



ORDER

March 21, 2008

Chisinau

No. 124

**On the Method of Development and
Approval of National Clinical Protocols**

In order to continuously improve the quality of health care services delivered to the population, to unify and co-ordinate in a centralized manner the development and approval of National Clinical Protocols and to standardize the delivered health care services, I

APPROVE:

1. the Regulation on the Method of Development and Approval of National Clinical Protocols (Attachment 1).
2. the Template of the National Clinical Protocols (Attachment 2), and

ORDER:

1. the Department of Quality Management and Treatment Standards (Mr. M. Rotaru, Head of Department) and the Coordinating-Consultative Council (Mr. Gh. Paladi, academician, Academy of Science of Moldova - President) to co-ordinate in a centralized manner the development and approval of the National Clinical Protocols in accordance with the List of priority nosologies, approved by the Ministry of Health for the respective year;
2. Heads of Departments of the Ministry of Health, director of the National Health Management Center (Mr. M. Ciocanu), director of the Institute of Scientific Research on Mother and Child Health Care (Mrs. L. Etco), director of the Institute of Neurology and Neurosurgery (Mr. O. Rusu), director of the Institute of Oncology (Mr. M. Sofroni), director of the Institute of Cardiology (Mr. M. Popovici), director of the Institute of Phtisiopulmonology "Ch. Draganiuc" (Mr. S. Sofronie), director of the National Scientific-Practical Center of Emergency Medicine (Mr. Gh. Ciobanu), director of the Scientific-Practical Center of Cardiovascular Surgery (Mr. A. Ciubotaru), director of the National Scientific-Practical Center of Preventive Medicine (Mr. I. Bahnarel), director of the Drug Agency (Mr. V. Verdes), interim rector of the State University of Medicine and

Pharmacy “N. Testemitanu” (Mr. N. Esanu), main specialists, heads of working groups on the development of National Clinical Protocols, directors of republican, municipal and raion health care facilities:

2.1. to co-ordinate the proposals on the development and implementation of National Clinical Protocols with the Department of Quality Management and Treatment Standards and the Coordinating-Consultative Council under this Department.

2.2. The National Clinical Protocols shall be developed:

- using updated evidence-based international guidelines on diagnosis and treatment;
- by multidisciplinary specialist groups, established for this purpose by the Ministry of Health for each specialty in accordance with the approved requirements (see Attachments 1 and 2);
- to serve as basis for the development of facility-level clinical protocols by each health care facility.

3. The Regulation on the Method of Development and Approval of National Clinical Protocols and the Template approved by this Order, shall be applied to Clinical Protocols developed with the support of international projects.

The enforcement of this Order shall be supervised by Mr. Mircea Buga, Vice Minister.

Minister

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**Regulation on the Method of Development and Approval of
National Clinical Protocols**

1. The Department of Quality Management and Treatment Standards (hereafter “the Department”) and the Coordinating-Consultative Council under this Department shall approve, on a yearly basis, the list of priority nosologies for which National Clinical Protocols (hereafter “NCP”) are to be developed.
2. The evidence-based international guidelines on diagnosis and treatment shall serve as basis for the development of NCPs.
3. The multidisciplinary groups of specialists, established for this purpose by the Ministry of Health for each specialty shall develop within 2 or 3 months the draft NCP, in accordance with the approved requirements.
4. The draft NCP and the accompanying documents shall be reviewed, within 1 month, by the Ministry of Health; the National Health Insurance Company; the National Council for Health Evaluation and Accreditation; profile medical associations; representatives of primary, secondary and tertiary health care facilities appointed by the Ministry of Health and by other health system stakeholders, which shall submit their advisory opinions in writing to the multidisciplinary groups developing the NCP. At the same time, the draft NCP shall be posted on the Ministry’s website for public debate.
5. The multidisciplinary groups of NCP developers shall review the proposals and introduce the changes within one week, inform the facilities and specialists participating in the review of the changes made and counter-sign the final version of the NCP to be submitted to the Department and to the Expert Council of the Ministry of Health for approval.
6. The Department shall enforce the approved NCP by Ministry Order, distribute them to health care facilities for implementation and development of facility-level clinical protocols and post them on the Ministry’s website.
7. The approved NCP shall:
 - serve as basis for the development of facility-level clinical protocols by each health care facility;
 - be accompanied by: a) proposals for the training of health care professionals on how to use the protocols and the procedures contained therein; b) recommendations on the development of facility-level clinical protocols.
8. Facility-level clinical protocols shall be developed by a specialist group established by order of the health care facility director.

