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Key words: rheumatoid arthritis, protocol of medical care.

DRAFT OF A STANDARDIZED CLINICAL PROTOCOL OF MEDICAL CARE FOR PATIENTS WITH RHEUMANOID ARTHRITIS

Pursuant the need to update the existing recommendations, this paper presents a draft of the Protocol of medical care for patients with rheumatoid arthritis in accordance with the current regulations of the Health Care Ministry of Ukraine.

Provision of protocol	Substantiation	Measures required
1. Out-patient stage		
Rheumatoid arthritis (RA) is a disease with a progressing irreversible course. RA patients require constant treatment by the disease modifying therapy (DMT) which allows to prevent primary disability and to prolong life. Treatment of RA patients may be both out- and in-patient.	In case of clear synovitis symptoms at least in one joint, which cannot be related to any other disease, patient should be sent to rheumatologist. 'Rheumatoid arthritis' diagnosis is established according to the classification criteria EULAR/ACR of 2010 (Addendum 1). Biological agents (BA) are administered only if the patient has RA according to the criteria ACR of 1987. (Addendum 2). Purpose of treatment is to achieve remission or minimal disease activity , moderation of structural changes in joints, prevention of incapacity and disability. Further referral to rheumatologist depends on the extent of treatment purpose achievement, disease activity, availability of factors of unfavourable RA course. Decision as to addition of BA or transition to other synthetic disease modifying agents (DMA) is taken if the purpose of therapy is not achieved by using the first DMA. In case of	**Compulsory:** Observation by rheumatologist. Timely RA diagnosis. Use of synthetic DMA should begin immediately after RA diagnosis is established. As long as the purpose of therapy is not achieved, treatment should be carefully monitored and overviewed every 1 to 3 months to estimate DMA efficacy and need for correction of further therapy. The monitoring of RA activity is performed using indexes DAS28, CDAI or SDAI or by a number of sore and swollen joints. X-ray control of the condition of joints is exercised every 6 or 12 months. Decision as to beginning of BA therapy and to further observation of efficiency and safety of treatment is taken by rheumatologist. During BA therapy the disease activity should be estimated according to index DAS28 taking

Provision of protocol	Substantiation	Measures required
	unfavourable prognostic factors the use of BA should be considered, and if they are absent, then to be considered is the possibility to replace synthetic DMA.	into consideration Erythrocyte Sedimentation Rate (ESR) or C-reactive protein (CRP)
2. Hospitalization		
Hospitalization is made in case of diseases or complications whose treatment requires in-patient observation of the patient.	Referral to hospitalization is made by rheumatologist	**Compulsory:** Pulse therapy and primary BA administration is made in the hospital **Desirable:** When necessary (in case of complications) the RA patients are hospitalized for in-patient treatment
3. Diagnostics		
Volume of diagnostics: Estimation of involvement of joints. The 'involvement of joints' means any sore or swollen joint detected during objective examination, which may be confirmed by the symptoms of synovitis from the results of the joint visualization (ultrasonic examination (USE), magnetic resonance tomography	1. Establishment of the diagnosis 'overt RA' in accordance with criteria ACR/EULAR, 2010, requires the sum of points ≥6 out of 10 possible). Patients having erosive changes characteristic for RA or relevant anamnesis which would retrospectively meet the criteria ACR/EULAR 2010, should be classified such as have RA. Patients with the number points <6 out of 10 cannot be classified such as have RA, their status in due course may be re-estimated and meet diagnostic criteria of RA. 2. Timely estimate of availability of unfavourable course factors, namely: - young age of the patient; - detection of autoantibodies (RF and/or ACCP), especially in high titres; - high disease activity (number of swollen and sore joints or acute phase indications: CRP, ESR); - early onset of osseous erosions. 3. Patients beginning BA treatment should undergo screening to detect	**Compulsory:** All the patients are examined in the following volume and with the following frequency: - biochemical blood analysis (urine, creatinine, crude protein, albumin, bilirubin, alanine dehydrogenase, aspartame dehydrogenase, glucose); - general blood analysis, general blood analysis primarily, then – at least once a month during induction of remission, and during remission – once in 3 months or when required; - determination of crude cholesterol, triglycerides of blood and other indicators of lipid profile at least once a year; serologic indicators (RF, ACCP) primarily, then – when required; - determination of HBsAg, HbsAb, HbcAg, anti-HCV antibodies before administration of any DMA; - Electrocardiogram (ECG), TO

