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**ASSESSMENT OF COMPLIANCE OF NATIONAL
REGULATIONS, GUIDELINES AND CLINICAL
PROTOCOLS ON OPIOID DEPENDENCE TREATMENT
WITH INTERNATIONAL TREATMENT STANDARDS
AND REQUIREMENTS TO MEDICAL AND TECHNICAL
DOCUMENTATION**



ASSESSMENT OF COMPLIANCE OF NATIONAL REGULATIONS, GUIDELINES AND CLINICAL PROTOCOLS ON OPIOID DEPENDENCE TREATMENT WITH INTERNATIONAL TREATMENT STANDARDS AND REQUIREMENTS TO MEDICAL AND TECHNICAL DOCUMENTATION

National regulations, guidelines and clinical protocols on opioid dependence treatment:
Assessment of compliance with international treatment standards and requirements to medical and technical documentation

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ABBREVIATIONS

AIDS	— acquired immune deficiency syndrome
ART	— antiretroviral therapy
ASI	— Addiction severity index
BBV-TRAQ	— The Blood Borne Virus Transmission Risk Assessment Questionnaire
HIV	— human immunodeficiency virus
ICD-10	— International classification of diseases, 10 th revision
IDT	— interdisciplinary team
IDU	— injecting drug users
NC	— narcological care
NGO	— non-governmental organization
OST	— opioid substitution treatment
PAS	— psychoactive substance
SMT	— substitution maintenance therapy
STD	— sexually transmitted diseases
TB	— tuberculosis
TPF	— treatment and prevention facilities
UIPHP	— Ukrainian Institute of Public Health Policies
UN	— United Nations
UNA	— Ukrainian Narcological Association
UNAIDS	— Joint United Nations Programme on HIV/AIDS
UNODC	— UN Office on Drugs and Crime
WHO	— World Health Organization

PART I.

REVIEW OF NATIONAL AND INTERNATIONAL DOCUMENTS ON OPIOID DEPENDENCE TREATMENT AND OF PREVIOUS ASSESSMENTS OF COMPLIANCE OF UKRAINIAN AND INTERNATIONAL GUIDELINES ON OPIATE DEPENDENCE TREATMENT

INTRODUCTION

In Ukraine, drug addiction treatment is entrusted with a specialized narcological service (drug addiction care) that was established as far back as the Soviet time in 1959. Doctors working in the system of narcological care had qualification of psychiatrists, and later on – of psychiatrists-narcologists (drug addiction doctors). “Narcology” as a doctor’s profession stood out as a separate field in Ukraine in 1997.

When providing care to addicted patients, the psychiatrists used to apply various regulations and technical guidelines that were developed by the respective departments of health care institutes and research centres. It is worth mentioning that in Soviet time narcology (though, it also concerns psychiatry) was quite far from international standards, because it was too much dependent on ideology. In particular, the Instruction on treatment of drug addicted persons approved by the Order of the Ministry of Health of USSR # 384-DSP in 1986 stipulated that at least 60-day in-patient treatment was mandatory. It also provided for using anxiolytic medication (aminazin/chloractil, haloperidol) and pyretic therapy, etc. Various methods of coercing to treatment were widely used (mandatory treatment in narcological clinics and penitentiary facilities upon court judgment), labour “treatment” (labour treatment centres), while substitution therapy was not available and rehabilitation programmes were not developed.

After independence, Ukraine had to review the entire regulatory framework in order to bring it in conformity with new developments.

UKRAINIAN REGULATORY DOCUMENTS ON OPIOID DEPENDENCE TREATMENT

Provisional sectoral unified standards of medical technologies of diagnostics and treatment process of in-patient care of adults in health clinics of Ukraine and Provisional standards of the scope of diagnostic studies, treatment and quality criteria of treatment of children became the first important documents in this field. These documents were enacted by the Order of the Ministry of Health # 226 of 27.07.1998¹.

For each clinical entity that corresponded to types and subtypes of block F10 of ICD-10 “Mental and behavioural disorders due to psychoactive substance use”, a standard set of diagnostic, treatment, prevention and rehabilitation interventions was proposed and the quality criteria were identified.

1 Order of the Ministry of Health of Ukraine # 226 of 27.07.1998 “On Approval of Provisional sectoral unified standards of medical technologies of diagnostic and treatment process of in-patient care of adults in health clinics of Ukraine and Provisional standards of the scope of diagnostic studies, treatment and quality criteria of treatment of children”, http://www.moz.gov.ua/ua/portal/dn_19980727_226.html. Abolished by the Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”, <http://document.ua/pro-viznannja-takimi-sho-vtratlili-chinnist-dejakih-nakaziv-m-doc189733.html>.

The Order of the Ministry of Health # 507 of 28.12.2002 “On Approval of Standards of Health Care and Quality Indicators of Health Care” was the next document adopted². It contained all sets of interventions developed earlier, while also providing for the particularities of their use in out-patient care and recommendations on clinical dynamic monitoring.

The last document – which is in force now – is the Order of the Ministry of Health Care # 681 of 21.09.2009 “On Approval of Clinical Protocols on Health Care in the field of Narcology”³. One can say that so far, it is the only document establishing the standards of narcological (drug addiction) care, whereas both former documents – the Order of the Ministry of Health # 226 of 27.07.1998 and the Order of the Ministry of Health # 507 of 28.12.2002 – *are not in force*. They both were abolished by the Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”⁴. This Order was approved “... *in order to bring normative legal acts in conformity with the legislation of Ukraine and prevent prescribing medications not registered or forbidden in Ukraine*”. One can suppose that some standards provided for the use of non-registered medications, hence the policy maker decided to abrogate these documents in full rather than to adjust them provision-by-provision. It resulted into a legal collision that directly affects protocols of drug addiction care. The matter is that these protocols were approved by the Order of the Ministry of Health # 681 of 21.09.2009, and a lot of their provisions duplicate previous documents and refer to diagnostic and preventive interventions that were approved earlier and are denoted by the figures (for example, “diagnostic intervention 1”, “preventive intervention 2”, etc.). At the same time, Order # 681 lacks a detailed description of these interventions, whereas all of them were elaborated in details in previous Orders that are not currently in force.

In addition to the above-mentioned protocols of drug addiction care, there are also some more documents that address specific issues of providing care to drug dependent patients. Most of them concern opioid substitution therapy.

For the time being, the most detailed and comprehensive are Technical guidelines “Substitution maintenance therapy for treatment of opioid dependent patients” that were approved by the Order of the Ministry of Health # 645 of 10.11.2008⁵. Importantly, provisions of these guidelines refer to a number of documents of WHO and other international agencies. In particular, they mention WHO/UNODC/UNAIDS Position Paper. Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention.

Another important document is the Order of the Ministry of Health # 200 of 27.03.2012⁶ “On Approval of the Procedure of Substitution Maintenance Therapy of Opioid Dependent

2 Order of the Ministry of Health # 507 of 28.12.2002 “On Approval of Standards of Health Care and Quality Indicators of Health Care”, http://www.moz.gov.ua/ua/portal/dn_20021228_507.html. Abolished by the Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”, <http://document.ua/pro-viznannja-takimi-sho-vtratili-chinnist-dejakih-nakaziv-m-doc189733.html>.

3 Order of the Ministry of Health Care # 681 of 21.09.2009 “On Approval of Clinical Protocols on Health Care in the field of Narcology”, http://moz.gov.ua/ua/portal/dn_20090921_681.html.

4 Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”, <http://document.ua/pro-viznannja-takimi-sho-vtratili-chinnist-dejakih-nakaziv-m-doc189733.html>.

5 Order of the Ministry of Health # 645 of 10.11.2008 “On Approval of Technical Guidelines “Substitution maintenance therapy for treatment of opioid dependent patients”, http://www.moz.gov.ua/ua/portal/dn_20081110_645.html.

6 Order of the Ministry of Health # 200 of 27.03.2012 “On Approval of the Procedure of Substitution Maintenance Therapy of Opioid Dependent Patients”, <http://zakon2.rada.gov.ua/laws/show/z0889-12/print1383034539203413>.

Patients”. This Order duplicates and specifies certain provisions of the Technical guidelines and approves the Model Regulation on the office of substitution maintenance therapy, as well as regiments an array of account forms and logs. This Order was amended (pursuant to the Order of the Ministry of Health # 238 of 27.03.2013 “On Amending the Order of the Ministry of Health # 200 of 27.03.2012), and the amended Order # 200 is currently on force.

On 17 December 2014, the web-site of the Ministry of Health informed about public discussion of a new Order of the Ministry of Health “On Amending the Order of the Ministry of Health # 200 of 27.03.2012”. The new text of this document was published and proposals to it were invited.

Substitution therapy for detained persons (under arrest or in pre-trial detention) are reflected in the Joint Order of the Ministry of Health, Ministry of Interior, Ministry of Justice and State Service for Drug Control # 821/937/1549/5/156 of 22.10.2012 “On Approval of the Procedure of interaction between health care facilities, law enforcement, pre-trial and correction centres for ensuring continuity of medicated substitution maintenance therapy”⁷.

It should be noted that the issue of drug addiction and treatment of it concerns a number of other health care fields, in particular, the field of prevention and treatment of infections – HIV, tuberculosis and hepatitis. Therefore, certain elements of drug addiction care are integrated into the standards of other medical specialties that treat such infections. One of such standards was approved by the Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug users”⁸. This document concerns drug addiction problems of HIV-positive patients and describes the elements of integrated approach to HIV treatment.

In addition to medical issues, social and psychological support is another important component of care for drug addicts. Its standards are governed by the Joint Order of the Ministry of Family, Youth and Sports, Ministry of Labour and Social Policy and Ministry of Health # 3123/275/770 of 13.09.2010 “Standard of providing social services to patients of opioid agonist substitution maintenance therapy”⁹.

