drugs are dispensed to patients. In order for the HCF to be included in the distribution plan, it must establish cooperation with the district TB service.

For a preliminary order of first line TB drugs for in-patients, the HCF's administration must submit an application to the regional TB facility in accordance with the Ukrainian Ministry of Health's specified list. The need is determined by the number of TB patients who were treated in the TB department (clinic) over the previous year. The facility incorporates the estimated need into the oblast application for TB drugs to be purchased from state budget funds. Second line TB drugs are dispensed directly to specific patients by a territorial TB dispensary, according to the decision of the Central MCC.

It is also possible for first and second line TB drugs to be supplied from TB dispensaries to other HCFs for specific patients, on an irregular basis. If a HCF has a DOTS site, according to item 3.2 of the Regulation [48], a district TB specialist is responsible for drug supply.

Step 5. Material and technical resources

Drugs should be kept in HCFs in accordance with the established procedure [143]. A month's supply of drugs for each patient should be stocked at DOTS sites [48].

Step 6. Regulatory requirements and record-keeping

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[147] Order of MoH Ukraine of 08.09.2010 №760 "On distribution of First and Second line TB drugs purchased from funds of the state budget of Ukraine for 2010".

The inventory system for TB drugs must be in compliance with the current Order on drug distribution. The recent Order on distribution provides for submission of drug write-off acts [145]. DOTS-sites submit reports on drug consumption to the district TB specialist [48].

Option 2. Purchase at patients' own expense
As long as some drugs are available through pharmacies (canamicine, fluoroquinolones), patients can buy them at their own expense, if they are not supplied centrally. Not all patients have sufficient funds to buy these drugs.

Option 3. Purchase from HCFs non-budgetary funds
Some drugs for treatment of TB can be purchased from HCF non-budgetary funds.

Supply of drugs to treat viral hepatitis

*Service component*21

Today, drugs for treatment of viral hepatitis are accessible in public pharmacies, and are provided by HCFs under the national distribution scheme for people with HIV, or by oblast distribution schemes under oblast level viral hepatitis programs. Accordingly, the following options can be applied to supply patients with drugs to treat viral hepatitis.

Option 1. Centralized supply for the needs of people with HIV
The Ministry of Health is responsible for distribution of a small amount of drugs purchased from World Bank money to treat viral hepatitis in people with HIV. Recipients of drugs are oblast AIDS centres. It is necessary to establish cooperation with the oblast AIDS centre and ensure patients inclusion on the list of prospective candidates.

If the State special purpose viral hepatitis treatment program is funded, this therapy will be available to other patient categories under the centralized distribution mechanism.

Option 2. Supply under Regional Program
In some oblasts of Ukraine, regional viral hepatitis programs are in operation; these programs provide for purchase of a certain number of viral hepatitis treatment courses. The distribution plan is approved by regional HAs, which also define recipients of drugs. In order to ensure that patients get their treatment, it is necessary to establish cooperation with drug recipients and ensure patients' inclusion on the list of prospective candidates.

Option 3. Purchase at patients' own expense
As long as some drugs for treatment of viral hepatitis are available through public pharmacies, patients can buy them at their own expense, in cases where they are not supplied centrally. Considering the extremely high prices for such drugs, this option is not feasible for most patients.

Supply of drugs to treat STIs

*Service component*29

All drugs recommended for STI treatment are readily available through public pharmacies. In order to improve accessibility of treatment, some types of drugs are also supplied by international donors and distributed by the MoH to oblast dermatological/venereological dispensaries. To provide patients with drugs to treat STIs the following options can be used.

Option 1. Centralized supply
Drugs purchased from Global Fund money under round 6 are distributed by the MoH to patients from HIV affected groups. Recipients of these drugs are oblast dermatology/venereology dispensaries. In order to provide patients with these drugs, it is necessary to establish cooperation with the oblast dermatology/venereology dispensary and detail the mechanism for receipt of these drugs by patients.

Option 2. Purchase at patients' own expense
As long as virtually all drugs are available through pharmacies, patients can purchase them at their own expense in cases where they are not supplied centrally. Not all patients have sufficient funds to buy these drugs.

Option 3. Purchase from HCF non-budgetary funds
Some drugs for treatment and prevention of STIs can be purchased from HCF non-budgetary funds.

Supply of drugs for opioid substitution therapy

*Service component*16

Currently, OST drugs are supplied to Ukraine as humanitarian assistance from international donors. Each delivery is distributed in accordance with MoH Order according to geographic region. In their turn, territorial HAs define end recipients and procedures for drug distribution among subordinate HCFs.

To provide patients with OST drugs, one or several of the following options can be used.

Option 1. Centralized supply
In accordance with the Ministry of Health-applied territory-based distribution principle, HAs issue a special Order to define a pharmacy that can receive the drug from a distributor (at present time it is the state joint-stock company *Liky Ukrainy*).After that, in accordance with a distribution schedule, HCFs receive the drug from this pharmacy. In some regions, HCFs receive drugs directly from the distributor. To get drugs under the territorial distribution scheme, the management of a HCF must apply to the oblast HA with a letter requesting inclusion in the drug distribution schedule. The letter needs to specify and justify the number of patients that this HCF is planning to cover with treatment. The relevant HA can consider this request during the preliminary needs assessment done by the MoH, prior to distribution of the next batch of drugs. In case drugs are needed earlier, the HA can conduct redistribution between the subordinate HCFs, within the confines of current supply.

Supply from pharmacies to HCFs is done in accordance with the current Order [60].

Option 2. Purchase from HCF funds
Last year in Ukraine, two locally manufactured buprenorphine hydrochloride products were registered; these drugs can be purchased by HCFs.

Option 3. Emergency supply
This option is used to provide drugs to patients on OST who are admitted as in-patients at other HCFs. Current normative documents do not describe the mechanisms for transferring narcotic drugs between HCFs. For this reason, the HA should store a certain amount of drugs at a pharmaceutical warehouse so that these drugs can be dispensed to the HCF where the patient is staying on an emergency basis. The mechanism and agreement of such supply must be approved in advance by HA Order. Also, such Orders may include a section about transferring information from the main OST Program to the facility where the patient is staying, as well as about the treating physician's visit for consultation.

Option 3. Supply by prescription
According to the Order[148], OST drugs can be dispensed to patients in pharmacies by prescription. This option should be included in the HA Order on regional distribution of drugs. The Order must include the name of the pharmacy and the amount of drugs that should be dispensed by prescription monthly.

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[148]Order of MoH Ukraine of 19.07.2005 № 360 "On approval of Regulations on issuing prescriptions and orders for drugs and medical products, Procedure for dispensing drugs and medical products from pharmacies and their structural divisions, Instruction on storage, inventory and disposal of prescription and order forms".

Supply of viral hepatitis B vaccine

*Service component*22

At present, the HBV vaccine is available at public pharmacies, can be purchased by HCFs, and is also supplied under oblast viral hepatitis programs. Accordingly, the following options can be used to provide patients with drugs to treat hepatitis.

Option 1. Supply under regional programs

Step 1. Including a HCF in the regional program as an implementer

In some oblasts of Ukraine, regional viral hepatitis programs are operational; the hepatitis B vaccine is purchased under these programs. Regional HAs approve the vaccine distribution plan, and define vaccine recipients. In order to have patients covered with vaccination, the HCF must be included in the list of program implementers.

Step 2. Providing for transportation and storage

Vaccines should be transported and stored under special conditions described in the Procedure[149]. This Procedure also stipulates that a deed of transfer and acceptance for immunobiological drugs must be issued.

Option 2. Purchase from HCF non-budgetary funds

Step 1. Purchase of vaccines

To cover patients' needs, the hepatitis B vaccine can be purchased from the facility's non-budgetary funds.

Step 2. Transportation and storage

Vaccines should be transported and stored under special conditions described in the Procedure [149]. This Procedure also stipulates that a deed of transfer and acceptance for immunobiological drugs must be issued.

Option 3. Purchase at patients' own expense

As long as the hepatitis B vaccine is available through public pharmacies, patients can buy it at their own expense, in cases when it is not supplied centrally. The vaccine is sold to the public in accordance with the established procedure[150].

Dispensing drugs under health worker supervision

*Service component*4, 11, 12

This mechanism is used for DOTS, using drugs that require a high level of adherence (TB drugs, ART).

Option 1. On-site

Step 1. Training of personnel

A health care worker dispensing drugs needs to undergo special orientation, understand the importance of DOTS, know procedures for drug administration and have adherence counselling skills.

Step 2. Material and technical resources and record-keeping

The site needs to have at least one working space for a nurse. The there must also be a cabinet or storage box for drugs. Requirements for equipping a DOTS office for out-patient treatment of TB are specifically detailed in item 10

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[149]"Procedure for ensuring appropriate conditions of storage, transportation, receipt and inventory of medical immunobiological drugs in Ukraine" approved by the Order of MoH Ukraine of 03.02.2006 № 48 "On Procedure on preventive vaccination in Ukraine and medical immunobiological drugs quality and circulation control".

[150]"Procedure for dispensing medical immunobiological drugs to citizens" approved by the MoH Order of Ukraine of 03.02.2006 № 48 "On the Procedures for preventive vaccination in Ukraine and medical immunobiological drugs quality and circulation control".

of the Regulation [48]. Also, DOTS site facilities need to conform with the general principles of infectious control [44].