Template of National Clinical Protocols

Basic requirements for National Clinical Protocols

Upon development of National Clinical Protocols (hereafter – “the NCP”) the following basic requirements shall be considered:

1. The NCP shall mandatorily include the following main parts:
 - A – Introduction;
 - B – General part (management of patient condition);
 - C – Patient diagnosis and treatment, which shall mandatorily include:
C.1. – Algorithms of diagnosis and treatment, C.2. – Detailed description of methods, techniques and procedures;
 - D – Human and material resources to implement the protocol provisions;
 - E – Performance indicators according to protocol goals;
 - Attachments;
 - Bibliography.
2. The main NCP parts described above shall have an internal structure in accordance with the sub-components of the NCP Template presented below. Deviations from the internal structure are possible only if reasoned in writing, if the condition differs from the one described in the NCP template (e.g.: emergency; surgery, etc.).
3. The NCP includes mandatory and recommended requirements. The mandatory requirements shall be mandatorily enforced and included in the facility-level clinical protocol, which shall also include chapters corresponding to the health care level of all the NCP main parts, adjusted to the logistic capacity of the respective health care facility.
4. The NCP shall include a description of diagnosis and treatment on all health care levels (primary, secondary, tertiary).
5. The information presented in the NCP shall be brief, preferably in the form of tables, charts and boxes.
6. The NCP shall be developed according to the unified requirements for document format.

Template of National Clinical Protocols

- Abbreviations used in the document
- Preface

A. INTRODUCTION

| |
|--|
| A.1. Diagnosis Examples of clinical diagnosis formulation |
| A.2. Code of disease (ICD 10) |
| A.3. Users |
| A.4. Protocol goals |
| A.5. Date of protocol development |
| A.6. Date of next revision |
| A.7. List and contact information of authors and persons participating in the protocol development Reviewers Protocol discussed and approved by: |
| A.8. Definitions used in the document |
| A.9. Epidemiologic information (<i>for infectious diseases, additional data on the source of infection, disease transmission, susceptibility, seasonality and evolution shall be included</i>) |

B. GENERAL PART (Management of patient condition)

1. Level of primary health care facilities

| Description | Rationale | Steps |
|--|--|--|
| <i>All measures relevant to the respective disease are listed (for primary health care facilities)</i> | | <i>Each measure will include the steps relevant to that particular disease, for the facilities of the respective level. The protocol will indicate whether the steps are Mandatory or Recommended. The steps will not be described in detail, just listed with a reference to the source (table, box, figure etc.) in Chapter C.2.</i> |
| ex. 1. Primary prophylaxis | To indicate briefly why is it important to conduct (ex. the primary prophylaxis)? (evidence-based, with reference to sources) | |
| ex. 2. Screening | | |
| ex. 3. Diagnosis | | Anamnesis Physical examination Paraclinical examination Differential diagnosis etc. |
| ex. 4. Treatment ex. 4.1. Pharmaceutical ex. 4.2. Non-pharmaceutical etc. | | Mandatory and recommended treatment |
| ex. 5. Follow-up | | |
| ex. 6. Recovery | | |

Note: Other relevant parts can also be included

2. Consultative specialized ambulatory level

| Description | Rationale | Steps (measures) |
|---|-----------|---|
| <i>All measures relevant to the respective disease are listed (for consultative-specialized health care facilities)</i> | | <i>Each measure will include the steps relevant to that particular disease, for consultative-specialized facilities. The protocol will indicate whether the steps are Mandatory or Recommended. The steps will not be</i> |

| | | |
|--|---|--|
| | | <i>described in detail, just listed with a reference to the source (table, box, figure etc.) in Chapter C.2.</i> |
| <i>ex. 1. Diagnosis</i> | To indicate briefly why is it important to conduct (<i>ex. the primary prophylaxis</i>)? (<i>evidence-based, with reference to sources</i>) | Mandatory and recommended investigations |
| <i>ex. 2. Decision on the treatment strategy: hospital versus ambulatory</i> | | Hospitalization criteria |
| <i>ex. 3. Ambulatory treatment, including recovery</i> | | Mandatory and recommended treatment |
| <i>ex. 4. Temporary follow-up</i> | | |