In addition to official regulations approved by the Ministry of Health, publications of Ukrainian Institute of Public Health Policies (UIPHP) are also worth attention. In particular, it concerns the guide “Agonist opioid maintenance therapy”¹⁰ and Technical guidelines “Social and psychological support of patients of substitution maintenance therapy”¹¹, published by a team of authors.

Further development of medical and technical framework is stipulated by the Order of

7 Joint Order of the Ministry of Health, Ministry of Interior, Ministry of Justice and State Service for Drug Control # 821/937/1549/5/156 of 22.10.2012 “On Approval of the Procedure of interaction between health care facilities, law enforcement, pre-trial and correction centres for ensuring continuity of medicated substitution maintenance therapy”, http://moz.gov.ua/ua/portal/dn_20121122_821.html.

8 Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug users”, http://www.moz.gov.ua/ua/portal/dn_20080819_476.html.

9 Joint Order of the Ministry of Family, Youth and Sports, Ministry of Labour and Social Policy and Ministry of Health # 3123/275/770 of 13.09.2010 “Standard of providing social services to patients of opioid agonist substitution maintenance therapy”, <http://zakon1.rada.gov.ua/laws/show/z0907-10>.

10 Поддерживающая терапия агонистами опиоидов: методическое пособие [Agonist opioid maintenance therapy: a Guide]. — Kyiv, UIPHP, 2010, <http://www.uiphp.org.ua/media/1500>.

11 Social and psychological support of patients of substitution maintenance therapy: Technical guidelines. Kyiv, UIPHP, 2008, <http://www.uiphp.org.ua/media/778>.

the Ministry of Health # 751 of 28.09.2012 “On Developing and Implementing Medical and Technical Documents for Standardizing Health Care in the System of the Ministry of Health of Ukraine”¹². Namely, medical and technical documents include clinical guidelines, standards of health care, unified clinical protocols and local protocols. This Order also approved special modality of evidence-based development and implementation of these documents. According to this modality, the first step is to develop a clinical guideline with the use of evidence-based data and best practices, including foreign ones. Based on clinical guideline, a standard of care is developed, and the unified clinical protocol is drafted only after it.

INTERNATIONAL REGULATIONS ON OPIOID DEPENDENCE TREATMENT

The majority of publications of international organizations on drug addiction and integrated care were developed during past decade. Some of them are political and advocacy materials. For example, it is the case of WHO/UNODC/UNAIDS Position Paper. Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention¹³ – the publication that summarizes the efficiency of substitution therapy and underlines its full legitimacy in terms of international conventions on narcotic drugs. Other documents – like Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO Department of Mental Health and Substance Abuse, 31 March 2009)¹⁴ or TREATNET Quality Standards for Drug Dependence Treatment and Care Services (UNODC, 2012)¹⁵ – that were published quite recently provide virtually all necessary recommendations for the efficient and evidence-based addiction treatment.

Therefore, by the time of drafting and approval of Provisional sectoral unified standards of medical technologies of diagnostic and treatment process of in-patient care of adults in health clinics of Ukraine and Provisional standards of the scope of diagnostic studies, treatment and quality criteria of treatment of children in 1998, one could be guided only by national standards. International organizations did not develop the systematized documents by then.

In July 2000 the Methadone Guidelines authored by Annett Verster and Ernst Buning were published upon request of the European Commission¹⁶. This document systematized all issues of organization and delivery of substitution therapy. Various details of drug addiction treatment are best elaborated in Discussion Paper. Principles of Drug Dependence Treatment (WHO, UNODC, 2008)¹⁷.

In addition, some documents were published on related medical fields (HIV, TB, etc.) that cover addiction treatment and integrated care. There most important are Basic Principles for Treatment and Psychosocial Support of Drug Dependent People Living with HIV/AIDS (WHO, 2006)¹⁸; Policy guidelines for collaborative TB and HIV services for injecting and other drug users: an integrated approach (WHO, Geneva, 2008)¹⁹, and Guidelines for

12 Order of the Ministry of Health # 751 of 28.09.2012 “On Developing and Implementing Medical and Technical Documents for Standardizing Health Care in the System of the Ministry of Health of Ukraine”, http://www.moz.gov.ua/ua/portal/dn_20120928_751.html.

13 http://www.who.int/substance_abuse/publications/en/PositionPaper_English.pdf.

14 http://www.who.int/substance_abuse/publications/opioid_dependence_guidelines.pdf.

15 http://www.unodc.org/docs/treatment/treatnet_quality_standards.pdf.

16 <http://www.vad.be/media/124853/european%20methadone%20guidelines.pdf>

17 <http://www.unodc.org/documents/drug-treatment/UNODC-WHO-Principles-of-Drug-Dependence-Treatment-March08.pdf>.

18 http://www.who.int/substance_abuse/publications/basic_principles_drug_hiv.pdf.

19 http://whqlibdoc.who.int/publications/2008/9789241596930_eng.pdf

identification and management of substance use and substance use disorders in pregnancy (WHO, 2014)²⁰.

The WHO Regional Office for Europe published clinical protocols “HIV/AIDS Treatment and Care. Clinical Protocols for the WHO European Region”²¹ that provide guidelines on management of drug addicted persons living with HIV/AIDS.

In addition to international protocols and guidelines, a lot of national documents were developed to be applied in specific countries, but still they are worth attention. First of all, we should refer to the UK guidelines on Drug Misuse and Dependence. UK Guidelines on Clinical Management (NICE)²², Methadone and Buprenorphine in the Management of Opiate Dependency (NICE, 2007)²³, U.S. TIP-series guidelines (Treatment improvement protocols), e.g., Medication-Assisted Treatment for Opiate Addiction in Opioid Treatment Programs (SAMSHA, USA, 2005)²⁴, and Australia guidelines: Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence (2003)²⁵.

FINDINGS OF PREVIOUS ASSESSMENTS OF COMPLIANCE OF UKRAINIAN AND INTERNATIONAL GUIDELINES ON OPIATE DEPENDENCE TREATMENT

Arguably, no data are currently available on previous assessment of compliance of Ukrainian addiction treatment guidelines with the respective international standards. Available surveys were mostly focused on standards of drug addiction care in terms of feasibility and efficiency. One of them is a survey report produced by Ukrainian Narcological Association (UNA) and Ukrainian Institute of Public Health Policies (UIPHP) entitled “Drug Addiction Treatment in Ukraine and its Efficiency”²⁶. One of sections of this survey concerns national treatment standards. In particular, it analyzes the Provisional sectoral unified standards of medical technologies of diagnostic and treatment process of in-patient care of adults in health clinics of Ukraine approved by the Order of the Ministry of Health # 226 of 27.07.1998, and the complementary Order of the Ministry of Health # 507 of 28.12.2002 that regulates out-patient clinical care. Authors note that although these standards include a wealth of types of addiction care (emergency care, detoxification, counselling, substitution treatment, etc.), their practical use is unfavourable and complicated. Quote: “*A clear algorithm of treatment plan is not available, a lot of types of treatment are proposed without indicating priorities... Outdated and unjustified methods are often recommended*”. An example of such unjustified methods is a recommendation to use Corazolium (medication) for treatment of opioid intoxication with convulsion, although it is well known that convulsion is one of side effects of this medication. Another example: haloperidol (sic!), up to 50 mg per day during three months, is recommended to treat nicotine addiction at the remission stage. Authors also point out that the majority of medications recommended for drug addiction treatment

20 http://www.who.int/substance_abuse/publications/pregnancy_guidelines/en/.

21 <http://www.who.int/hiv/topics/idu/care/E90840.pdf>.

22 http://www.nhs.uk/uploads/clinical_guidelines_2007.pdf.

23 <http://www.nice.org.uk/guidance/ta114/resources/guidance-methadone-and-buprenorphine-for-the-management-of-opioid-dependence-pdf>.

24 <http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf>.

25 [https://www.health.gov.au/internet/main/publishing.nsf/Content/D7138B36FFD6F4A6CA257BF000209CC4/\\$File/methadone_cgguide.pdf](https://www.health.gov.au/internet/main/publishing.nsf/Content/D7138B36FFD6F4A6CA257BF000209CC4/$File/methadone_cgguide.pdf).

26 Вієвський А. М., Дворяк С. В., Сидяк С. В. Лікування наркозалежності в Україні та оцінка його ефективності: звіт про дослідження [Drug Addiction Treatment in Ukraine and its Efficiency: a Survey Report]. — К.: 2008.

were never tested by means of evidence-based medicine. The very sets of interventions recommended for use “*are more like a handbook listing all possible medications that were ever used to treat drug addiction*”, and it is impossible to use them as the protocols. Authors underline that the standards “*lack main principles of providing drug addiction care, and – most importantly – treatment objectives... They do not set forth guidelines on how to evaluate various types of treatment*”. The conclusions and recommendations of the survey point out *inter alia* the need “*to develop contemporary protocols of drug addiction treatment, supplement the standards with provisions that would prevent doctors from applying methods of treatment which efficiency was not proven (in particular, anxiolytics, hypnotics, “drug abuse hypnosis”, etc.*”.