DOTS-therapy sites must have the relevant documentation stipulated by Standards and Protocols to regulate this type of treatment. For TB patients, in addition to standard medical documentation, a TB medical record must be kept (TB form01) [46] in which daily drug consumption is recorded.

Case management and counselling activities

Service component5, 11, 16, 21, 22, 26, 33, 34, 36, 37

The psychosocial component of a patient's management is an important part for many services. Case management is a complex service that includes many types of activities; many of them can be provided outside the HCF.

From an organizational perspective, the primary activity of case management is counselling clients on an individual or group basis. Regardless of the topic of counselling, there are two possible ways to organize this work.

Option 1. Providing case management by HCF personnel

Step 1. Involving personnel

Most frequently, case management is the responsibility of a psychologist or a social worker. If HCF staff does not include a psychologist or a social worker to cover the needs of all clients, there are several options to involve such a specialist (на стNu0440 67).

Step 2. Training personnel

Current regulations do not specify the qualifications of a specialist providing case management. There are training programs to train social or health care workers to provide different kinds of psychosocial activities. Trainings are conducted on a regular basis on OST case management (Ukrainian institute for public health policy, www.uiphp.org.ua) and ART case management (National training centre, www.hivtri.org.ua).

Step 3. Material and technical resources

It is necessary for HCF management to provide adequate material and technical conditions for a psychologist or social worker, including an adequately equipped room with the necessary conditions to ensure confidentiality.

Option 2. Providing case management by cooperating with a different facility

If case management cannot be provided by a HCT's own personnel, it should be provided through cooperation with a different facility that has specially trained personnel.

Step 1. Identifying a partner

Case management services can be provided by specialists of regional branches of the State social service for families, children and youth, under a relevant Order [119]. Also, in many regions, HIV-service NGOs are operating case management projects for vulnerable populations and/or people with HIV, funded by donors or other funds.

Step 2. Cooperation agreement

To formalize the terms of cooperation and the responsibilities of parties, a Cooperation agreement must be signed.

Step 3. Ensuring conditions for work

To be efficient, case management should be provided on-site; for this reason, the HCF should provide an office that suits the needs of case management (individual or group work).

Electrocardiography

*Service component*3, 21, 25, 26, 31

Electrocardiographic testing can be a component of some services, or a service on its own.

Option 1. Using the HCF's own equipment

Step 1. Material and technical resources

If a HCF has an ECG machine, this resource should be used. If it is not available, or it cannot cover the need, it is possible to purchase the machine:

- with HCF money (budgetary or non-budgetary);
- through donor organizations.

It is not necessary to allocate a separate room for the ECG because the majority of modern machines are portable. However, a couch is needed for out-patient assessment.

Step 2. Staffing

Electrocardiographic readings are done by a nurse who has the relevant skills. Interpretation of results is done by a treating physician; in case of unclear diagnosis, an internist or a cardiologist can be invited for consultation using one of the mechanisms.

Option 2. Using the portable machine of a different facility

Step 1. Partnering

It is reasonable to partner with the closest HCF that has an ECG machine. To formalize terms of cooperation and responsibilities of parties, a Cooperation agreement should be signed.

Step 2. Allocating a room and setting working hours

It is not mandatory to allocate a separate room for the ECG because the majority of modern machines are portable, but to make an assessment on an out-patient basis, a couch is required.

Ultrasonography

*Service component*3, 20, 24, 25, 26, 31

Ultrasonography can be a component of other services, or a separate service in its own right.

Option 1. Using the HCT's own machine

Step 1. Material and technical resources

If a HCF has its own ultrasonography machine, this resource should be used. If it is not available, or it cannot cover the need, it is possible to purchase the machine:

- with HCF money (budgetary or non-budgetary);
- as part of centralized supply by health ministry (HA) with high-cost equipment;
- through donor organizations.

If a HCF sets up a separate ultrasonography room, it must meet the requirements described in the Standard Regulation[151].

Step 2. Staffing

Ultrasonography is done by a specially trained physician. Depending on the physician's expected workload, he/she can be involved through any of the described mechanisms (на стNu0440 65). Staffing for an ultrasonography room is described in the Standard regulation [155].

Step 3. Ensuring quality and safety of testing

The head of a HCF is responsible for ensuring the quality and safety of ultrasonographic testing. During testing, it is necessary to observe testing quality and timing requirements approved by the Order[152]. Test findings must be registered in a special log, as well as in a day journal filled out in accordance with forms approved by the Order[153].

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[151]"Regulation on Unit (room) of ultrasonography" approved by MoH Order of Ukraine of 28.11.1997 № 340 "On improving radiology and radiotherapy service".

[152]"Recommended estimated standard time for ultrasonographic testing" approved by the MoH Order of 28.11.1997 № 340 "On improving radiology and radiotherapy services".

Option 2. Using the portable machine of a different facility

If a city HCF has a portable machine, it can be used; with this option, a partner facility must also send an appropriate physician for operating this machine.

Step 1. Partnering

It is reasonable to partner with the closest HCF that has a machine. To formalize terms of cooperation and responsibilities of parties, a Cooperation agreement should be signed.

Step 2. Allocating a room and setting working hours

It is not mandatory to allocate a separate room as the majority of modern machines are portable, but to make an assessment on an out-patient basis, a couch is required.

Tuberculin test (PPD)

*Service component*3, 8

Tuberculin tests are the basis of diagnosing TB. Intradermal tuberculin Mantoux test with 2 TUs (tuberculin units) of purified protein derivative (PPD) in standard dilution is a specific diagnostic test used for monitoring of TB and, in clinical practice – for diagnosis (including differential diagnosis) of TB.

Test procedure, indications and contraindications are detailed in Instructions [28, 29] and in the Procedure [30] that supplements the Instruction [29]. Practical steps of testing are as follows:

Step 1. Supply of tuberculin

Usually tuberculin is purchased from state or local budget funds, and than transferred to HCFs to test target groups in accordance with the annual plan for tuberculin diagnostic testing, developed by sanitary and epidemiological stations together with TB dispensaries. To obtain tuberculin under the centralized distribution scheme, it is necessary to file an application with the territorial HA and Sanitary-epidemiological station with estimates of the quantities (depending on the number of patients in the Program), and ensure that the HCF is included in the plan for tuberculin diagnostic testing. Calculation procedures are described in the Instruction [29] and the Procedure [30] which supplements the Instruction.

There is also an option for redistribution of tuberculin from TB facilities, and purchase from the non-budgetary funds of a HCF.

Step 2. Storage and transportation of tuberculin

Tuberculin is stored in dry dark rooms at +2 to +8˚C (in refrigerators). It can be transported in all types of closed-top vehicles under conditions that prohibit both freezing, and heating of the product to over +18˚C. In case of violation of tuberculin storage requirements, false-negative results are possible during testing. Shelf life is 12 months.

Step 3. Staffing and personnel training

Mantoux tests are performed by a physician or specially trained nurse under a physician's supervision. According to the Instruction [28], training of nurses to perform the Mantoux test with 2 TU of tuberculin is conducted by the health care personnel of TB dispensaries (physician, qualified nurse). The training facility can follow up with nurses on a regular basis to ascertain whether they observe testing protocols, and issue them a permit certificate for one year.

Tuberculin test findings are interpreted by the physician or the nurse who performed the testing, in accordance with the Procedure described in the Instructions [28, 29].

Step 4. Material and technical resources and regulatory basis

Diagnostic testing with tuberculin is performed in a procedure room or other room where there is a separate table for that purpose. Requirements regarding instruments and disposable items (syringes, sterilizer boxes, pincers, rulers,

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[153]MOH Ukraine Order of 29.12.2000 № 369 "On approval of medical record forms used in in-patient and out-patient (ambulatories) facilities".

disinfectants) are stipulated in the Instruction [29] and the Procedure [30] that supplements the Instruction. Test findings are interpreted in accordance with the Instruction [29] and entered into an out-patient record and a dispensary record (form № 131/c).

X-ray/photofluorography

*Service component*3, 4, 9, 11, 12, 25, 26, 31

X-ray can be a component of some services, or a separate service in its own right.

Option 1. Using a HCT's own X-ray or fluoroscopy machine

Step 1. Equipment and material resources and technical basis

If a HCF has its own unit, it reasonable to use it. If not, or if the unit does not cover all needs, it is possible to purchase a unit:

- with HCF funds (budgetary or non-budgetary);
- as part of the centralized supply from the health ministry (HA) with high-cost equipment;
- with local or state budget money under the current National TB response program;
- with donor funds.

When equipping rooms for X-ray diagnostics, it is necessary to observe construction [127] and sanitary[154]norms (regulations). Rooms for X-ray diagnostics and photofluorography must conform with the requirements of Standard regulations[155, 156].

X-ray and fluoroscopy film and reagents are purchased in accordance with appropriate state and local budgets, and transferred to the HCFs where testing is performed.

Step 2. Staffing

Staffing of X-ray and fluoroscopy rooms is described in Standard regulations [155]. According to the Order [11], virtually all HCFs having the relevant equipment can add positions for X-ray physicians and technicians. The position of an X-ray physician can be added to the list of staff in accordance with workload standards, or a part-time specialist from a different facility can be engaged using one of the above mechanisms.