Provision of protocol	Substantiation	Measures required
(MRT) of joints). Serologic criteria (to establish a diagnosis the results of at least one analysis are needed): rheumatoid factor (RF) and/or anti-Cyclic Citrullinated Peptide (ACCP) antibodies.	tuberculosis of any localization (Addendum 3). In the course of treatment the routine check for presence of tuberculosis should be performed during each visit to the doctor's. Radiography of thorax organs (TO) should be made once a year or when administered.	radiography, radiography of hands and feet, echocardiogram (echoCG) primarily, then during treatment – at least once a year; radiography of other joints is to be made if required.
Acute phase indications (to establish a diagnosis, the results of at least one analysis are needed): ESR and/or CRP	4. Risk of cardiovascular pathology (hyperglycemia, dislipidemia and hypertension) with each patient should be formally estimated and documented at the onset of treatment and once a year. To be determined for all the patients are crude cholesterol, triglycerides and cholesterol of lipoproteides of high density at the onset of treatment, then – once a year	**Desirable:** USE of joints MRT of joints with obligatory use of STIR-mode to detect swelling of marrow and osseous erosions
4. Treatment		

Provision of protocol	Substantiation	Measures required
1. Purpose of treatment is to achieve remission. 2. In case of absence of contra-indications, DMA treatment is administered immediately after the RA diagnosis is established. 3. Addition of glucocorticoids (GC) to monotherapy with DMA or DMA combination is reasonable during the starting short-term therapy. 4. GC dosage should be gradually reduced depending on the extent of RA activity. 5. Decision as to addition of BA or transition to other synthetic DMA is taken if the treatment purpose is not achieved by using the first	1. The first line agent among synthetic DMA is methotrexate (MT). 2. MT is administered in the dosage of 10–15 mg/week, with further increase depending on efficacy by 5 mg every 2 to 4 weeks up to 20 to 30 mg/week. To raise efficacy of MT taken in tabloid form, its replacement with parenteral form is possible. 3. On the background of MT therapy folic acid is administered in the dosage of not lower than 5 mg/week depending on MT dosage. 4. In case of contra-indications or hypersensitivity towards MT, the next DMA are to be leflunomide (LEF), sulfasalazin (SSZ) or injection agents of gold. 5. In case of insufficient efficacy of MT monotherapy and absence of contra-indications, combined therapy of MT + SSZ or MT + LEF etc. is used 6. Blockers of tumour necrosis factor (TNF) are administered for treatment of adult RA patients: In case of moderate and high RA activity, insufficient efficacy of at least two synthetic DMA during 6 month treatment (MT exclusively in case of no contra-indications), which were administered in standard dosage without significant toxicity which limits dosage and duration of treatment. The TNF blockers adalimumab (ADA), infliximab (INF) etc.) for treatment of adult RA patients should be used in combination with MT; in case the patient has hypersensitivity towards MT or MT therapy is considered inexpedient, ADA may be used in monotherapy. Treatment with TNF blockers may be	**Compulsory:** Treatment of RA patients is conducted and corrected depending on the results of examination. Data of dynamic observation of the patient condition are entered in the file of the ambulant patient. Disease activity in case of RA is determined using the following clinical indexes: DAS 28 — disease activity index including 28 joints; SDAI — simplified disease activity index; CDAI — clinical disease activity index (Addendum 2). When taking tocilizumab it is necessary to monitor lipid level every 6 months, aminotransferase, bilirubin, neutrophils – every 1 to 2 months. **Desirable:** 1. Monitoring of osseous tissue condition and X-ray changes of big joints (pelvic and hip joints, knee joints) to timely determine if prosthetics is required.