Final report on evaluation of needs and capacity of the system of drug addiction treatment in the selected cities: Kyiv, Poltava, and Kharkiv (UNODC, 2013) is virtually the only document to assess effective standards and protocols of drug addiction care. It is authored by Professor A.L.Katkov, UNODC HIV-PLEDGE project consultant. This survey is also important because it was undertaken by external international expert. It was focused *inter alia* on the following groups of sectoral orders of the Ministry of Health of Ukraine aiming at regimentation and unification of the main interventions delivered by drug addiction medical facilities: Order of the Ministry of Health of Ukraine # 226 of 27.07.1998 “On Approval of Provisional sectoral unified standards of medical technologies of diagnostic and treatment process of in-patient care of adults in health clinics of Ukraine and Provisional standards of the scope of diagnostic studies, treatment and quality criteria of treatment of children”, Order of the Ministry of Health of Ukraine # 67 of 14.02.2007 “On Approval of Provisional sectoral classification code of medical interventions and surgery operations” with additional section “Drug addiction interventions”, and Order of the Ministry of Health Care # 681 of 21.09.2009 “On Approval of Clinical Protocols on Health Care in the field of Narcology”. Author notes that “*the entire structure of interventions and specification of protocols doesn’t fully reflect the need to classify the system of drug addiction care by sectors and stages*”, and that “*the above-mentioned orders of the Ministry of Health of Ukraine are focused on narrow medical rather than on integrated status of narcology (drug addiction care) and the entire system of drug addiction care at large*”.

Another issue is the regulatory framework of integrated care to IDU living with HIV and tuberculosis. It is pointed out that a number of documents of the Ministry of Health provide regulations for contributions of drug addiction specialists to interventions related to HIV. For example, Order of the Ministry of Health # 120 of 25.05.2000 “On Improving Health Care of HIV/AIDS Patients”²⁷ stipulates that specialized care to drug addicted patients living with HIV/AIDS shall be provided in drug addiction clinics and hospitals due to their somatic diseases; Order of the Ministry of Health # 415 of 19.08.2005²⁸ calls for HIV voluntary counselling and testing in drug addiction clinics; Order of the Ministry of Health # 446 of 06.07.2006 “On Approval of the Instruction on introducing the procedure of HIV voluntary counselling and testing (protocol) in tuberculosis, dermatology and syphilology and drug addiction health facilities”²⁹ is aimed at improving the coverage of patients and quality of interventions in these fields; Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug

27 Order of the Ministry of Health # 120 of 25.05.2000 “On Improving Health Care of HIV/AIDS Patients”.

28 Order of the Ministry of Health # 415 of 19.08.2005 “On Improving HIV Voluntary Counselling and Testing”.

29 Order of the Ministry of Health # 446 of 06.07.2006 “On Approval of the Instruction on introducing the procedure of HIV voluntary counselling and testing (protocol) in tuberculosis, dermatology and syphilology and drug addiction health facilities”.

users”³⁰ provides for certain components of integrated approach to organization and scope of health care to HIV-infected IDU; etc.

Author notes that *“in general, this array of legal acts gives a perspective on the model of integrated care and proves a basic principle that such care should be ideally provided in one facility or a group of collaborative organizations and agencies having well established relationships. At the same time, this array of legal acts – like previous – is not in full compliance with standard requirements to staff schedule of drug addiction facilities, specification and qualification of staff. As a minimum, it jeopardizes the feasibility of the full-fledged implementation of the model of integrated care in the system of drug addiction facilities of the Ministry of Health of Ukraine”*.

The report also mentions the Order of the Ministry of Health # 200 of 27.03.2012 “On Approval of the Procedure of Substitution Maintenance Therapy of Opioid Dependent Patients”, *“which, on the one hand, is quite clear in regulating the components of SMT, but on the other – sets forth some unjustified limitations for providing such type of care”*.

While summarizing his assessment, the author states *“Therefore, the legal framework regulating the activities of sector of state drug addiction care provided within the system of the Ministry of Health of Ukraine is mostly based on narrow medical vision of the objectives of drug addiction care, slows down development of the system of drug addiction care, hinders proper implementation of legal acts and provisions aimed at expansion, improving quality and scope of care”*.

Author recommends: *“it is necessary to develop and approve adequate standards of staff specification, qualification, pre-service, in-service, additional and continued training of specialists employed in the system of drug addiction care. Moreover, it is also necessary to develop and approve contemporary and relevant standards of organization of drug addiction care system that would reflect particular features of macrostructure (sectors and stages of drug addiction care) and best requirements to organization of internal structure of drug addiction facilities”*.

Several isolated assessments of current standards in the field of drug addiction care and integrated care can be found in documents focused on HIV and TB. For example, Comprehensive External Evaluation of the National AIDS Response in Ukraine: Consolidated Report (UNAIDS) points out that *“the existing regulatory framework also impedes the availability of suitable (liquid) formulations of OST and the ability to provide OST as take home doses for stable patients”*.

In the same way, HIV Policy Assessment: Ukraine (Health Policy Project, USAID, 2011) notes that the existing regulations of the system of SMT do not allow for independent intake of a medicine by patients. It makes treatment impossible if a patient cannot come to a site daily or is admitted to hospital.

Complexity of providing comprehensive care to drug addicted patients with co-morbidities (HIV, TB, etc.) is outlined in the guidelines “Providing integrated services at health care facilities for people who use drugs in Ukraine”³¹ and an array of other publications, such as “An integrated approach to the provision of medical and psychosocial services for clients

30 Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug users”.

31 Providing integrated services at health care facilities for people who use drugs in Ukraine: Guidelines / Compiler – K.V. Dumchev, specialist on HIV/AIDS/STIs prevention, WHO Country Office in Ukraine. http://www.euro.who.int/_data/assets/pdf_file/0005/167315/e96608-update.pdf

of substitution maintenance therapy in Ukraine”³², the report “Evaluation of accessibility of comprehensive medical and social services for injecting drug users (IDU) in integrated care centres”³³, etc.

CONCLUSIONS

As the literature review demonstrates, effective clinical protocols on drug addiction care have considerable drawbacks: narrow medical approach hindering integration of care and unclear algorithm of providing care that make it complicated to implement it. We did not find any surveys or assessments demonstrating to what extent these clinical protocols comply with contemporary international principles of drug addiction and integrated care that are elaborated in the documents of international organizations. Neither were we able to find assessments on to what extent effective regulations in the field of drug addiction care are in line with the Order of the Ministry of Health # 751 of 28.09.2012 “On Developing and Implementing Medical and Technical Documents for Standardizing Health Care in the System of the Ministry of Health of Ukraine”.

32 Интегрированный подход к предоставлению медицинских и психосоциальных услуг для клиентов программы заместительной поддерживающей терапии в Украине: опыт МБФ «Международный Альянс по ВИЧ/СПИДу в Украине» [An integrated approach to the provision of medical and psychosocial services for clients of substitution maintenance therapy in Ukraine: experience of ICF “International HIV/AIDS Alliance in Ukraine”] — К.: МБФ «Международный Альянс по ВИЧ/СПИДу в Украине», 2013. — 72 с.

33 Думчев К., Форостяная О. Оценка доступности комплексных медико-социальных услуг потребителям инъекционных наркотиков (ПИН) в центрах интегрированной помощи [Dumchev K., Forostianaia O. Accessibility of comprehensive health and social care services for injecting drug users (IDUs) in integrated care centers].

PART II.

ASSESSMENT OF COMPLIANCE OF NATIONAL REGULATIONS, GUIDELINES AND CLINICAL PROTOCOLS ON OPIOID DEPENDENCE TREATMENT WITH INTERNATIONAL TREATMENT STANDARDS AND NATIONAL REQUIREMENTS TO MEDICAL AND TECHNICAL DOCUMENTS

COMPARISON METHODOLOGY

Contemporary medicine becomes more and more technology-oriented. It derives from the development of its research and evidence-based nature. One of the most crucial advantages of technological approach is a possibility to formally specify the entire process of health care and to integrate it with social services and interventions. Development of main medical principles and standards allows for tracking the entire process of providing care and assess its efficiency on the basis of specific indicators. It is also important in terms of funding of public health care, whereas it informs the respective calculations and forecasts. The quality of technical documents that provide grounds for various fields of health care determines the quality of care, and eventually the health of people. While moving to evidence-based medicine, it is necessary to review previous approaches in terms of evidence-base, cost effectiveness and reasonability for the public health. Experience of other countries and especially the documents of international organizations are very helpful in this process.

Current standards of treatment of addictions are specified in Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO Department of Mental Health and Substance Abuse, 31 March 2009), TREATNET Quality Standards for Drug Dependence Treatment and Care Services (UNODC, 2012), Discussion Paper. Principles of Drug Dependence Treatment (WHO, UNODC, 2008) and other documents.

These principles and standards concern not only clinical diagnostics and treatment, but the organization of entire care at both national and local levels. Therefore, all types of medical and technical documents (such as clinical guidelines, standards of care, protocols (both unified and local) should comply with these fundamental principles. The main principles laid down in Principles of Drug Dependence Treatment (WHO, UNODC, 2008) are classified into several groups:

1. Availability and accessibility of drug dependence treatment (geographical and financial accessibility, timeliness and flexibility of opening hours, availability and accessibility of other services, etc.).
2. Screening, assessment, diagnosis and treatment planning.
3. Evidence-informed treatment (detoxification, SMT, brief interventions, etc.).
4. Human rights and patient dignity (rights of patient).
5. Targeting special subgroups and conditions (adolescents, women, pregnant women, people with medical co-morbidities, etc.).
6. Addiction treatment and the criminal justice system.
7. Community involvement.
8. Clinical governance (treatment protocols, supervision, monitoring system, etc.).

9. Policy development, strategic planning and coordination of services (multidisciplinary approach, capacity building, evaluation, etc.).

To facilitate the analysis, all principles are summarized in a table (Annex 1), and the available national standards, protocols and treatment guidelines are analyzed in terms of compliance with every element of these principles. As we may see from sections “Community involvement”, “Policy development” and “Addiction treatment and the criminal justice system”, the international principles cover larger topics and do not limit themselves to medical treatment only. One can suppose that these principles could be elaborated in more details in the documents of other agencies.