Step 3. Ensuring quality and safety of testing

The head of a HCF bears the responsibility for ensuring the quality and safety of X-ray testing. Radiation safety requirements are outlined in the Sanitary norms (rules) [154]. During testing, it is necessary to observe the testing quality and timing requirements approved by the Order [157].

Option 2. Testing at the closest HCF

A Special Order issued by the territorial HA can designate a HCF where patients referred by the AIDS centre or by other specialists, will undergo X-ray testing free-of-charge.

Option 3. Testing using a portable fluoroscopymachine

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[154]"Hygiene requirements for equipping and operability of X-ray rooms and X-ray testing" approved by the MoH Ukraine Order of 04.06.2007 № 294 On approval of State sanitary rules and regulations "Hygiene requirements for equipping and operability of X-ray rooms and X-ray testing".

[155]"Regulation on X-ray testing room" approved by the MoH Ukraine Order of 28.11.1997 № 340 "On improving radiology and radiotherapy service".

[156]"Regulation on fluoroscopy unit" approved by the MoH Ukraine Order of 28.11.1997 № 340 "On improving radiology and radiotherapy service".

[157]"Recommended estimated standard time for X-ray testing" approved by the MoH Order of 28.11.1997 № 340 "On improving radiology and radiotherapy service".

It is convenient to use a mobile fluoroscopy vehicle to screen for TB; usually, a territorial TB dispensary will have such a vehicle. It is important to agree on the outreach schedule with the head of the dispensary, and obtain approval for the schedule by joint Order or HA Order. The Order should define the mechanism for supplying X-ray film. Usually, one mobile fluoroscopy vehicle can test 50–80 patients per one outreach session.

Sputum collection

*Service component*3, 4, 10, 11, 12

Sputum collection is the pre-analytical step of microscopic and bacteriologic TB testing. The procedure for sputum collection is not complicated, and HCFs of any level are able to do this at their respective sites. The analytical testing step can be performed either at a HCFs own lab (sputum microscopy station – first level TB diagnostic testing) or sputum can be transported to another HCF's lab (for bacteriology testing – II–III level TB diagnostic testing). Sputum collection consists of the following steps:

Step 1. Establishing a sputum collection station

Sputum for microscopy testing can be collected in a specially designated room at a HCF that is well-ventilated, or outside, in a specially designated area (also at syringe exchange points or on an outreach basis). Sputum can be collected at a patient's home.

Closed rooms where sputum is collected must meet sanitary-hygiene requirements, be well-ventilated, equipped with bactericidal lamps and have disinfectants in place for decontamination of items and surfaces. Sputum collection points (inside or outside) must be arranged in accordance with the Standard Regulation [43] and Standard [44].

Step 2. Supply of containers and disposable items

Sputum is collected in special containers (gallipots) ordered by the HCF and purchased from local budget funds (or the regional TB control program) in accordance with the need.

Containers must be made of transparent durable material, have screw-on or tight lids that are leak-proof and airtight with a volume of no less than 30 ml and opening diameter no less than 35 mm. According to the Standard [44], only disposable containers (gallipots) can be used for sputum; after use, they must be decontaminated and incinerated in a special furnace for disposing of infectious materials.

Personnel working at sputum collection points or at bacteriologic lab, must be provided with protective equipment.

Step 3. Storage and transportation

Before transportation to the lab for microscopy, sputum samples are kept at room temperature for no longer than one hour, after which time they must be stored in a refrigerator for no longer than 4 days. For bacteriologic testing, sputum needs to be sent immediately after collection, or put into a fridge right away and kept there for no longer than 24 hours.

Disposable containers (gallipots) are labelled and put into a multi-use plastic container with a lid for transportation to the level I lab for microscopy; (such a lab can be established in the majority of HCFs).If both microscopy and bacteriology testing need to be performed on the same sample, the material is sent to a level II or III testing laboratory located in specialized TB facilities. Multi-use transportation containers are subject to disinfection after samples are left with the laboratory.

Step 4. Staffing

A nurse responsible for sputum collection, sample labelling and filling out requisition forms, must undergo special training. Samples are transported by a designated nurse or feldsher. If sputum is collected by NGOs, sputum samples can be transported in special containers by specially trained social workers or volunteers. Sputum transportation to the lab cannot be entrusted to untrained individuals.

Step 5. Observing sputum collection procedures and regulatory requirements

Sputum collection procedures and rules are described in item 3.6–3.8 of the Standard [44] and in the Instruction [134]. For AFB microscopy testing according to Ziehl-Nielsen procedures, sputum is collected 2–3 times (no less than 2 samples). The first sample is provided by the patient during a visit to the HCF. For the second sample, the patient is given a container to collect the sample at home in the morning before breakfast. The third sputum sample

is collected during the patient's visit to the HCF. Each container is labelled with the patient ID number, and the same number is written in the requisition form.

All the samples are accompanied by their respective requisition forms; when several samples are transported, a general inventory for all samples is issued in accordance with the approved forms [45].

Collection of liver biopsies

*Service component*21, 22

Current methodologies consider aspiration liver biopsy to be the gold standard for diagnosing chronic liver diseases, as this test allows differentiation of the diagnosis, identification of disease activity, stage of fibrosis, as well as evaluation of therapy efficiency and prognosis. This procedure is associated with clear indications.

Option 1. On-site

Currently, the equipment for liver biopsy is included in the official equipment list for gastroenterology rooms at GI centres or polyclinics of district/city hospitals only[158]. It may therefore be difficult to try to undertake biopsy in other types of HCFs.

Step 1. Equipment and material resources and technical basis

Biopsies are taken in the OR or specially equipped procedure room. When equipping the procedure room, construction [127] and sanitary [128] norms must be observed.

Biopsy requires special instruments. If there are no such instruments or if the available instruments are not sufficient, it is possible to purchase them:

- with HCF funds (budgetary or non-budgetary);
- with local or state budget funds;
- with donor funds.

Usually, liver biopsy is done with ultrasound guidance. The set-up for sonography guidance is described in a separate section.

Step 2. Staffing

Liver biopsy is performed by a gastroenterologist who has received special training. Staffing for gastroenterology rooms is described in an exemplary Regulation[159]and the Order [11]. An X-ray specialist can be included among the staff according to his/her workload, or it is possible to involve a specialist from a different facility on a part-time basis, per one of the described mechanisms.

Option 2. At a specialized HCF by agreement

Step 1. Defining a partner HCF

When identifying a partner facility, it is necessary to consider the distance that will have to be covered when transporting the material. It is possible to use several options to cooperate with partner facilities and use their labs:

- using the HCF that serves the same catchment population within a specific region (for patients residing on in certain region);
- using a specialized facility designated by a higher health care authority;
- using the laboratory of a different HCF by agreement (paid services).

[158]Order of MoH Ukraine of 28.12.2009 № 1051 "On care provision to gastrointestinal patients".

[159]"Exemplary Regulation on a consultation gastroenterology office" approved by the MoH Ukraine Order of 28.12.2009 № 1051 "On care provision to gastrointestinal patients".

Whichever option is selected, it is best to conclude a cooperation agreement or get approval by Order of the territorial HA, to define the responsibilities and cooperation mechanism for all parties. Services can be paid (if necessary) from non-budgetary funds, or by patients themselves.

Diagnostic reproductive health and STIs exams

*Service component*24, 25, 28

There are special requirements for performing an examination to diagnose reproductive health disorders or STIs. This component covers material and technical aspects of diagnostics and staffing, covered in the service description.

There are 2 possible options to implement this component without referrals.

Option 1. On-site

Women are examined for reproductive health disorders and STIs in an examination room that must be equipped with a gynaecology chair. Men can be examined in a general examination room (or separate part of the physician's office) or in an andrology room. Space for setting up the room can be allocated by an ambulatory-polyclinic; the room must meet all the Construction [127] and Sanitary [128] norms and rules.

According to the exemplary list[160], gynaecology offices must be equipped with the necessary instruments (specula, gynaecology sets etc.). The room must also have the necessary equipment for cervical smear for cytology testing, material collection equipment to test for STIs, material collection equipment for other tests (brushes, universal probes, Folkman spoons, applicators etc.).

Equipment and staffing recommendations for the andrology room are described in the Regulation[161].

Option 2. At a mobile point

Gynaecological examination and examination by a dermatologist/venereologist can be performed in specially equipped vehicles. Physicians with relevant qualifications work at such mobile points.

There are no approved regulations governing mobile points' activities. Currently, mobile points are coordinated by HIV-service NGOs in cooperation with AIDS centres and dermatology/venereology dispensaries. Management of HCFs can conclude an agreement to include the HCF in a schedule for mobile point visits, in order to serve patients at the location most convenient for them.

Setting-up rooms to work with narcotics and substances

*Service component*16

The Requirements [**62**] describe two types of rooms at a HCF that can be used for narcotic drugs circulation: storage rooms and wards (stations).The two types of rooms differ in terms of their level of protection and possible drug storage time; (storage time is defined in the Procedure for narcotic drugs circulation [61]). Rooms can be set-up at the HCF's own expense or through funding by international donors.