Provision of protocol	Substantiation	Measures required
DMA In case of unfavourable prognostic factors the use of BA should be considered, and if they are absent, then to be considered is the possibility to replace synthetic DMA.	longer than 6 months only if either remission or minimal activity is achieved. During a long-term therapy without adequate efficacy of TNF blockers, the TNF agent is withdrawn. One TNF blocker may be replaced with another if side responses to the previous agent developed or the achieved effect is lost. This needs detailed substantiation and consent of the patient. 7. Receptor blocker to IL-6 for treatment of adult RA patients is administered: In case of moderate and high RA activity (as monotherapy or in combination with MT) with patients whose treatment with synthetic DMA and/or TNF blockers is not efficient enough. Tocilizumab may be used as monotherapy with patients who previously did not take synthetic disease modifying antirheumatic drugs (DMARD)/MT or with patients who inadequately respond to DMARD. In case of insufficient efficacy of TNF and IL-6 blockers during 6 months or in case of side-effects, the agent is withdrawn. 8. Blocker of B-lymphocytes (rituximab) for treatment of adult RA patients is administered in combination with MT: In case of moderate and high RA activity when previous treatment with at least one TNF blocker was not efficient enough. Rituximab may be used when it is impossible to use TNF blockers. Repeated infusion of rituximab once in 6 to 12 months are made if M and G immunoglobulin levels are within norm. Monitoring of B cells is not regarded as expedient. 9. Patients with factors of unfavourable	

Provision of protocol	Substantiation	Measures required
	course who, at the moment of decision-taking as to administration of therapy, did not use any DMARD, may be primarily administered combination of MT with TNF blockers or tocilizumab (TOC), or TOC in monotherapy. 10. In case of refractoriness of RA patients towards several synthetic DMARD it is recommended to administer azathioprine, cyclosporine A or cyclophosphamide.	
5. Rehabilitation		
The following patients are subject to the treatment at sanatoriums and health resorts: RA patients including those with RA in combination with secondary deforming OA, RA patients in non-active disease phase (clinically induced or spontaneous remission of disease) if they are able to move independently /to care of themselves. Contra-indications as to treatment at sanatoriums and	Details of treatment at sanatoriums and health resorts: In case of steady arthralgia and slight exudative changes — administration of sanatorium and health resort treatment with radon-containing waters. In case of mainly exudative and proliferative RA symptoms — administration of sanatorium and health resort treatment with sulfur-hydrogen baths. In case of mainly proliferative changes and contractures of joints (X-ray stages II-IV according to the accepted classification) – sanatoriums with mud factors.	**Compulsory:** Patients are to be observed by cardiologist, ophthalmologist, neurologist and other specialists. Prevention of cardiovascular complications. Timely examination defined in p.3 of this Protocol

Provision of protocol	Substantiation	Measures required
health resorts: RA patients with systemic symptoms (joint-visceral form), high stage (II-III) of activity, presence of irreversible affections of joint apparatus (ankylosis), loss of ability to care of themselves		

ADDENDUM 1
ALGORITHM OF RA DIAGNOSIS ESTABLISHMENT

Criteria of 'rheumatoid arthritis' diagnosis (ACR/EULAR, 2010)

Target group (who should be estimated under these criteria?) — patients having:

- clear symptoms of synovitis of at least one joint (swelling)*
- synovitis cannot be better related to another disease†

RA classification criteria (algorithm is based on calculation of the sum of points for categories A–D; to establish the diagnosis 'overt RA' the sum of points ≥6/10 is required)‡

A	Involvement of joints§	
	1 big joint¶	0
	2–10 big joins¶	1
	1–3 small joints (with or without involvement of big ones)#	2
	4–10 small joints (with or without involvement of big ones)	3
	>10 joints (at least 1 is small one)**	5
B	Serologic criteria (the results of at least one analysis are required for classification)††	
	Negative rheumatoid factor (RF) and negative ACCP	0
	Weakly positive RF or weakly positive ACCP	2
	Sharply positive RF or sharply positive ACCP	3
C	Acute phase indicators (the results of at least one analysis are required for	

	classification)‡‡	
	Normal level of CRP and ESR	0
	Increase of CRP or increase of ESR	1
D	Duration of symptoms§§	
	<6 weeks	0
	≥6 weeks	1

*The purpose of the criteria is classification of the patients with whom the disease was detected for the first time. Patients having erosive changes characteristic for RA or relevant anamnesis which would retrospectively meet the criteria ACR/EULAR 2010, should be classified such as have RA.

†Differential diagnosis may be other than among patients with different disease manifestations but may include such diseases as systemic lupus erythematosus, psoriatic arthritis, and gout. In case of doubts as to differential diagnosis, an expert rheumatologist is to be consulted.

‡Although patients with the number points <6/10 cannot be classified such as have RA, their status in due course may be re-estimated and meet diagnostic criteria of RA.