As mentioned above, three Orders of the Ministry of Health on addiction treatment are currently effective in Ukraine:

1. Order of the Ministry of Health Care # 681 of 21.09.2009 “On Approval of Clinical Protocols on Health Care in the field of Narcology”
2. Order of the Ministry of Health # 645 of 10.11.2008 “On Approval of Technical Guidelines “Substitution maintenance therapy for treatment of opioid dependent patients”
3. Order of the Ministry of Health # 200 of 27.03.2012 “On Approval of the Procedure of Substitution Maintenance Therapy of Opioid Dependent Patients”.

Another important document in this field is the Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug users”.

Few issues of social and psychological components of addiction treatment are mentioned in the Joint Order of the Ministry of Family, Youth and Sports, Ministry of Labour and Social Policy and Ministry of Health # 3123/275/770 of 13.09.2010 “Standard of providing social services to patients of opioid agonist substitution maintenance therapy”.

Hence, these 5 documents are listed in comparison table to perform formal assessment of compliance with international drug addiction treatment standards (Annex 1).

To analyze the compliance of effective protocols with existing requirements to medical and technical documents, we input the Structure of a unified clinical protocol of health care to the evaluation matrix approved by the Order of the Ministry of Health # 751 of 28.09.2012, and then we evaluate the currently effective narcology documents according to matrix parameters. In particular, we will evaluate clinical protocols on health care in the field of narcology approved by the Ministerial Order # 681 of 21.09.2009 and Technical guidelines “Substitution maintenance therapy for treatment of opioid dependent patients” that were approved by the Order of the Ministry of Health # 645 of 10.11.2008 (Annex 4).

Based on these evaluation matrixes, we will devise a general evaluation of documents that is provided in Annexes.

ASSESSMENT OF COMPLIANCE OF EFFECTIVE LEGAL DOCUMENTS WITH INTERNATIONAL RECOMMENDATIONS

CLINICAL PROTOCOLS ON HEALTH CARE IN THE FIELD OF NARCOLOGY APPROVED BY THE MINISTERIAL ORDER # 681 OF 21.09.2009

Clinical protocols are developed in accordance with diagnosis codes of ICD-10: a separate protocol corresponds to every code of diagnostic blocks and sub-blocks. As a result, treatment of mental and behavioural disorders provoked by use of certain substance is regulated by more than a dozen separate protocols that usually have similar texts with minor differences. Introduction specifying main principles of drug addiction care is not available. Each section contains a description of diagnostic criteria according to ICD-10.

Diagnostic procedures are classified into the sets of recommended interventions, like medical examinations, laboratory tests, psychological and assessment tests, etc. (see

Annex 2). These sets are entitled “Diagnostic sets”, there are 7 of them. Each code of ICD-10 block “Mental and behavioural disorders due to psychoactive substance use” relates to one or several diagnostic sets. For example, in case of diagnosis under code F11.22 “Opioid dependence. At present abstain in clinical controlled maintenance or substitute treatment“ (see Annex 3), diagnostic sets 3, 4, and 5 are prescribed. However, the document does not provide for contents of these sets. One can suppose that they correspond to those specified earlier in the Order of the Ministry of Health # 507 of 28.12.2002 “On Approval of Standards of Health Care and Quality Indicators of Health Care”. Currently, this Order is no longer in force – therefore, the diagnostic sets lack legal regulation. Notwithstanding, it should be noted that such sets usually prescribe routine laboratory tests like clinical blood and urine analysis, biochemistry of blood as well as toxic chemical tests that concern directly diagnostics of addiction. Tests for viral infections (HIV, hepatitis) and tuberculosis are not set forth. Diagnostic sets 3, 4, and 5 that are mentioned above (SMT) do not stipulate clinical analyses at all. Positive feature is the availability of a wealth of various psycho diagnostic methods, as well as assessment of addiction severity, although its methodology or assessment tool is not specified.

Treatment interventions are stipulated both for out-patient and in-patient care. Their description includes virtually only the name of intervention or product group to be prescribed. The protocols do not specify how, when and in what cases each intervention or product group should be used. For example, it says about substitution therapy only the following: “Substitution therapy cycle with narcotic analgesics”. Medicated interventions are also described in general words: it is presumed that either a doctor should know treatment regimens or everything is specified in other documents, although references are not provided. For example, a block of treatment of opioid withdrawal syndrome just lists main groups of products: “anti-depressants”, “neuroleptics”, “antiepileptic drugs”, “adrenergic centrally-acting drugs”, “cycle of substitution therapy with narcotic analgesics”, without any additional guidelines, except for the duration of intake. In addition of medicated treatment, the protocols also describe a comprehensive social psychological rehabilitation that includes consultations of a social worker, therapeutic communities (art-therapy, body-oriented therapy, personal advancement groups, etc.). Behaviour therapy is not mentioned. Details on contents of these interventions are not provided. The 12 steps programme is elaborated in more details: topics of sessions, their quantity and duration, targeting family and self-help groups are described. Given that these interventions involve psychologists and social workers, we can presume that interdisciplinary approach is used, although the text does not mention interdisciplinary team (IDT).

When it comes to treatment of co-morbidities, the protocol just refers to “implementation of standards and protocols of other fields”. Neither has it described the particularities of targeting special groups (adolescents, women, pregnant women, etc.).

Preventive interventions are described as 3 sets that mention brief interventions, as well as dissemination of information materials (although, their contents are not specified). Harm reduction is not mentioned.

In terms of quality criteria, the protocol suggests using “interim history mutually agreed with a patient”, as well as a condition of remission or “considerable amelioration” agreed with a patient.

TECHNICAL GUIDELINES “SUBSTITUTION MAINTENANCE THERAPY FOR TREATMENT OF OPIOID DEPENDENT PATIENTS” THAT WERE APPROVED BY THE ORDER OF THE MINISTRY OF HEALTH # 645 OF 10.11.2008

It is a quite detailed document that concerns only substitution therapy. It specified the objectives and principles of therapy, criteria for its start (which are quite low threshold, whereas the main criteria is a diagnosis “opioid addiction”), and counter-indications. It describes the activity of IDT consisting of a doctor, nurse, psychologist and social worker. It also provides detailed instructions for selecting certain maintaining medication, for dosing of both methadone and buprenorphine, and induction and maintenance phase. The guidelines have separate sections on targeting special groups (HIV, TB, hepatitis patients, pregnant women). They suggest carrying out monitoring of admission and discharge, provision of services, side effects and rehabilitation interventions during treatment. They also list necessary documents for collecting information. To evaluate the efficiency, they recommend to use such indicators as treatment retention, questionnaires of Addiction severity index (ASI) and Blood Borne Virus Transmission Risk Assessment Questionnaire (BBV-TRAQ), HIV and seroconversion incidence, percentage of ART patients, percentage of employed patients, etc.

Although the document is well-elaborated, it still has some drawbacks. Unfortunately, it does not provide guidance on a timeframe for admitting to the programme (prescribing therapy on the day of visit) – it could hinder accessibility.

The main drawback is that although the need to pay attention to co-morbidities (in particular, HIV, TB and hepatitis) is declared, the very text of the document does not provide guidance on voluntary counselling and testing of these infections, neither does it indicate interventions for detecting tuberculosis infection (X-ray, collecting and testing sputum). For further management of HIV-infected opioid addicted patients, it recommends to develop SMT in AIDS centres. With regard to drug addiction facilities, it only says about the need to “provide conditions for cooperation between SMT sites and AIDS centre”, without specifying the procedure of such cooperation, focal points and doers. The Guidelines lack instructions for treatment of patients with mental co-morbidity. In addition, they fail to provide recommendations on organizational issues, like funding, projected staff load (doctors, nurses, social workers and psychologists).

PROCEDURE OF SUBSTITUTION MAINTENANCE THERAPY OF OPIOID DEPENDENT PATIENTS APPROVED BY THE ORDER OF THE MINISTRY OF HEALTH # 200 OF 27.03.2012

This document focuses on a narrow array of the organizational issues and does not almost concern scope and contents of care. The document is first of all about formal procedures of circulation of SMT medications, admission, discharge, and ensuring continuity of care in various situations. It mentions the need to provide special training to non-drug addiction doctors (family doctors) for them to be eligible to deliver SMT. One of important features of the document is that it approves the regulation on SMT office which makes the first endeavour to link SMT to the units of health facilities and staff schedule. At the same time, the positives of this document are abated by lack of standards of staff load. Therefore, in no way it can replace a clinical protocol and handle all issues related to organization of treatment.

STANDARD OF TREATMENT OF HIV-POSITIVE INJECTING DRUG USERS APPROVED BY THE ORDER OF THE MINISTRY OF HEALTH # 476 OF 19.08.2008

This document strives to unite drug addiction care with HIV diagnostics and treatment. The preamble states that the target audience includes drug addiction doctors, infection doctors, nurses, social workers and psychologists. A considerable part of the document focuses on drug addiction and its relation to HIV. It also describes international recommendations on drug addiction treatment, screening, diagnostics, assessment of health and addiction severity (ASI, BBV-TRAQ). Almost the entire section elaborates on the substitution therapy and contains a lot of duplications with Technical guidelines mentioned above. Other sections concern treatment of other PAS addiction and provide for social and psychological follow-up and referral routes.

One can say that this document has the most detailed reflection of international recommendations on addiction treatment, but they concern only IDU living with HIV, and cannot be formally applied to drug addiction care to HIV-negative patients. This document – like others, though – contains no recommendation on staffing and standards of staff load.

STANDARD OF PROVIDING SOCIAL SERVICES TO PATIENTS OF OPIOID AGONIST SUBSTITUTION MAINTENANCE THERAPY APPROVED BY THE JOINT ORDER OF THE MINISTRY OF FAMILY, YOUTH AND SPORTS, MINISTRY OF LABOUR AND SOCIAL POLICY AND MINISTRY OF HEALTH # 3123/275/770 OF 13.09.2010

This Standard elaborates on social services for SMT patients. Many of its interventions duplicate those referred to in Technical guidelines and Standard of treatment of HIV-positive IDU. Importantly, it specifies main sets of services, including a group of legal services.