Option 2. Ward set-up

To implement the above activities, a HCF should have a ward or a station where drugs can be dispensed and consumed. The simplest option, in order to satisfy licensing requirements, is to set up the ward only, without arranging for a separate room for storing drugs. According to the current Circulation procedure [60], wards can keep

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[160]Order of MoH Ukraine of 04.11.2010 № 951 "On approval of Exemplary lists of equipping with equipment, medical devices and medical products (obstetrical and gynecological care)".

[161]"Regulation on andrology office" approved by the Order of MoH Ukraine of 27.11.1992 № 171 "On improving sexology and andrology care of the population of Ukraine".

narcotics and substances to cover needs for three days only. Under these circumstances, it is necessary to bring drugs from the pharmacy every three days.

Requirements for setting-up the ward are described in items 2.1.4and3.1.4 of the document [**62**] which include a description of all the required elements (walls, window security bars, windows, alarm system etc.).

Option 3. Setting-up a room for storage and use

The best option is to set up both types of rooms—one for storage and one for use. This will allow the HTC to maintain a two-week stock of drugs at the facility and will reduce transportation cost. To ensure that need is covered, drugs can be delivered from the hospital storage facility every 3 days.

Set-up of the room is described in items 2.1.3 and 3.1.3; set-up of the ward is described in items 2.1.4 and 3.1.4 of the Requirements [**62**]. These items have descriptions of all required elements (walls, security bars, doors, windows, alarm system etc.).

Licensing of offices where narcotics circulation is provided

Service component16

An absolute prerequisite for OST provision at a HCF is availability of rooms that conform to requirements. There are two options for legal drug circulation in these rooms.

Option 1. Licensing of HCF

HCFs involved in activities associated with narcotics or substance circulation must be licensed in accordance with the Laws of Ukraine[162,163], Resolution of CM[164]and other normative documents. The licensing authority is the State service of Ukraine for medications and drug control.

After setting-up the rooms, a HCF must obtain approval from the MIA[165]and meet all other requirements pertaining to personnel, structures and organizational aspects outlined in the licensing conditions[166]. In order to get licensed, a HCF must file an application with the licensing authority according to the form in appendix 1, adhering to the Licensing conditions [166]. The application must be supplemented with a package of documents specified in the List[167]. Applications are processed in accordance with defined criteria and within the term specified on the health ministry's web site[168].

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[162] Law of Ukraine of 15.02.1995 № 60/95-ВР"On narcotic substances, psychotropic substances and precursors".
[163] Law of Ukraine of 01.06.2000 № 1775-III "On licensing certain types of business activities".
[164]Resolution of CM Ukraine of 05.12.2007 № 1387 "On approval of Procedure for licensing activities related to circulation of narcotic substances, psychotropic substances and precursors, and making revisions to the Resolutions of the Cabinet of Ministers Ukraine of November 14, 2000 № 1698 and of July 4, 2001 № 756".
[165] Letter of MIA Ukraine of 22.08.2004 № 40/2-1447 "On Procedure for obtaining approval of MIA Ukraine for activities related to the circulation of narcotic substances, psychotropic substances and precursors".
[166]"Licensing conditions for conducting business activities in cultivation of plants included in Table I of the List of narcotic substances, psychotropic substances and precursors approved by the Cabinet of Ministers Ukraine, development, production, manufacturing, storage, transportation, acquisition, selling (dispensing), import to the territory of Ukraine, export from the territory of Ukraine, use, disposal of narcotic substances, psychotropic substances and precursors included into the mentioned List" approved by the MoH Ukraine Order of 02.02.2010 № 66"On approval of Licensing Conditions for conducting business activities in cultivation of plants included in Table I of the List of narcotic substances, psychotropic substances and precursors".
[167] Resolution of CM Ukraine of 04.07.2001 № 756 "On approval of the list of documents attached to the application for issuing Licenses for individual business activities".
[168]"Licensing of activities related to circulation of narcotic substances, psychotropic substances and precursors", MoH Ukraine.

During preparation of the package of documents, it is necessary to ensure that all relevant HCF employees are included on the list of people involved in drug circulation, and all the rooms where drugs are going to be stored and consumed – on the relevant list of rooms.

To provide OST at a division with an address that is different from the legal address of the HCF, it is necessary to obtain a copy of the main License, and for that purpose, a separate application must be filed.

Option 2. Renting space to a HCF with an active license

If it is not possible for a HCF to obtain its own license in due time, there is the option to rent set-up rooms at a HCF that already holds a license. After concluding an agreement, the lessee must apply to the licensing authority to have a copy of the license issued for its branch or separate division in accordance with form 5 of the appendix to the Licensing Conditions [166]. After obtaining the copy, a lessee can conduct business activities in rented space according to the conditions of the main license.

The only step for this option is concluding and signing a lease contract with the HCF that agrees to establish an OST office on rented space. The lessee is responsible for observing licensing conditions, ensuring drug supply, prescription, transportation and dispensing by its own personnel.

Involving a legal consultant

Service component35

Beside a professional lawyer, other trained specialists can provide consultations on legal issues.

Option 1. Involving a qualified lawyer

There are three main ways of involving a qualified lawyer.

- The best way to involve a qualified lawyer is cooperation with a human rights organization implementing a project to provide care for vulnerable groups.
- Some social service centres invite lawyers to cooperate, under partnership agreements; they may provide services to PWID and patients on OST.
- If there is a justified need, consultations with a professional lawyer can be paid for through OST or ART case management projects.

Option 2. Training a staff worker on legal issues

It is possible to train a staff worker to be a consultant. In this case, the worker must have the relevant ability and desire, access to the regulatory documentation (for example, web-based) and databases of contacts and organizations responsible for resolving the necessary issues.

Option 3. Involving a volunteer from a legal clinic

Some legal educational establishments have legal clinics where students can practice and provide consultations on legal issues.

Option 4. Interface with public reception offices

Some city administrations and headquarters of political parties may have public reception offices that facilitate resolution of some legal issues. Cooperation with such a public reception office may ensure better access for clients to this service.

Appendix. List of documents

No.	Type of document	Issuing authority	Date	Reg. No.	Name of document	Internet links	Comments
1.	Study report	WHO, UIPHP	2009		Assessment of accessibility of comprehensive health and social care services for people who inject drugs (PWID) in integrated care centres	http://www.uiphp.org.ua/media/789	
2.	Publication	WHO	2010		Building integrated care services for people who inject drugs in Ukraine	http://www.euro.who.int/en/what-we-do/health-topics/diseases-and-conditions/hivaids/publications/2010/building-integrated-care-services-for-injection-drug-users-in-ukraine	
3.	Evaluation report	Alliance	2009		Report on pharmacological treatment of opioid dependence and integrated health care system: Ukraine		
4.	Evaluation report	UIPHP	2009		Assessment of integrated service provision in Ukraine	http://www.uiphp.org.ua/media/1191	
5.	Law	VR	19.02.2009	1026-VI	On approval of the National program for HIV prevention, treatment, care and support for HIV-infected and AIDS patients in 2009-2013	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=1026-17	current, no revisions
6.	Assessment tool	WHO	2008		“Assessing feasibility of a HCF to provide integrated care”.		
7.	Law	VR	23.12.2010	2861-VI	On countering the spread of diseases caused by human immune deficiency virus, and legal and social protection of people living with HIV	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=2861-17	current, no revisions
8.	Order	MoH	19.08.2005	415	On improvement of voluntary counselling and testing for HIV-infection	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1404-05	current, no revisions, registered with MOJ Ukraine on 22.11.2005 at № 1404/11684
9.	Procedure to Order	MoH	19.08.2005	415	Procedure (protocol) of voluntary counselling and testing for HIV-infection	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1404-05	current, no revisions

10.	Draft guideline to Order	MoH			Guideline for health care workers on delivering HIV counselling and testing services	www.stop-aids.gov.ua/attachments/530_PITC_Nastanova.doc	
11.	Order	MoH	23.02.2000	33	On staffing norms and standard staffing of HCFs	http://www.moz.gov.ua/ua/portal/dn_20000223_33n.html	current, with revisions and amendments, recent revisions per MoH Order of 5.07.2010 № 532
12.	Draft Order	MoH			On approval of Standard regulation on specialized units "Mobile point of counselling and testing for HIV-infection and mobile ambulatory unit for counselling and testing HIV-infection and sexually transmitted infections (STI) and treatment of STIs"	http://www.stop-aids.gov.ua/index.php?option=com_content&view=article&id=555:-l-&catid=43:2009-01-16-16-53-55&Itemid=11	draft not approved yet
13.	Regulations to Order	MoH	25.02.2008	102	Standard regulation on "Dovira" (VCT) office	http://www.moz.gov.ua/ua/portal/dn_20080225_102.html	current, no revisions, registered with MOJ Ukraine on 19.03.2008 at № 220/14911
14.	Attachment to Protocol in Order	MoH	19.08.2005	Appendix 1 to item 12 Sec. 4 of Order 415	Specific features of counselling for different population groups	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1404-05	current, no revisions
15.	Procedure to Resolution	CM	18.02.1998	2026	Procedure for accreditation of special laboratories for AIDS diagnosis	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=2026-98-%EF	current, no revisions
16.	Order	MoH	22.02.2002	71	On approval of Instruction on organization of laboratory diagnosis of HIV- infection	http://zakon.nau.ua/doc/?uid=1039.82.0	current, no revisions
17.	Order	MoH	27.08.2009	639	On approval of Provisional Procedure of testing for HIV-infection with rapid tests, their use, storage and recording of results	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1026-09	current, no revisions, registered with MOJ Ukraine on 4.11.2009 at № 1026/17042