Note: Other relevant parts may also be included

3. Hospital (in-patient) level

| Description | Rationale | Steps (measures) |
|---|--|--|
| <i>All measures relevant to the respective disease are listed (for in-patient health care facilities)</i> | | <i>Each measure will include the steps relevant to that particular disease, for in-patient health care facilities facilities. The protocol will indicate whether the steps are Mandatory or Recommended. The steps will not be described in detail, just listed with a reference to the source (table, box, figure etc.) in Chapter C.2.</i> |
| <i>ex.1. Hospitalization</i> | To indicate briefly why is it important to conduct (<i>ex. the primary prophylaxis</i>)? (<i>evidence-based (international guidelines), with reference to sources</i>) | Hospitalization criteria; General therapy units (raion, municipal) Specialized profile units (municipal, republican) |
| <i>ex. 2. Diagnosis</i> | | Anamnesis Physical examination Paraclinical examination Differential diagnosis etc |
| <i>ex. 3. Treatment, including recovery</i> | | Mandatory and recommended treatment |
| <i>ex. 4. Discharge with referral (ex. : family doctor, recovery etc.)</i> | | |

Note: Other relevant parts may also be included

If necessary, long-term care and palliative care can also be included in point B General Part.

For emergency conditions, the following levels shall be mandatorily included: Emergency health care teams of doctor assistants/medical attendants 903; Emergency health care teams of general and specialized profile 903; Emergency Department, specialized and intensive therapy units.

C. 1. ALGORITHMS OF DIAGNOSIS AND TREATMENT (*in the form of diagram or chart*)

- ex. C.1.1. General algorithm of patient diagnosis and treatment*
- ex. C.1.2. Intervention algorithm*
- ex. C.1.3. Algorithm of pharmaceutical treatment and other*

C. 2. DESCRIPTION OF METHODS, TECHNIQUES AND PROCEDURES (*detailed description of elements specific to the treatment process – methods; techniques and procedures*)

- C.2.1. Clinical classification (*mandatory*)
- C.2.2. (Primary, hospital) prophylaxis (*if necessary*) (*for infectious diseases: immunoprophylaxis, antiepidemic measures in the focus*)
 - C.2.2.1. Risk factors (*if necessary*)
 - C.2.2.2. Screening (*if necessary*)
- C.2.3. Patient diagnosis and treatment (*mandatory*)

- C.2.3.1. Anamnesis (*mandatory*)
- C.2.3.2. Physical examination (objective data) (*mandatory*)
- C.2.3.3. Paraclinical investigations (*mandatory*)
- C.2.3.4. Differential diagnosis (*mandatory*)
- C.2.3.5. Prognosis (*if necessary*)
- C. 2.3.6. Hospitalization criteria (*mandatory*)
- C.2.3.7. Treatment: *Non-pharmaceutical (if necessary); Pharmaceutical (mandatory); Surgical (if necessary); Endoscopic (if necessary); Physiotherapy (if necessary); Palliative care (if necessary) etc.*
- C.2.3.8. Evolution (*mandatory*)
- C.2.3.9. Follow-up (*mandatory*)
- C.2.3.10. Rehabilitation (*if necessary*)
- C.2.4. Emergency conditions (*a SEPARATE PROTOCOL is recommended*)
- C.2.5. Complications (*a SEPARATE PROTOCOL is recommended*)
- C.2.6. Other chapters (*if necessary*)

Note: *The structure and numbering of part C.2. may differ depending on the disease nosology and protocol type (emergency, surgery, internal diseases etc.). It is recommended that the information in this chapter be placed in boxes, tables, figures, algorithms, mandatorily with references to part B of the protocol (ex.: Anamnesis (box x)).*

D. HUMAN AND MATERIAL RESOURCES TO IMPLEMENT THE PROTOCOL PROVISIONS

- D.1. for primary health care facilities
- D.2. for consultative-diagnosing facilities
- D.3. General profile units of raion and municipal hospitals
- D.4. Specialized units of (raion, if applicable), municipal and republican hospitals

Note: *The levels of health care facilities shall be similar to the ones in part B.*

E. PERFORMANCE INDICATORS ACCORDING TO PROTOCOL GOALS

| Protocol goals | Goal attainment | Method of indicator calculation | | |
|----------------|-----------------|---------------------------------|-----------|-------------|
| | | Formula | Numerator | Denominator |
| | | | | |

ATTACHMENTS

- ex. Attachment 1. Patient guideline
- ex. Attachment 2. Forms for the monitoring of facility-level protocol implementation
- ex. Attachment 3. Other

BIBLIOGRAPHY – all relevant sources used in the NCP development.