ASSESSMENT OF COMPLIANCE OF MAJOR EFFECTIVE LEGAL DOCUMENTS WITH THE REQUIREMENTS OF THE ORDER OF THE MINISTRY OF HEALTH # 751 OF 28.09.2012 “ON DEVELOPING AND IMPLEMENTING MEDICAL AND TECHNICAL DOCUMENTS FOR STANDARDIZING HEALTH CARE IN THE SYSTEM OF THE MINISTRY OF HEALTH OF UKRAINE”

According to **Order of the Ministry of Health # 751 of 28.09.2012**, currently the new base of medical and technical documents is being developed. This Order classifies various groups of documents, describes their contents and inter-relation. The new system consists of several types of documents.

A Clinical guideline is a document regimenting evidence-based provisions on health and medical and social care, the reliability and validity of which is proved. It aims at helping a doctor and a patient to make reasonable decisions in various clinical situations.

A Standard of health care is a document that determines rules and requirements on organization and quality criteria of health care, and indicators that inform subsequent clinical audit. It is developed on the basis of clinical guidelines and reflects the opportunities of health care system. To be approved by the Ministry of Health of Ukraine.

A Unified clinical protocol of health care is a document that is developed on the basis of clinical guideline with due account of the opportunities of health care system, if the respective Standard of health care is available (and in conformity with it). It determines the process of health care provision, its scope and results at certain conditions. To be

approved by the Ministry of Health of Ukraine.

Local protocol of health care is a document aiming at ensuring continued care, efficient and cost effective health care at certain conditions and other pathologies in line with clinical guidelines, standards and unified clinical protocols. It provides for coordination and time-wise adjustment of technologies and methods of multi- and inter-disciplinary health care; and regulates key issues of documenting medical information and clinical audit. To be approved by the head of health facility.

Clinical protocols of health care and medical standards are evidence-based (these documents are based on clinical recommendations, being tertiary resources of evidence-based medicine). The documents are developed by inter-disciplinary teams (representatives of all stakeholders) according to the issue (topic) rather than to the field of health care. They have to be periodically reviewed and publicly discussed.

The **Order of the Ministry of Health # 751 of 28.09.2012** has also approved:

- 1) Methodology of development and implementation of evidence-based medical standards (unified clinical protocols) of health care (hereinafter – the Methodology);
- 2) Methodology of development of the system of quality indicators of health care;
- 3) Regulation on Inter-disciplinary working group on development of evidence-based medical standards (unified clinical protocols) of health care;
- 4) Regulation on the register of medical and technical documents on standardization of health care.

To carry out the analysis, we input to the matrix the Structure of a unified clinical protocol of health care approved by the Methodology and effective narcology documents: Clinical protocols on health care in the field of narcology approved by the Ministerial Order # 681 of 21.09.2009 and Technical guidelines “Substitution maintenance therapy for treatment of opioid dependent patients” that were approved by the Ministerial Order # 645 of 10.11.2008. Results of comparison are provided in Annex 4.

CLINICAL PROTOCOLS ON HEALTH CARE IN THE FIELD OF NARCOLOGY APPROVED BY THE MINISTERIAL ORDER # 681 OF 21.09.2009

Structure of Clinical protocols is significantly inconsistent with the Structure of a unified clinical protocol of health care.

It lacks such necessary elements as epidemiological information, general part with data about particularities of health care. Neither does it specify the reasons for preventive interventions, their mandatory and optimal scope, the reasons for other interventions and their mandatory and optimal scope during out-patient care and at pre-hospital period. In addition, it does not define criteria for hospital admission and profile of beds. Diagnostic section does not describe the scope and particularities of history taking, physical examination and differential diagnostics. The document does not indicate mandatory and optimal methods of out-patient and in-patient treatment and criteria for discharge. Neither does it stipulate the reasons for clinical dynamic monitoring, nor does it refer to a respective standard of treatment or a clinical guideline. It lacks the entire section on resource support (information about staffing, lists of equipment and drugs according to their international names). Quality criteria are not described as indicators according to the Methodology. List of sources and annexes are missing as well.

TECHNICAL GUIDELINES “SUBSTITUTION MAINTENANCE THERAPY FOR TREATMENT OF OPIOID DEPENDENT PATIENTS” THAT WERE APPROVED BY THE ORDER OF THE MINISTRY OF HEALTH # 645 OF 10.11.2008

Similarly, the structure of Technical guidelines has some inconsistencies with the Methodology. Namely, it does not mention preventive interventions, while describing only SMT treatment. It does not specify scope and contents of physical examination, methods of laboratory tests, and differential diagnostics. Criteria for admission and discharge are not stipulated clearly, and the stages of drug addiction care are not specified.

DISCUSSION

Findings of this survey were presented at the round table in Kyiv on 8 April 2015 with UNODC support. The event was attended by representative of Ukrainian Centre for Socially Dangerous Disease Control of the Ministry of Health of Ukraine, Ukrainian Research Institute of Social and Forensic Psychiatry and Narcology of the Ministry of Health of Ukraine, State Penitentiary Service of Ukraine, State Expert Centre of the Ministry of Health of Ukraine, Poltava, Kharkiv, Vinnytsia, Dnipropetrovsk, Odesa, Cherkasy oblast drug addiction clinics, the Clinton Foundation, Ukrainian Institute of Public Health Policies, UNAIDS, WHO, and USAID HIV Reform in Action Project.

During the discussion, speakers underlined the need to revise effective guidelines and protocols. In particular, **Serhii Dvoriak**, Head of UIPHP, noted that effective protocols of drug addiction care were too schematic and hardly suitable for practical activities. When it comes to Technical guidelines on substitution therapy, they were developed back in 2008 when substitution therapy was just introduced; therefore many provisions were a kind of compromise that aimed at providing regulation for SMT (that was not available by that time). For sure, it is high time to revise legal framework on drug addiction treatment.

Olena Leshchyshyna, Director of Department of Standardization of Medical Services of State Expert Centre of the Ministry of Health of Ukraine, introduced the structure of medical and technical documents, stages of their developments and options to launch the process. During the discussion, participants asked about the steps to start development of medical and technical documents. First, the Order of the Ministry of Health is adopted to set up a working group for development of adapted clinical recommendations on the basis of international guidelines selected in line with AGREE questionnaire. Then, a standard of health care, a unified clinical protocol and a patient route are developed. These documents are approved by the Ministry, and all health facilities of Ukraine are obliged to implement them.

Participants of the round table decided:

- To support conclusions and recommendations of the report authored by UNODC consultant Leonid Vlasenko; to recommend the Ministry of Health Care of Ukraine to set up a working group for development of medical and technical documents on opioid addiction treatment;
- To recommend advocacy measures to call the government to continue funding of National Programme on Combatting HIV 2014-2018;
- To advocate for the development of legal framework (eliminate over-burden from staff of clinics, legal barriers for service provision, etc.), integrate SMT into current health care infrastructure and grant it status of a standard type of health care of

IDU; introduce self-supporting model of service provision; provide patients with a possibility to buy prescribed SMT medicine in drugstores);

- To review and assess regional needs for SMT, given the developments of drug and epidemiological situation;
- To assess the compliance of national system of indicators of drug addiction care with indicators of efficiency of HIV response in Ukraine.

CONCLUSIONS

Therefore, we can state that the effective clinical protocols of drug addiction care are significantly inconsistent with international standards. Some discrepancies with national standards are also observed (for example, with the Standard of treatment of HIV-positive injecting drug users). First of all, it concerns managing co-morbidities, integrated care and resource support. Effective clinical protocols are too schematic and can be hardly applied as a practical tool. Additional effective documents regulating standards of care of HIV-infected IDU and SMT do not fully redress the existing drawbacks. A number of fundamental international principles, like Community involvement, Policy development and Addiction treatment and the criminal justice system, are not reflected in the legal framework.

Effective legal documents on drug addiction care are not in line with recent national requirements to medical and technical documents: both in terms of procedure of developing them and in structure – they miss important components in the description of diagnostic process, justifications of scope and contents of interventions, and staffing.

We can conclude that it is high time to revise main medical and technical documents that regulate health care of drug addicted patients. They should reflect most vital requirements of international treatment standards and follow the entire logic of development and structure of such documents. Another task is to develop the system of indicators of drug addiction care.

LIST OF SOURCES

INTERNATIONAL AND FOREIGN GUIDELINES AND PROTOCOLS OF DRUG DEPENDENCE TREATMENT

1. “HIV/AIDS Treatment and Care. Clinical Protocols for the WHO European Region”. — 2007.
2. Drug Abuse Treatment and Rehabilitation: A Practical Planning and Implementation Guide. — UNODC, 2003.
3. Policy guidelines for collaborative TB and HIV services for injecting and other drug users: an integrated approach. — WHO, Geneva, 2008.
4. WHO/UNODC/UNAIDS Position Paper. Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention. — 2004.
5. Management of TB and HIV Co-infection. Clinical Protocols for the WHO European Region. — 2006.
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7. Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence. — Commonwealth of Australia, 2003.
8. Discussion Paper. Principles of Drug Dependence Treatment. — WHO, UNODC, 2008.
9. Drug Misuse and Dependence. UK Guidelines on Clinical Management. — NICE.
10. Guidelines for Identification and Management of Substance Use and Substance Use Disorders in Pregnancy. — WHO, 2014.
11. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence. — WHO Department of Mental Health and Substance Abuse, 31 March 2009.
12. Methadone and Buprenorphine in the Management of Opiate Dependency. — NICE, 2010; TIP (Treatment Improvement Protocols) Medication-Assisted Treatment for Opiate Addiction in Opioid Treatment Program. — SAMSHA, USA, 2005.
13. TREATNET Quality Standards for Drug Dependence Treatment and Care Services. — UNODC, 2012.