18.	Order	MoH	21.12.2010	1141	On approval of Procedure for detection of serological markers of HIV-infection and ensuring the quality of tests	http://www.nau.kiev.ua/druk.php?name=354179-25012011-0.txt	according to MOJ Ukraine Order of 25.01.2011 № 299/5 was returned back to MoH Ukraine for finalization for 1 month term
19.	Order	MoH, State statistics comm.	24.12.2004	640/ 663	On approval of forms of primary recording and reporting forms on HIV/AIDS and instructions for their completion	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0062-05	current, no revisions, registered with MOJ Ukraine on 19.01.2005 at № 62/10342
20.	Order	MoH	28.12.2002	507	On approving norms of health care delivery and indicators of quality of health care	http://www.moz.gov.ua/ua/portal/dn_20021228_507.html	current, no revisions
21.	Protocol to Order	MoH	12.07.2010	551	Clinical protocol of antiretroviral therapy of HIV-infection for adults and adolescents	http://moz.gov.ua/ua/portal/dn_20100712_551.html	current, no revisions
22.	Protocol to Order	MoH	13.04.2007	182	Clinical protocol for diagnosis and treatment of opportunistic infections and general symptoms in adults and adolescents with HIV-infection	http://moz.gov.ua/ua/portal/dn_20070413_182.html	current, no revisions
23.	Protocol to Order	MoH	03.07.2007	368	Clinical protocol for provision of palliative care; symptomatic and pathogenetic therapy for patients with HIV/AIDS	http://moz.gov.ua/ua/portal/dn_20070703_368.html	current, no revisions
24.	Protocol to Order	MoH	28.05.2008	276	Clinical protocol for provision of medical care to patients with co-infection of TB and HIV	http://moz.gov.ua/ua/portal/dn_20080528_276.html	current, no revisions
25.	Protocol to Order	MoH	30.12.3008	826	Clinical protocol for diagnosis and treatment of viral hepatitis C in adults with HIV	http://moz.gov.ua/ua/portal/dn_20081230_826.html	current, no revisions
26.	Recommendations to Order	MoH	12.12.2003	580	Guidelines for laboratory monitoring of HIV infection and antiretroviral therapy	http://moz.gov.ua/ua/portal/dn_20031212_580.html	current, revised per MoH Order of 13.04.2007 № 182
27.	Order	MoH	07.04.2008	187	On approval of provision for recording and reporting forms for monitoring treatment of HIV/AIDS and instructions on their completion	http://www.moz.gov.ua/ua/portal/dn_20080407_187.html	became null and void per MoH Order of 06.08.2010 № 660
28.	Instructions to Order	MoH	05.04.2006	198	Instruction on medical use of tuberculin for making diagnosis of TB	http://moz.gov.ua/ua/portal/dn_20060405_198.html	became null and void per MoH Order of 20.11.2006 № 767

29.	Instruction	Chief Sanit. Doctor Ukraine	19.06.1995		Instruction on medical use of TB liquid purified allergen in standard dilution for intracutaneous use	http://salutna23.kiev.ua/privivki/60-2008-11-16-23-28-28.html	current, no revisions
30.	Instructions to Order	MoH	29.07.1996	233	Procedure of performing tuberculin diagnostics in Ukraine	http://moz.gov.ua/ua/portal/dn_20030729_233.html	current, no revisions, registered with MOJ Ukraine on17.09.1996 № 538/1563
31.	Resolution	CM	15.02.2006	143	On approval of mandatory preventative check-up of certain categories of the population for detection of TB	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=143-2006-%EF	current, no revisions
32.	Instructions to Order	MoH	17.05.2008	254	Instruction on periodicity of radiographic evaluation of the chest organs for certain categories of the population of Ukraine	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0524-08	current, no revisions, registered with MOJ Ukraine on12.06.2008 № 524/15215
33.	Protocol to Order	MoH	09.06.2006	384	Protocol for health care provision for patients with TB	http://moz.gov.ua/ua/portal/dn_20060609_384.html	current, no revisions
34.	Order	MoH	04.06.2010	461	On approval of Comprehensive plan for scaling up access of the population to HIV prevention, diagnosis, treatment, and care and support for people with HIV/AIDS in Ukraine in the quarter II –IV of the year 2010 –quarter I of the year 2011	http://www.moz.gov.ua/ua/portal/dn_20100604_461.html	current, no revisions
35.	Standard to Order	MoH	19.08.2008	476	Standard of treatment of HIV-positive people, who are using injecting drugs	http://moz.gov.ua/ua/portal/dn_20080819_476.html	current, no revisions
36.	Standard to Order	Ministry for Families, Children and Youth Ukraine	18.12.2008	4941	Standard of the minimal package of social services, aimed at prevention of HIV/STI and complications associated with injecting drug use	http://www.dcssm.gov.ua/ua_orders.phtml	cancelled by the Order of Ministry for Family, Youth and Sports Ukraine of 23.11.2010 № 4180

37.	Order	Ministry for Families, Children and Youth Ukraine, Ministry for Labour and Social Policy Ukraine, MoH	13.09.2010	3123/275/770	On approval of standards for provision of social services for the representatives of risk groups	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0903-10	current, no revisions, registered with MOJ Ukraine on8.10.2010 at № 903/18198
38.	Law	VR	19.06.2003	966-IV	On social services	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=966-15	current, recent revisions15.12.2009
39.	Protocol to Order	MoH	24.05.2006	318	Protocol for implementation of DOTS strategy in Ukraine	http://moz.gov.ua/ua/portal/dn_20060524_318.html	current, no revisions
40.	Standard to Order	MoH	22.10.2008	600	On approval of Standards for medical care provision to patients with drug-resistant TB	http://www.moz.gov.ua/ua/portal/dn_20081022_600.html	current, no revisions
41.	Instructions to Order	MoH	09.06.2006	385	Instruction on clinical classification of TB and its use	http://moz.gov.ua/ua/portal/dn_20060609_385.html	current, no revisions
42.	Order	MoH	06.02.2006	50	On approval of Standard regulations on laboratories and points for diagnosis of TB and collection of sputum	http://moz.gov.ua/ua/portal/dn_20060206_50.html	current, no revisions, registered with MOJ Ukraine on 30.05.2006 at № 627/12501
43.	Regulations to Order	MoH	06.02.2006	50	Standard regulations on sputum collection points based in HCFs	http://moz.gov.ua/ua/portal/dn_20060206_50.html	current, no revisions
44.	Standard to Order	MoH	18.08.2010	684	Standard of infection control of TB in HCFs, place of long-term stay of people and residence of patients with TB	http://www.nau.kiev.ua/index.php?page=hotline&file=338924-18082010-0.txt&code=z0803-10	current, no revisions, registered with MOJ Ukraine on 10.09.2010 at № 803/18098

45.	Order	MoH, State Statistics Comm.	25.03.2002	112/ 139	On approval of form for primary records N 089/o “Notification about a patient with newly diagnosed active TB or its relapse” and Instruction on filling it out	http://moz.gov.ua/ua/portal/dn_20020325_112_.html	current, no revisions, registered with MOJ Ukraine on 29.04.2002 at № 405/6693
46.	Order	MoH	02.09.2009	657	On approval of form for primary recording and reporting forms for TB and instructions on how to complete them	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1069-09	current, no revisions, registered with MOJ Ukraine on 16.11.2009 at № 1069/17085
47.	Order	CM	24.06.2006	354-p	On approval of the Concept of the National program to respond to TB in the years 2007-2011	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=354-2006-%F0	current, no revisions
48.	Regulations to Order	MoH	07.12.2009	927	Regulation on offices for directly observed treatment of patients with TB at the outpatient level	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1276-09	current, no revisions, registered with MOJ Ukraine on 30.12.2009 at № 1276/17292
49.	Law	VR	05.07.2001	2586-III	On control of TB disease	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=2586-14	current, recent revisions16.04.2009
50.	Order	MoH	21.09.2009	681	On approval of clinical protocols of medical care provision in the specialization “narcology”	http://moz.gov.ua/ua/portal/dn_20090921_681.html	current, no revisions
51.	Recommendations to Order	MoH	10.11.2008	645	Guidelines on opioid maintenance therapy in treatment for people with dependence on opioids	http://www.moz.gov.ua/ua/portal/dn_20081110_645.html	current, no revisions
52.	Order	MoH	27.10.2000	271	On approval of Criteria for diagnosis and treatment of mental and behavioural disorders	http://uazakon.com/documents/date_2f/pg_isgaxc.htm	current, no revisions
53.	Order	MoH	05.02.2007	59	On approval of clinical protocols for care provision in the specialization “Psychiatry”	http://moz.gov.ua/ua/portal/dn_20070205_59.html	current, no revisions
54.	Law	VR	22.02.2000	1489-III	On psychiatric care	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=1489-14	current, recent revisions17.09.2007