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2. Думчев К., Форостяная О. Оценка доступности комплексных медико-социальных услуг потребителям инъекционных наркотиков (ПИИ) в центрах интегрированной

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3. Интегрированный подход к предоставлению медицинских и психосоциальных услуг для клиентов программы заместительной поддерживающей терапии в Украине: опыт МБФ «Международный Альянс по ВИЧ/СПИДу в Украине» [An integrated approach to the provision of medical and psychosocial services for clients of substitution maintenance therapy in Ukraine: experience of ICF “International HIV/AIDS Alliance in Ukraine”] — К.: МБФ «Международный Альянс по ВИЧ/СПИДу в Украине», 2013. — 72 с.
4. Final report on evaluation of needs and capacity of the system of drug addiction treatment in the selected cities: Kyiv, Poltava, and Kharkiv UNODC. — 2013.
5. Поддерживающая терапия агонистами опиоидов: методическое пособие [Agonist opioid maintenance therapy: a Guide]. — Kyiv, UIPHP, 2010.
6. Order of the Ministry of Health # 446 of 06.07.2006 “On Approval of the Instruction on introducing the procedure of HIV voluntary counselling and testing (protocol) in tuberculosis, dermatology and syphilology and drug addiction health facilities”.
7. Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”.
8. Order of the Ministry of Health # 645 of 10.11.2008 “On Approval of Technical Guidelines “Substitution maintenance therapy for treatment of opioid dependent patients”.
9. Order of the Ministry of Health # 551 of 12.07.2010 “On Approval of Clinical Protocol of HIV antiretroviral therapy in Adults and Adolescents”.
10. Order of the Ministry of Health # 415 of 19.08.2005 “On Improving HIV Voluntary Counselling and Testing”.
11. Order of the Ministry of Health # 476 of 19.08.2008 “On Approval of the Standard of treatment of HIV-positive injecting drug users”.
12. Order of the Ministry of Health Care # 681 of 21.09.2009 “On Approval of Clinical Protocols on Health Care in the field of Narcology”.
13. Order of the Ministry of Health # 120 of 25.05.2000 “On Improving Health Care of HIV/AIDS Patients”.
14. Order of the Ministry of Health # 200 of 27.03.2012 “On Approval of the Procedure of Substitution Maintenance Therapy of Opioid Dependent Patients”.
15. Order of the Ministry of Health of Ukraine # 226 of 27.07.1998 “On Approval of Provisional sectoral unified standards of medical technologies of diagnostic and treatment process of in-patient care of adults in health clinics of Ukraine and Provisional standards of the scope of diagnostic studies, treatment and quality criteria of treatment of children” (abolished by the Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”).
16. Order of the Ministry of Health of Ukraine # 819 of 27.09.2010 “On Development, Piloting and Implementation of Medical and Technical Standards of Health Care” (abolished by the Order of the Ministry of Health of Ukraine # 751 of 28.09.2012 “On Developing and Implementing Medical and Technical Documents for Standardizing

Health Care in the System of the Ministry of Health of Ukraine”).

17. Order of the Ministry of Health # 751 of 28.09.2012 “On Developing and Implementing Medical and Technical Documents for Standardizing Health Care in the System of the Ministry of Health of Ukraine”.
18. Order of the Ministry of Health # 507 of 28.12.2002 “On Approval of Standards of Health Care and Quality Indicators of Health Care” (abolished by the Order of the Ministry of Health of Ukraine # 310 of 08.05.2014 “On Revoking Certain Orders of the Ministry of Health of Ukraine”).
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20. Joint Order of the Ministry of Family, Youth and Sports, Ministry of Labour and Social Policy and Ministry of Health # 3123/275/770 of 13.09.2010 “Standard of providing social services to patients of opioid agonist substitution maintenance therapy”.
21. Социально-психологическая поддержка клиентов программ заместительной поддерживающей терапии: методические рекомендации [Social and psychological support to clients of substitution maintenance therapy: Technical guidelines]. — К., 2008.
22. Providing integrated services at health care facilities for people who use drugs in Ukraine: Guidelines / Compiler – K. V. Dumchev, specialist on HIV/AIDS/STIs prevention, WHO Country Office in Ukraine.

ANNEX 1

International treatment standard	Effective protocols of drug addiction care Ministerial Order # 681 of 21.09.2009	Technical guidelines on SMT Ministerial Order # 645 of 10.11.2008	Procedure of SMT Ministerial Order # 200 of 27.03.2012	Standard of treatment of HIV-positive IDU Ministerial Order # 476 of 19.08.2008	Standard of providing social services to patients of SMT Joint Order of the Ministry of Family, Youth and Sports, Ministry of Labour and Social Policy and Ministry of Health # 3123/275/770 of 13.09.2010
1. Availability and accessibility					
1.1. Geographical accessibility	Not specified	Not specified	Not specified	Not specified	Not specified
1.2. Flexibility of opening hours (same-day admission)	Not specified	Partially (refers to the need of flexible working hours)	Not specified	Not specified	Not specified
1.3. Legal framework (confidentiality of treatment, registration of drug addicts does not discourage patients)	Clinical dynamic monitoring is mentioned, but its contents and legal status are not specified	Not specified	Partially, item 9 provides for medical secrecy, issues of registration are not addressed	The right to anonymity of treatment is mentioned, but no instructions on how to ensure it	Not specified
1.4. Availability and accessibility (removal of unnecessarily selective criteria, low threshold services)	Not specified	Criterion for inclusion - only the opioid dependence syndrome, section 3.4.2	Criteria for inclusion - opioid dependence syndrome and signed informed consent form	Criteria for inclusion - opioid dependence syndrome and signed informed consent form	Not specified
1.5. Affordability (free treatment or insurance coverage)	Not specified	Not specified	Not specified	Not specified	Not specified
1.6. Cultural relevance	Not specified	Not specified	Not specified	Not specified	Not specified
1.7. Responsiveness to multiple needs (patients with associated somatic or psychiatric disorders)	Partially, via consultations of narrow specialists and referral	Provision of care in case of associated somatic disorder is stipulated, section 3.9	Item 3.8 provides for continued care in case of hospital admission. Referral	Various HIV and drug addiction treatment options both in drug addiction facilities and AIDS centres are described	Services of informing and follow-up in treatment and prevention clinics are provided (item 2.4)
1.8. Cooperation with criminal justice system on encouraging to enter treatment	Not specified	Not specified	Not specified	Not specified	Not specified
1.9. Gender-sensitiveness of services (women, pregnant women)	Not specified	Описано в разделе 3.9.4	Not specified	Not specified	Not specified
2. Screening, assessment, diagnosis and treatment planning					
2.1. Screening (identification and assessment of problems provoked by drug use)	Partially, diagnostic sets	Assessment, diagnosis and treatment planning, section 3.4.4	Not specified	Partially addressed in section 4.1.1	Not specified
2.2. Standard assessment and diagnosis, including HIV and hepatitis	Partially. Diagnostics of dependence according to ICD-10, diagnostics of HIV, TB and hepatitis not addressed.	Diagnostics of dependence is described in section 2.2.3. Diagnostics of HIV, TB and hepatitis is mentioned in section 3.3, but it is not a part of examination set	Partially. Diagnostics of dependence according to ICD-10, participation in voluntary counselling and testing is described in section «Rights of staff» of the Regulation on SMT office	Available. HIV testing in drug addiction facilities, section 15.2	Not specified

2.3. Comprehensive assessment of severity of the disease, somatic and mental health status (employment, family status, legal situation, etc.)	Mentioned in diagnostic sets 3, 4, and 5, includes Addiction severity index	Partially covered in section 3.3	Not specified	Use of assessment tests is described (ASI, BBV-TRAQ)	Assessment of social and psychological problems is performed item, 3.3.1
2.4. The treatment plan (agreed treatment goals, interventions to meet them, plan of cooperation with various agents, revised in case of need)	Not mentioned	Partially covered in section 3.3	Not specified	Joint planning with a drug addiction doctor, section 4.1.1	Plan of individual rehabilitation is developed
3. Evidence-informed drug dependence treatment					
3.1. Multidisciplinary approach	Not mentioned directly	Partially covered in section 3.3	Not specified	Covered in section 3.2.2	Covered in item 3.1
3.2. Sufficient duration (at least 90 days of in-patient care or at least 12 months of out-patient SMT)	Duration of treatment: individually	Duration: at least one year, section 3.5.5	Not specified	Not specified	Not specified
3.3. Pharmacological and psychosocial interventions based on individual needs	Mentioned	Partially covered in section 3.8	Not specified	Covered in section 4.5.1	Not specified
3.4. Brief interventions	Mentioned in preventive and rehabilitation sets	Not specified	Not specified	Not specified	Not specified
3.5. Outreach and low-threshold interventions (harm reduction)	Not specified	Not specified	Not specified	Covered in section 3.3	Not specified
3.6. Basic services	Specified in accordance with ICD-10 code	Partially mentioned: only with regard to SMT	Not specified	Not specified	Not specified
3.7. Medically supervised withdrawal treatment (a first step to rehabilitation)	Covered in general terms	Covered in section 3.5.7	Not specified	Covered in section 4.5	Not specified
3.8. Opioid dependence substitution treatment	Covered in general terms	Described in details in recommendations	Described in terms of organization and drug traffic	Covered in details in section 4.4.1	Not specified
3.9. Psychological and social interventions	Described in rehabilitation sets	Partially covered in section 3.8	Not specified	Covered in section 4.1.1	Social and medical, awareness raising, legal and psychological interventions are provided for
3.10. Self-help support groups	Described in rehabilitation sets	Partially covered in section 3.8	Not specified	Covered in section 4.5.1	Mentioned
3.11. Economic and cultural relevance	Not specified	Not specified	Not specified	Not specified	Not specified
3.12. Knowledge transfer and ongoing clinical research to improve the treatment programmes	Not specified	Not specified	Not specified	Not specified	Not specified
3.13. Training of treatment professionals	Not specified	Not specified	Partially. Item 2.12 just states the need for «systemic capacity building», no details provided	Not specified	Not specified
4. Human rights and patient dignity					
4.1. Adequate access to treatment for all and at all the stages of the disease	Not specified	Partially covered in section 3.3	Not specified	Covered	Not specified
4.2. Discrimination should not occur based on any grounds	Not specified	Partially covered in section 3.3	Not specified		Not specified

4.3. Protection of human rights (inhumane practices, punishment, etc.)	Not specified	Not specified	Not specified	Not specified	Not specified
4.4. Rights of a patient	Not specified	Partially	Right to confidentiality of treatment, informed consent form and a leaflet are provided for	Right to confidentiality of treatment, informed consent form and a leaflet are provided for	Legal support to the protection of rights, item. 2.5
5. Targeting special groups and conditions					
5.1. Adolescents	Not specified	Not specified	Only the possibility of treatment for minors upon consent of their legal representatives is provided for	Not specified	Not circled out specially
5.2. Women	Not specified	Partially covered in section 3.9.4	Not specified	Not specified	Not circled out specially
5.3. Pregnant women	Not specified	Covered in sections 3.9.4 и 3.9.5	Not specified	Not specified	Not circled out specially
5.4. People with medical comorbidities	Not specified	Covered in sections 3.9.1, 3.9.2 и 3.9.3	Partially, referral to narrow specialists is mentioned in item 2.6 of the Regulation on SMT office	Treatment of HIV and TB comorbidity is described	Not circled out specially
5.5. People with psychiatric comorbidities	Not specified	Not specified	Not specified	Not specified	Not circled out specially
5.6. Sex-workers	Not specified	Not specified	Not specified	Not specified	Not circled out specially
5.7. Ethnic minorities	Not specified	Not specified	Not specified	Not specified	Not circled out specially
5.8. Marginalized/street people/unemployed, etc.	Not specified	Not specified	Not specified	Not specified	Not circled out specially
6. Addiction treatment and the criminal justice system					
6.1. Diversion schemes from criminal justice system into treatment	Not specified	Not specified	Not specified	Not specified	Not specified
6.2. Human rights (access to treatment in prisons)	Not specified	Partially, section 3.10.1	Not specified	Addressed in section 3.4.3	Not specified
6.3. Continuity of services (SMT, NSP in prisons)	Not specified	Adressed, during the arrest and apprehension, section 3.10.1	Not specified	Addressed in section 3.4.3	Not specified
6.4. Continuous care in the community upon release	Not specified	Not specified	Not specified	Addressed in section 3.4.3	Not specified
6.5. Non-use of forced labor	Not specified	Not specified	Not specified	Not specified	Not specified
7. Community involvement in the treatment					
7.1. Patient active involvement	Not specified	Not specified	Not specified	Not specified	Not specified
7.2. Accountability to the community	Not specified	Not specified	Not specified	Not specified	Not specified
7.3. Community-oriented interventions	Not specified	Not specified	Not specified	Not specified	Not specified
7.4. Promoting a paradigm that drug addiction is a multi-factorial disorder	Not specified	Not specified	Not specified	Not specified	Not specified
7.5. Establishing linkages with various organizations	Not specified	Not specified	Item 2.11 of the Regulation on SMT office	Not specified	Not specified
7.6. NGO involvement	Not specified	Not specified	Item 2.10 of the Regulation on SMT office	Not specified	Not specified

8. Clinical governance					
8.1. Protocols of services provided	Reference to Technical guidelines on organization and activity of centres for re-socialization of drug addicts, 2004	Not specified	Not specified	Not specified	Not specified
8.2. Treatment protocols	Not specified	Not specified	Not specified	Not specified	Not specified
8.3. Qualified staff	Drug addiction doctor and general practitioner (family doctor) are mentioned	Drug addiction doctor or a doctor who received training	Qualification requirements to staff (drug addiction doctor or a doctor who received special training)	Not specified	Not specified
8.4. Supervision	Not specified	Not specified	Supervision is a job of the head	Not specified	Not specified
8.5. Financial resources	Not specified	Not specified	Not specified	Not specified	Not specified
8.6. Communication structures	Not specified	Not specified	Not specified	Modality of inter-service cooperation is provided in item 3.4.2	Not specified
8.7. Monitoring systems	Not specified	Not specified	Data about SMT (number of patients, sex, status, etc.), as well as information about the needs for medicines are submitted to Ukrainian Medical and Monitoring Centre for Alcohol and Drugs	Not specified	Not specified
8.8. Human resources (wages, load, etc.)	Not specified	Not specified	Partially. Staff load is not stipulated. In the SMT office, there is a staff position of a drug addiction doctor and two nurses, no staff position of social worker	Not specified	Not specified
9. Policy development, strategic planning and coordination of services					
9.1. Multi-sector treatment policy	Not specified	Not specified	Not specified	Not specified	Not specified
9.2. Linkage to prevention	Not specified	Not specified	Not specified	Not specified	Not specified
9.3. Situation assessment	Not specified	Not specified	Not specified	Not specified	Not specified
9.4. Coordination and balance between specialised services and primary care	Not specified	Not specified	Not specified	Not specified	Not specified
9.5. Continuum of care	Not specified	Not specified	Not specified	Not specified	Not specified
9.6. Multidisciplinary approach	Not specified	Not specified	Not specified	Not specified	Not specified
9.7. Capacity building	Not specified	Not specified	Not specified	Not specified	Not specified

ANNEX 2

PREVENTIVE SET 1

A set of consistent interventions, with keeping necessary documents:

- Consultation of a drug addiction doctor or a nurse with provision of information (preventive brief intervention);
- Providing information to patient and his/her family through printed information and motivation materials.

PREVENTIVE SET 2

A set of consistent interventions, with keeping necessary documents:

- Preventive consultations of a social worker or a nurse or a psychologist (preventive brief intervention, at least two in total);
- Providing information to patient and his/her family through printed information and motivation materials (according to case plan).

PREVENTIVE SET 3

A set of consistent interventions, with keeping necessary documents:

- Targeted consultations of a social worker or a nurse or a psychologist or a doctor (at least three times a week and at least six in total);
- Preventive consultations of a social worker or a nurse or a psychologist or a doctor (preventive brief intervention, at least twice a week and at least three in total);
- Consultations of a social worker or a nurse or a psychologist or a doctor with regard to patient's participation in a mutually agreed comprehensive individual programme of psychological, social, professional and medical and biological rehabilitation (see Rehabilitation interventions) (at least twice a week and at least three in total);
- Providing information to patient and his/her family through printed information and motivation materials (according to case plan).

DIAGNOSTIC SET 1

Examination at drug addiction doctor in cases stipulated by effective legal documents – comprehensive laboratory toxicological test of substance in the body by gas chromatography (GC), thin layer chromatography (TLC) or immune diagnostic rapid testing (IDRT). If the results are positive – confirmation of substance in the body by mass-selective gas chromatography (MGC) or by at least three others test methods. Duration of examination is 50 minutes, duration of comprehensive laboratory toxicological test – up to 10 days. Repeated examination is possible not later than in one hour.

DIAGNOSTIC SET 2

A set of consistent interventions, with keeping necessary documents:

- Examination at drug addiction doctor, therapist, neurophatist, ophthalmologist, psychiatrist, sexual health specialist, gynecologist (for women);
- Clinical blood analysis, clinical urine analysis, biochemistry of blood (aspartate

transaminase, alanine transaminase, thymol test, total bilirubin, total protein, BUN and glucose tests). In case of need – gamma glutamine transferase, electrocardiogram. Number and frequency of examinations, procedures and tests depend on patient's condition.

DIAGNOSTIC SET 3

Psychodiagnostic examination: diagnostics of cognitive functions (methods: pictograms, the Schulte test, classification, concept exclusion and generalization test); diagnostics of thought disorder (methods: Luscher test, depression and anxiety test). Duration of examination is 45 minutes. Screening (diagnostics of risky behaviour types, AUDIT, diagnostics of level of alcohol (opiate) addiction). Psychodiagnostics of features of personality (IQ test, MMPI, Cattell's test, Shmishek's test). Psychodiagnostics of self-evaluation and self-awareness (methods: Dembo-Rubinstein test, Leary test). Duration of examination is 3 hours. Patient is examined twice when in in-patient care. Psychodiagnostics of professional and social adaptation in line with objective of examination and patient's condition. Duration of examination is 1 hour.

DIAGNOSTIC SET 4

A set of consistent interventions, with keeping necessary documents: examination at drug addiction doctor. In case of need – examination of medical consultative board, comprehensive laboratory toxicological test (GC, TLC or IDRT. If the results are positive – MGC or at least three others test methods), AUDIT. Number and frequency of examinations, procedures and tests depend on patient's condition.

DIAGNOSTIC SET 5

Examination of functional status of nervous system (Aschner test, orthotest and klinotest). Functional tests of cardiovascular and respiratory systems (heart rate, blood pressure measurement, Martine-Kushelevsky test, Letunov combined test, Stange-Hench test, Rosenthal test, lung capacity, Serkin combined test).

DIAGNOSTIC SET 6

A set of consistent interventions, with keeping necessary documents: examination at drug addiction doctor. In case of need – examination of medical consultative board, comprehensive laboratory toxicological test (GC, TLC or IDRT. If the results are positive – MGC or at least three others test methods). Number and frequency of examinations, procedures and tests depend on patient's condition.