55.	Law	VR	15.02.1995	62/95-VR	On measures for countering illegal circulation of narcotic substances, psychotropic substances and precursors and their abuse	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=62%2F95-%E2%F0	current, recent revisions22.12.2006
56.	Order	MoH, MIA, General Prosecutor's, MOJ	10.10.1997	306/ 680/21/ 66/5	Instruction on the Procedure of identification and registration of persons illegally using narcotic substances or psychotropic substances	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0534-97	current, no revisions, registered at MOJ Ukraine 5.11.1997 at № 534/2338
57.	Order	MoH USSR	12.09.1988	704	On timing of regular outpatient follow-up of patients with alcohol abuse, drug abuse and substance abuse	http://www.lawrussia.ru/texts/legal_469/doc469a379x152.htm	current, no revisions
58.	Order	MoH	13.04.2005	161	On development and improvement of substitution maintenance therapy for prevention of HIV/AIDS among drug users	http://moz.gov.ua/ua/portal/dn_20050413_161.html	current, recent revisions3.03.2006
59.	Order	MoH	20.12.2006	846	On measures concerning organization of prevention of HIV/AIDS and substitution maintenance therapy for injecting drug users	http://www.moz.gov.ua/ua/portal/dn_20061220_846.html	current, no revisions
60.	Procedure to Resolution	CM	03.06.2009	589	Procedure for Implementing activities related to circulation of narcotic substances, psychotropic substances and precursors, and control of their circulation	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=589-2009-%EF	current, recent revisions12.10.2010
61.	Procedure to Order	MoH	21.01.2010	11	Order on circulation of narcotic substances, psychotropic substances and precursors in HCFs of Ukraine	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0347-10	current, no revisions, registered at MOJ Ukraine 27.05.2010 at № 347/17642
62.	Requirements to Order	MIA	15.05.2009	216	Requirements for sites and premises intended for implementation of activities on circulation of narcotic substances, psychotropic substances, precursors and storage of such substances removed from illegal circulation	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0759-09	current, no revisions, registered at MOJ Ukraine 12.09.2009 at № 759/16775
63.	Order	MoH	27.12.1999	302	On approval of forms for the recording of statistical documentation used in polyclinics (ambulatories)	http://mozdocs.kiev.ua/view.php?id=1476	current, recent revisions1.12.2004
64.	Order	MoH	26.07.1999	184	On approval of forms for recording statistical documentation used in the in-patient departments of the HCFs	http://moz.gov.ua/ua/portal/dn_19990726_184.html	current, recent revisions13.02.2006
65.	Recommendations	KHMAPE			Guideline on accelerated detoxification with injectable buprenorphine		
66.	Protocol to Order	MoH	13.06.2005	271	Clinical protocol for provision of medical care to patients with chronic hepatitis	http://www.moz.gov.ua/ua/portal/dn_20050613_271.html	current, no revisions

67.	Sets of Assessments toOrder	MoH	28.12.2009	1051	Sets of diagnostic assessments and scope of activities for treatment and prevention in regular outpatient follow-up for patients with gastroenterological problems	http://www.moz.gov.ua/ua/portal/dn_20091228_1051.html	current, revisions per MoH Order of21.09.2010 № 794
68.	Order	MoH	27.07.1998	226	On approval of Provisional sectoral unified standards of medical technologies for diagnostic and treatment processes during in-patient care for the adult population in HCFs of Ukraine and Provisional standards of the scope of diagnostic evaluations, treatment and criteria of quality for treating children	http://moz.gov.ua/ua/portal/dn_19980727_226.html	current, revisions per MoH Order of02.04.2010 № 297
69.	Protocol to Order	MoH	13.06.2005	271	Clinical protocol of medical care provision for patients with liver cirrhosis	http://zakon1.rada.gov.ua/cgi-bin/laws/main.cgi?page=3&nreg=v0271282-05	current, no revisions
70.	Vaccination calendar to Order	MoH	03.02.2006	48	Calendar of preventative immunization in Ukraine	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0665-06	current, recent revisions17.04.2008, registered at MOJ Ukraine 2.06.2006 at № 665/12539
71.	Regulation to Order	MoH	03.02.2006	48	Regulation on organization and performance of preventative immunizations	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0666-06	current, registered at MOJ Ukraine 2.06.2006 at № 666/12540
72.	Regulation to Order	MoH	31.12.2009	1095	Exemplary regulation on Immunization offices	http://moz.gov.ua/ua/portal/dn_20091231_1095.html	current, no revisions
73.	List to Order	MoH	31.12.2009	1095	Exemplary list of equipment of the Immunization office	http://moz.gov.ua/ua/portal/dn_20091231_1095.html	current, no revisions
74.	List to Order	MoH	03.02.2006	48	List of medical contraindications to preventative immunization	http://www.moz.gov.ua/ua/portal/dn_20060203_48.html	current, registered at MOJ Ukraine 2.06.2006at № 667/12541
75.	Order	MoH	28.12.2002	503	On improvement of out-patient obstetric-gynaecological care in Ukraine	http://www.moz.gov.ua/ua/portal/dn_20021228_503.html	current, no revisions

76.	Norms to Order	MoH	28.12.2002	503	Norms of medical care provision to the female population in the specialization “Obstetrics/gynaecology” in ambulatory-polyclinic HCFs	http://www.moz.gov.ua/ua/portal/dn_20021228_503.html	current, no revisions
77.	Order	MoH	15.12.2003	582	On approval of clinical protocols for obstetric and gynaecological care	http://moz.gov.ua/ua/portal/dn_20031215_582.html	current, recent revisions3.11.2008
78.	Order	MoH	31.12.2004	676	On approval of clinical protocols on obstetric and gynaecological care	http://moz.gov.ua/ua/portal/dn_20041231_676.html	current, revisions per MoH Order of 3.11.2008 № 624
79.	Order	MoH	29.12.2005	782	On approval of clinical protocols on obstetric and gynaecological care	http://moz.gov.ua/ua/portal/dn_20051229_782.html	current, revisions per MoH Order of 24.03.2008 № 182
80.	Order	MoH	03.11.2008	624	On amendments to MoH Ukraine Order of December 15, 2003 № 582 “On approval of clinical protocols on obstetric and gynaecological care”, MoH Order of31.12.2004 № 676 “On approval of clinical protocols on obstetric and gynaecological care”	http://moz.gov.ua/ua/portal/dn_20081103_624.html	current, no revisions
81.	Order	MoH	06.12.2004	604	On approval of clinical protocols in the specialization “Urology”	http://moz.gov.ua/ua/portal/dn_20041206_604.html	current, no revisions
82.	Order	MoH	17.01.2005	23	On approval of separate protocols on provision of medical care in the specialization “Urology”	http://www.moz.gov.ua/ua/portal/dn_20050117_23.html	current, no revisions
83.	Order	MoH	03.07.2006	431	On approval of protocols of provision of medical care in specialization “Sexopathology”	http://moz.gov.ua/ua/portal/dn_20060703_431.html	current, no revisions
84.	Order	MoH	15.06.2007	330	On improvement of provision of urological care forthe population of Ukraine	http://moz.gov.ua/ua/portal/dn_20070615_330.html	current, no revisions
85.	Order	MoH	27.11.1992	171	On improvement of sexological and andrologial care for population of Ukraine	http://zakon.nau.ua/doc/?uid=1039.627.0	current, no revisions

86.	Order	MoH, MOES, Min. for Families, Youth and Sport, State Penitentiary Dept. Ukraine, Ministry for Labour and Social Policy Ukraine	23.11.2007	740/ 1030/ 4154/ 321/ 614a	On activities for the organization of prevention of mother-to-child transmission of HIV, medical care and social case management of HIV-infected families and their children	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1405-07	current, no revisions, registered at MOJ Ukraine 26.12.2007 at № 1405/14672
87.	Attachment to recommendations in Order	MoH	28.12.2002	Appendix 17 to recomm. in Order 503	Specific features of the family doctor's role in provision of obstetric-gynaecological care	http://www.moz.gov.ua/ua/portal/dn_20021228_503.html	current, no revisions
88.	Order	MoH	14.11.2007	716	On approval of clinical protocols on obstetric care "Prevention of mother-to-child transmission of HIV"	http://moz.gov.ua/ua/portal/dn_20071114_716.html	current, no revisions
89.	Order	MoH	13.02.2006	67	On approval of primary recording forms in the facilities providing prenatal, intranatal and postnatal medical care to women, and instructions concerning their completion	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0221-06	current, no revisions, registered at MOJ Ukraine 2.03.2006 at № 221/12095
90.	Resolution	CM	08.02.1994	66	On additional social guarantees for families with low income having sick children and children of one and two years of age	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=66-94-%EF	current, no revisions
91.	Order	MoH	08.05.2009	312	On approval of clinical protocols on provision of medical care to patients with dermatological/venereological diseases	http://www.moz.gov.ua/ua/portal/dn_20090508_312.html	current, no revisions
92.	Procedures to Order	MoH	07.06.2004	286	Methods of diagnosis, treatment and prevention of sexually transmitted infections	http://moz.gov.ua/ua/portal/dn_20040607_286.html	current, revisions per MoH Order of 31.05.2007 № 293
93.	Order	MoH	30.12.1992	207	On organization of dermatological/venereological care for the population of Ukraine	http://zakon.nau.ua/doc/?code=v0207282-92	current, no revisions