DIAGNOSTIC SET 7

A set of consistent interventions, with keeping necessary documents:

- Examination at drug addiction doctor, therapist, neurophysiologist, ophthalmologist, in case of need – at psychiatrist, anesthesiologist (resuscitator);
- 24-7 surveillance of a nurse and everyday medical supervision of patient's condition;
- Every three hours – thermometry and blood pressure measurement, clinical blood analysis, clinical urine analysis, biochemistry of blood (aspartate transaminase, alanine transaminase, thymol test, total bilirubin, total protein, BUN and glucose tests, comprehensive laboratory toxicological test (GC, TLC or IDRT. If the results are

positive – MGC or at least three others test methods), gamma glutamine transferase, electrocardiogram, alkaline reserve. Number and frequency of examinations, procedures and tests depend on patient's condition.

QUALITY CRITERIA 1

Valid conclusion of medical examination of intoxication. Detoxification (in case of need) – pursuant to a patient's consent.

QUALITY CRITERIA 2

Mutually agreed with a patient or his/her representative interim history with recommendations (at least three reports during treatment cycle, and one separate report after its termination).

QUALITY CRITERIA 3

Mutually agreed with a patient or his/her representative interim history with recommendations on further treatment and rehabilitation due to drug addiction (at least three reports during treatment cycle, and one separate report after its termination). Remission or sustainable amelioration of a patient's condition, identified after mutual agreement with a patient or his/her representative.

QUALITY CRITERIA 4

Mutually agreed with a patient or his/her representative interim history with recommendations on further treatment and rehabilitation due to drug addiction. Remission or sustainable amelioration of mental condition of a patient (psychotic symptoms and abstinence effects, identified after mutual agreement with a patient or his/her representative).

ANNEX 3

Approved
by the Order of the Ministry of Health of Ukraine
681 of 21.09.2008

Clinical protocol of health care of patients with mental and behavioural disorders due to opioid use

Opioid dependence. At present abstain in clinical controlled maintenance or substitute treatment

ICD-10 Code: F11.22

Objective of necessary interventions: consultation of drug addiction doctor, prescription of substitution medicine at maintenance or substitution treatment and psychosocial rehabilitation.

Clinical criteria of dependence syndrome are used to make a diagnosis.

Consultations and specialized health care of people of various age are provided by a drug addiction doctor, family doctor (general practitioner) in accordance with qualification of a doctor on a specialty “General Practice and Family Medicine) in out-patient health facilities of third level. Duration of treatment is case-based. Evidence-base of expected results of diagnostics and treatment: D.

Treatment setting is selected according to severity of condition of drug addicted patients.

Out-patient setting

Diagnostic interventions: diagnostic sets 3,4, and 5

Treatment interventions

1. Set of consistent out-patient interventions, with keeping necessary documents.
2. Cycle of substitution maintenance therapy with the use of narcotic analgesics.

Duration of treatment: individually.

3. Rehabilitation programme “12 steps” including:

- Work of patient in out-patient psychotherapeutic communities and individually on information and motivation (at least 12 hours of groups sessions and at least 7 consultations (duration of each is 1 hour during at least 12 days);
- Work of patient in out-patient psychotherapeutic communities for overcoming psychological defense and reforming inter-personal relations (at least 90 hours of groups sessions during at least 60 days);
- Written assignments on topics of the First, Second and Third steps of 12 steps programme (at least 12 hours);
- “Stress reaction prevention programme”: at least two group sessions aimed at informing (total duration is 2 hours) and at equipping client with relaxation technique (at least 24 sessions, 30 min each);

- Participation of a patient in the work of self-help and peer support groups (at least 1 session per week during at least 3 weeks or at least 90 days in 12 steps programme);
- Participation of a patient's family in the work of psychological rehabilitation and peer-support groups according to individual programme (at least 5 group sessions and 4 consultation per week during at least 6 weeks) and self-help groups;
- Work of a patient with social worker on professional rehabilitation programme.

In case of co-morbidity (non-drug), standards and protocols of other fields of health care should be implemented.

Preventive interventions: preventive set 3

Results of health care and quality criteria 3

Mutually agreed with a patient or his/her representative interim history with recommendations on further treatment and rehabilitation due to drug addiction (at least three reports during treatment cycle, and one separate report after its termination).

Clinical dynamic drug monitoring

Dietary recommendations in line with somatic co-morbidity of a patient. Requirements to work-rest cycle in line with somatic co-morbidity of a patient

Additional information for a patient and his/her family is provided according to the effective legal documents (Technical guidelines on organization and activity of centres for re-socialization of drug addicts. — Kyiv, Ministry of Family, Youth and Sports, Ministry of Health. State Institute for Family and Youth Problems, Scientific and Technical, Clinical and Rehabilitation Centre on Chemical Dependencies. Ukrainian Medical and Monitoring Centre for Alcohol and Drugs of the Ministry of Health of Ukraine, 2004).

Requirements to implementation of protocols are amended:

- a) as evidence-based data of the efficiency of certain examination and treatment methods appear;
- b) as amendments are made to the State Register of Medicines.

*Director of Department
of health care development*

M.P.Zhdanova

ANNEX 4

	Effective protocols	Technical guidelines on SMT
I. Cover page		
Diagnosis, wording of diagnosis (nosology or syndrome)	Yes	Yes
Codes of condition or disease according to ICD-10	Yes	Yes
Protocol is intended for ____ (users)	Yes	Intended for drug addiction doctors and managers of health care system
Objective of protocol	Not specified	Not specified
Date of creating a protocol	21.09.2009	10.11.2008
Date of revision of a protocol (due to revision of a clinical guideline, a standard of health care, to change of resource support)	Not revised	Not revised
List and contacts of developers. Reviewers	Yes	Yes
Summary of epidemiological information - general prevalence of a pathology, prevalence among certain population groups (age, sex, etc., risk factors, forecast)	No	Yes, section 2.2.4
Epidemiological information (for infectious disease, brief information about sources of disease, its prevalence, seasonality, etc. should be provided)	No	No
II. General part that contains data about particularities of providing health care at the respective diagnosis, pathway of disease, etc.	No	Yes, section 3.1
III. Main part (for each type of health care separately, lists of medical interventions, methods of diagnostics, treatment, rehabilitation, clinical monitoring, criteria for hospital admission, particularities of preparation for discharge, recommendations on next stages of health care should be specified according to questions in the table		
1. Prevention		
It is necessary to briefly specify the reason for intervention	No	No
Mandatory and optimal requirements, methods	Described in preventive sets, no classification on mandatory and optimal	No
2. Out-patient treatment, including rehabilitation and prevention		
It is necessary to briefly specify the reason for intervention	Not specified	Only SMT is described
Mandatory and optimal requirements, methods	Listed in general, no classification on mandatory and optimal	Only SMT is described
3. Pre-hospital stage		
It is necessary to briefly specify the reason for intervention	Not specified	Not specified
Mandatory and optimal requirements, methods	Not specified	Not specified
4. Hospital admission		
It is necessary to briefly specify the reason for intervention	Not specified	Hospital admission if making diagnosis is challenging and if somatic complications are observed, sections 3.4.4 and 3.10.5
Mandatory and optimal requirements. Criteria for hospital admission, defining the profile of beds	Criterion for admission is severity of condition, no details	Criteria are not specified clearly
5. Diagnostics		
Mandatory and optimal diagnostic methods — particularities of history taking	History taking not specified	Checklist for diagnostics according to ICD-10 (Annex 1) is described
Physical examination	Not described	Scope and procedure not described

Laboratory, instrumental and functional test methods	Described in diagnostic sets	Not described (except for toxic chemical urinoscopy)
Differential diagnostics	Not described	Not described
6. Out-patient and in-patient treatment, non-pharmacological, pharmacological, etc.		
Mandatory and optimal treatment methods	Methods listed without classification on mandatory and optimal	Only SMT is described
7. Discharge with recommendations for post-hospital period		
Mandatory and optimal interventions	Mandatory and recommended interventions not classified	Not specified
Criteria for discharge	Not specified	Not specified
8. Rehabilitation		
Mandatory and optimal interventions (treatment, prevention, including recommendations on diet, working pattern, physical activity and resort treatment)	Interventions listed without classification on mandatory and optimal	Described in section 3.8
9. Clinical monitoring, including recommendations on diet, working pattern, physical activity and resort treatment		
It is necessary to specify the reason for intervention with reference to a clinical guideline or a standard of health care	Reason for clinical dynamic monitoring not specified, reference to a standard or clinical guidelines are missing	Reason for clinical dynamic monitoring not specified, reference to a standard or clinical guidelines are missing. Voluntary nature of clinical monitoring is underlined
Mandatory and optimal methods	Not specified	Not specified
IV. Description of stages of health care		
Detailed information is provided (algorithms, graphs, schemes, tables, texts) on prevention, diagnostics, treatment, rehabilitation, medical checkup that is necessary for implementation of protocols and activities of a doctor	Stages are described in the scheme	Stages not described
V. Resource support for implementation of a protocol		
Information about staff resources (list of specialties)	No	Yes, section 3.3
Equipment and furniture (list of medical equipment)	No	No
List of medicines (international and non-proprietary names)	No	Yes, section 3.2
VI. Quality indicators of health care are developed in line with the Methodology of developing the system of quality indicators of health care	Quality criteria not described as indicators in line with the Methodology	Quality indicators are described, section 3.11
VII. List of literature used during the development of a unified clinical protocol of health care	No	Yes
VIII. Annexes to a unified clinical protocol of health care, in particular, memo for a patient, clinical classification, etc.	No	Yes, 8 annexes



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