94.	Order	MoH	07.06.2004	286	On improvement of dermatological/venereological care for the population of Ukraine	http://moz.gov.ua/ua/portal/dn_20040607_286.html	see item №84
95.	Order	MoH	29.12.1992	204	On organization of laboratory diagnostics of syphilis in Ukraine	http://mozdocs.kiev.ua/view.php?id=828	current, recent revisions 30.01.1997, registered at MOJ Ukraine 19.02.1997 at № 33/1837
96.	Article	Dermatology and Venereology Journal	2007	1(35)	Protocols of laboratory diagnostics of infections caused by *Neisseria Gonorrhoeae*	http://www.medsci.uu.se/klinbakt/stigup/Publications/ARTICLES/article%20archive/036A.pdf	additionally see MoH Order of 08.05.09 № 312 (item 91)
97.	Order	MoH	12.06.1996	163	On approval of Instructions on diagnosis and treatment o gonorrhoea and syphilis	http://lawua.info/bdata2/ukr2833/index.htm	current, no revisions
98.	Publication	NAMS Ukraine	2009		Diagnostics of sexually transmitted infections in groups of the population vulnerable to HIV-infection	http://www.nbuv.gov.ua/portal/chem_biol/Zhdk/2009_1_2/st4.html	
99.	Manual	MoH, Committee on Response to HIV/AIDS and Other Socially Dangerous Diseases, Ukrainian AIDS center	2009		Models of organization of provision of services in diagnostics and treatment of STIs in representatives of vulnerable groups of the population	http://www.aidsalliance.org.ua/ru/ippp/4_Guidelines/g1.pdf	current, approved by Specialty Commission of MoH and NAMS Ukraine for specialty “Dermatology and Venereology”, Protocol № 6of 26.12.2008

100.	Guidelines	MoH, NAMS Ukraine, Ukrainian Centre for scientific medical information and patenting and licensing	2009		Specific features of treating sexually transmitted infections in groups of the population vulnerable to infection with human immune deficiency virus (guidelines)	http://www.aidsalliance.org.ua/ru/ippp/4_Guidelines/g2.pdf	Approved by Deputy Head of Treatment-and-Organization Board of NAMS Ukraine, O.O. Petrichenko, 15.12.2008; Approved by Director of Department for Health Care Development,MoH M.P.Zhdanova 15.02.2009
101.	Sanitary rules	MoH USSR	29.06.1990	5179-90	Sanitary rules of setting, equipping and running hospitals, maternity hospitals and in-patient departments	http://www.tehbez.ru/Docum/DocumShow_DocumID_331.html	current, no revisions
102.	Guidelines	UIPHP	2008		Social and psychological support for clients of substitution maintenance therapy programs	http://www.uiphp.org.ua/media/778	it is not a normative act
103.	Order	MoH, Ministry for Labour and Social Policy Ukraine	05.10.2005	308/ 519	On regulating wage conditions for employees of health care and social welfare institutions	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1209-05	current, recent revisions6.12.2010, registered at MOJ Ukraine 17.10.2005 at № 1209/11489
104.	Order	MoH	22.07.1993	166	On further improvement of the system for postgraduate education of physicians (pharmacists)	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0113-93	current, no revisions, registered at MOJ Ukraine 27.09.1993 at № 113
105.	Letter	MoH	19.02.2009	10.03.68/315	On the procedure to formalize labour relations between a HCF and a physician involved in consultation activities	http://mozdocs.kiev.ua/view.php?id=8651	no revisions, it is not a normative act
106.	Letter	MoH	23.10.2008	10.03.68/1698	On payment to specialists involved in consultation activities	http://pravo.levonevsky.org/bazaua09/pismo/sbor01/text01729.htm	no revisions, it is not a normative act

107.	Order	MoH	29.09.2009	694	On approval of officially recommended equipment lists covering medical devices and medical products for structural divisions of HCFs providing care to people with TB,by level of care	http://www.moz.gov.ua/ua/portal/dn_20090929_694.html	current, no revisions
108.	Order	MoH	19.07.2010	590	On approval of officially recommended equipment lists covering medical items for specialized HCFs and structural divisions of HCFs providing clinical and diagnostic assessment and care to people with HIV/AIDS	http://www.moz.gov.ua/ua/portal/dn_20100719_590.html	current, no revisions
109.	List to Order	MoH	05.06.1998	153	Equipment table covering medical items for treatment and diagnostic rooms of HCFs	http://moz.gov.ua/ua/portal/dn_19980605_153.html	current, recent revisions per MoH Order of 11.04.2005 № 158
110.	Order	MoH	25.02.2008	102	On VCT office operation	http://zakon1.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0220-08	current, no revisions, registered at MOJ Ukraine 19.03.2008 at № 220/14911
111.	Attachment to Order	MoH	23.02.2000	Appendices 3 and 52 to Order 33	On staffing norms and standard staffing of HCFs	http://www.moz.gov.ua/ua/portal/dn_20000223_33n.html	current
112.	Order	MoH	27.06.2006	421	On approval of Standard Regulations on a VCT office	http://moz.gov.ua/ua/portal/dn_20060627_421.html	current
113.	Attachment to Order	MoH	19.08.2005	Appendix 2 to Order 415	Training of VCT counsellors, list of topics mandatory for the procedure of HIV voluntary counselling and testing (Protocol)	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1404-05	current
114.	Instructions to Order	MoH	19.08.2005	415	Instruction on filling out primary record form N 503-1/o “Informed consent to HIV testing”	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1404-05	current

115.	Order	MoH	11.05.2010	388	On improvement of HIV diagnosis	http://www.stop-aids.gov.ua/index.php?option=com_content&view=article&id=485:-388-11052010-q-qq&catid=56:2009-04-10-19-23-12&Itemid=70	current, no revisions, registered at MOJ Ukraine 9.07.2010 at № 499/17794
116.	Order	MoH	19.04.2006	236	On implementation of Procedure for voluntary HIV counselling and testing (Protocol) at HCFs	http://www.moz.gov.ua/ua/portal/dn_20060419_236.html	
117.	Order	MoH	14.11.2005	604	On improving provision of medical and social care to children and youth	http://www.moz.gov.ua/ua/portal/dn_20051114_604.html	current, no revisions
118.	Order	MoH	04.08.2006	539	On setting up operation of family planning and reproductive health Service in Ukraine	http://www.moz.gov.ua/ua/portal/dn_20060804_539.html	current, no revisions
119.	Order	MoH, Min. for Families, Youth and Sport Ukraine	17.11.2006	3925/ 760	On approval of Procedure for collaboration between Centres of social services for families, children and youth and HCFs regarding various aspects of HIV/AIDS prevention	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z1320-06	current, no revisions, registered at MOJ Ukraine 18.12.2006 at № 1320/13194
120.	Order	MoH	05.06.1998	153	On approval of lists of medical items that structural divisions of HCFs need	http://www.moz.gov.ua/ua/portal/dn_19980605_153.html	current, recent revisions11.04.2005
121.	Attachment to Protocol in Order	MoH	30.12.2008	Appendix 7 to item 2.6 of Protocol in Order 826	Clinical protocol for hepatitis C virus diagnosis and treatment in adults with HIV	http://www.moz.gov.ua/ua/portal/dn_20081230_826.html	current, no revisions
122.	Protocol to Order	MoH	31.12.2004	676	Benign and premalignant cervical lesions	http://www.moz.gov.ua/ua/portal/dn_20041231_676.html	became null and void
123.	Order	MoH	16.09.2009	673	On approval of lists of AIDS centres performing HIV and antiretroviral therapy laboratory monitoring, and confirmatory testing in Ukraine	http://moz.gov.ua/ua/portal/dn_20090916_673.html	current, recent revisions17.01.2011

124.	Order	State Committee for Consumer Policy	29.03.2005	71	On approval of Regulations for authority delegation and attestation in the state metrological system	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0392-05	current, no revisions, registered at MOJ Ukraine 13.04.2005 at № 392/10672
125.	Order	MoH	19.04.2007	196	On attestation of measurement laboratories at facilities, establishments and organizations	http://www.moz.gov.ua/ua/portal/dn_20070419_196.html	current, no revisions
126.	Booklet	MoH	04.08.2009		Information for licensees doing business in the medical field in specializations of clinical biochemistry, clinical immunology, clinical laboratory diagnostics, laboratory immunology, bacteriology, virology	http://www.moz.gov.ua/ua/portal/licen2.html	no revisions, it is not a normative act
127.	Construction norms	State Committee for Construction, Architecture and Housing Policy Ukraine	04.01.2001	ДБН В.2.2-10-2001	Buildings and structures – HCFs	http://uazakon.com/document/spart35/inx35764.htm	current, no revisions
128.	Sanitary rules	MoH, State sanitary and epidemiological service	28.01.2002	ДСП 9.9.5.-080-02	Regulation on lab set-up and work safety in microbiology laboratories (departments, divisions)	http://mozdocs.kiev.ua/view.php?id=6667	current, no revisions
129.	Guidance	MoH USSR	21.11.1979	1175	Instruction on application of unified clinical laboratory testing procedures	http://rudoctor.net/medicine2009/bz-sv/med-rqtaa/index.htm	current, no revisions
130.	Draft Order	MoH			On approval of provisional sectoral standards regarding clinical laboratory testing quality assurance	http://www.moz.gov.ua/ua/portal/Pro_20100817_0.html	not approved
131.	Guidelines	Chief sanitary doctor Ukraine	09.07.2003	24	On approval of provisional guidance of MoH Ukraine “Polymerase chain reaction for detection of pathogens”		
132.	Guidelines		2007		Laboratory management for testing biological specimens by polymerase chain reaction (guidelines)		

133.	Instructions to Order	MoH	22.02.2002	71	Instruction about organization of work of HIV testing laboratories	http://www.moz.gov.ua/ua/portal/dn_20020222_71.html	current, no revisions
134.	Instructions to Order	MoH	06.02.2002	45	Instruction on bacteriologic testing for TB infection	http://www.moz.gov.ua/ua/portal/dn_20020206_45.html	current, no revisions
135.	Resolution	CM	17.09.1996	1138	On approval of the list of paid services provided by state HCFs and higher medical educational establishments	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=1138-96-%EF	current, recent revisions28.07.2010
136.	Order	MoH	09.06.2003	255	On approval of guidelines on rapid tests used for HIV antibodies detection in blood, records form N 498/o, and instructions to fill it out	http://moz.gov.ua/ua/portal/dn_20030609_255.html	current, no revisions
137.	Order	MoH	23.09.2004	467	On approval of guidelines on rapid blood tests use for diagnosing infections, records form and instructions to fill it out	http://moz.gov.ua/ua/portal/dn_20040923_467.html	current, no revisions
138.	Guidelines	MoH, Ukrainian research institute for social, forensic psychiatry and narcology	2006		Use of rapid tests to check for substance use in general medical practice (guidelines)	http://www.simmed.com.ua/news.php?id=8	no revisions, it is not a normative act
139.	Order	MoH	06.06.2007	304	On approval of primary record form on using rapid tests in HCFs, and instructions to fill it out	http://moz.gov.ua/ua/portal/dn_20070606_304.html	current, revised on 06.08.2010 № 660
140.	Order	MoH	24.03.2006	158	On approval of record form № 498-2/o “Immunochromatographic test report (CITO TEST)”	http://moz.gov.ua/ua/portal/dn_20060324_158.html	current, no revisions
141.	Order	MoH	21.09.2010	795	On distribution of antiretroviral drugs for treatment of HIV/AIDS and HIV prevention purchased from state budget funds for the year 2010	http://moz.gov.ua/ua/portal/dn_20100921_795.html	current, recent revisions17.11.2010
142.	Assessment tool	JSI/ DELIVER	2003	Version 1.1	Tool to Assess Site Program Readiness for Scaling Up Antiretroviral Therapy (ART) and Requirements for Further Training and Systems Development		adapted by International HIV/AIDS Alliance in Ukraine

143.	Order	MoH	16.12.2003	584	On approval of Regulations on drugs storage and quality control at HCFs	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0275-04	current, recent revisions14.09.2010, registered at MOJ Ukraine 3.03.2004 at № 275/8874
144.	Standard to Order	MoH	15.04.2008	205	Base standard for implementation (scale-up) of antiretroviral therapy for people with HIV/AIDS in the region	http://triton.moz.gov.ua/ua/main/docs/?docID=9851	current, no revisions
145.	Order	MoH	26.03.2003	136	On procedure to show material assets in a centralized supply activities record	http://moz.gov.ua/ua/portal/dn_20030326_136.html	current, revisions per MoH Order of 17.06.2004 № 313
146.	Order	MoH	08.04.2009	222	On distribution of drugs for treatment of opportunistic infections and other comorbidities in people with HIV and AIDS purchased in 2009 under the HIV/AIDS component of the project “TB and HIV/AIDS control in Ukraine”	http://www.moz.gov.ua/ua/portal/dn_20090408_222.html	current, revisions per MoH Order of 08.09.2010 № 762
147.	Order	MoH	08.09.2010	760	On distribution of I and II line TB drugs purchased from state budget funds of Ukraine for 2010	http://www.moz.gov.ua/ua/portal/dn_20100908_760.html	current, revisions per MoH Order of 19.01.2011 № 19
148.	Order	MoH	19.07.2005	360	On approval of Regulation on issuing prescriptions and orders for drugs and medical products, Procedure for dispensing drugs and medical products from pharmacies and their structural divisions, Instruction on storage, inventory and disposal of prescription and order forms	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0782-05	current, recent revisions22.05.2009, registered at MOJ Ukraine 20.07.2005 at № 782/11062
149.	Procedure to Order	MoH	03.02.2006	48	Procedure for ensuring appropriate conditions of storage, transportation, receipt and inventory of medical immunobiological drugs in Ukraine	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0670-06	current, recent revisions17.04.2008, registered at MOJ Ukraine 2.06.2006 at № 670/12544
150.	Procedure to Order	MoH	03.02.2006	48	Procedure for dispensing medical immunobiological drugs to citizens	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=z0669-06	current, no revisions, registered at MOJ Ukraine 2.06.2006 at № 669/12543
151.	Regulation to Order	MoH	28.11.1997	340	Regulation on unit (room) of ultrasonography	http://www.moz.gov.ua/ua/portal/dn_19971128_340.html	current, no revisions

152.	Norms to Order	MoH	28.11.1997	340	Recommended estimated standard time for ultrasonographic testing	http://www.moz.gov.ua/ua/portal/dn_19971128_340.html	current, no revisions
153.	Order	MoH	29.12.2000	369	On approval of medical record forms used in in-patient and out-patient facilities (ambulatories)	http://mozdocs.kiev.ua/view.php?id=1783	current, recent revisions25.03.2002
154.	Requirements to Order	MoH	04.06.2007	294	Hygiene requirements for equipping and operation of X-ray rooms and X-ray testing	http://moz.gov.ua/ua/portal/dn_20070604_294.html	current, no revisions, registered at MOJ Ukraine 07.11.2007 at № 1256/14523
155.	Regulation to Order	MoH	28.11.1997	340	Regulation on X-ray testing rooms	http://www.moz.gov.ua/ua/portal/dn_19971128_340.html	current, no revisions
156.	Regulation to Order	MoH	28.11.1997	340	Regulation on fluoroscopy units	http://www.moz.gov.ua/ua/portal/dn_19971128_340.html	current, no revisions
157.	Norms to Order	MoH	28.11.1997	340	Recommended estimated standard time for X-ray testing	http://www.moz.gov.ua/ua/portal/dn_19971128_340.html	current, no revisions
158.	Order	MoH	28.12.2009	1051	On care provision to gastrointestinal patients	http://moz.gov.ua/ua/portal/dn_20091228_1051.html	current
159.	Regulation to Order	MoH	28.12.2009	1051	Exemplary regulation on a consultation gastroenterology office	http://moz.gov.ua/ua/portal/dn_20091228_1051.html	current
160.	Order	MoH	04.11.2010	951	On approval of Exemplary lists of equipment, medical devices and medical products (obstetric and gynaecological care)	http://moz.gov.ua/ua/portal/dn_20101104_951.html	current, no revisions
161.	Regulation to Order	MoH	27.11.1992	171	Regulation on andrology office	http://zakon.nau.ua/doc/?uid=1039.627.0	current, no revisions
162.	Law	VR	15.02.1995	60/95-VR	On narcotic substances, psychotropic substances and precursors	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=60%2F95-%E2%F0	current, recent revisions22.12.2007
163.	Law	VR	01.06.2000	1775-III	On licensing certain types of business activities	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=1775-14	current, recent revisions19.10.2010
164.	Resolution	CM	05.12.2007	1387	On approval of Procedure for licensing activities related to circulation of narcotic substances, psychotropic substances and precursors, and making revisions to the Resolutions of the Cabinet of Ministers Ukraine of November 14, 2000 № 1698 and of July 4, 2001 № 756	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=1387-2007-%EF	current, recent revisions12.10.2010

165.	Letter	MIA	22.08.2004	40/2-1447	On Procedure for obtaining approval of MIA Ukraine for activities related to circulation of narcotic substances, psychotropic substances and precursors	http://www.narko.gov.ua/licens/normatact/1001.html	no revisions, it is not a normative act
166.	Conditions to Order	MoH	02.02.2010	66	Licensing conditions for conducting business activities in cultivation of plants included in Table I of the List of narcotic substances, psychotropic substances and precursors approved by the Cabinet of Ministers Ukraine, development, production, manufacturing, storage, transportation, acquisition, selling (dispensing), import to the territory of Ukraine, export from the territory of Ukraine, use, disposal of narcotic substances, psychotropic substances and precursors included in the mentioned List	http://www.moz.gov.ua/ua/portal/dn_20100202_66.html	current, no revisions, registered at MOJ Ukraine 12.03.2010 at № 213/17508
167.	Resolution	CM	04.07.2001	756	On approval of the list of documents attached to the application for issuing Licenses for individual business activities	http://zakon.rada.gov.ua/cgi-bin/laws/main.cgi?nreg=756-2001-%EF	current, recent revisions10.09.2010
168.	Publication	MoH			Licensing of activities related to circulation of narcotic substances, psychotropic substances and precursors	http://www.moz.gov.ua/ua/portal/lic_narkot.html	no revisions, it is not a normative act

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