§The 'involvement of joints' means any sore or swollen joint detected during objective examination, which may be confirmed by the symptoms of synovitis from the results of the joint visualization. Distal interphalangeal joints, the first carpometacarpal joints, the first phalangeal joints of hallux are not estimated. Categories of joint involvement are classified according to their quantity and location. A patient is to be classified with the category with highest possible number of points according to the quantity and character of involvement of joints. E.g. if a patient has synovitis of four big and two small joints he is classified with the category '1-3 small joints'.

¶'Big joints' include shoulder, elbow, hip, knee, and ankle joints.

#'Small joints' include finger phalangeal joints, proximal interphalangeal joints, 2–5 phalangeal loints of hallux, interphalangeal joints of the first hand fingers, and wrist joints.

**In this category at least one of the involved joints has to be a small joint. Other joints may include any combinations of small and big joints. For a patient to be included in this category also other joints apply which are not given in the list above.

††'Negative' result corresponds to the value which less than or equal to the upper limit of norm (ULN) of the indicator in this laboratory; 'low positive' result – to the value >ULN, but ≤3 x ULN; 'highly positive' result — to the value >3 x ULN of this laboratory. If the results of RF analysis are estimated only as 'positive' or 'negative', then the 'positive' result of such analysis corresponds to the 'low positive' RF in these classification criteria.

‡‡Normal/increased indicators are defined according to the standards of each specific laboratory.

§§Duration of synovitis symptoms (pain, swelling) is determined from the words of the patient relating to the joints which at the moment of the estimation have clinical indications of involvement, regardless of the treatment status.

Aletaha D., Neogi T., Silman A.J. et al. (2010) 2010 Rheumatoid Arthritis Classification Criteria. Arthritis & Rheumatism, 62(9): 2569–2581.

Addendum 2

A.3.2. ALGORITHM OF RA ACTIVITY DETERMINATION

Disease activity in case of RA is determined using the following clinical indexes: DAS 28 — disease activity index including 28 joints; SDAI — simplified disease activity index; CDAI — clinical disease activity index.

Formulas to calculate the disease activity indexes:

$$DAS\ 28 = 056\sqrt{NSJ} + 0{,}28\sqrt{NSwJ} + 070[ln(ESR)] + 0{,}014GEPH,$$

$$SDAI = NSJ + NSwJ + GEDAP + GEDAD + CRP,$$

$$CDAI = NSJ + NSwJ + GEDAP + GEDAD,$$

Where *NSJ* — number of sore joints (0–28), *NSwJ* — number of swollen joints (0–28), *ESR* — erythrocyte sedimentation rate in mm/min, *GEPH* — general estimate of patient's health assessed using visual analog scale in mm (0–100), *GEDAP* — general estimate of the disease activity by patient assessed using visual analog scale in cm (0–10), *GEDAD* — general estimate of the disease activity by doctor assessed using visual analog scale in cm (0–10), CRP — C-reactive protein content in mg/dl.

Comparative data of above-mentioned indexes

Item	SDAI	CDAI	DAS 28
Number of swollen joints	Simple count 0–28	Simple count 0–28	0,28√NSwJ 0 — 1,48
Number of sore joints	Simple count 0–28	Simple count 0–28	0,56√NSJ (0–28) 0–2,69
Reactants of acute phase	CRP in mg/dL 0,1 — 10	–	0,7[ln (ESR)] 0,49–3,22
General estimate of patient's health	–	–	0,07 visual analog scale in mm 0–1,4
General estimate of disease activity by patient	Visual analog scale in cm 0–10	Visual analog scale in cm 0–10	
General estimate of disease activity by doctor	Visual analog scale in cm 0–10	Visual analog scale in cm 0–10	
Range of index values	0,1—86	0—76,0	0,49—9,07

Disease activity criteria depending on values of indexes DAS 28, CDAI and SDAI

Criteria	SDAI	CDAI	DAS 28
Remission	≤3,3	≤2,8	≤2,4
Low disease activity	≤11	≤10	≤3,6

Criteria	SDAI	CDAI	DAS 28
Moderate disease activity	≤26	≤22	≤5,5
High disease activity	>26	>22	>5,5

Alethaha D., Smolen J. (2005) The Simplified Disease Activity Index (SDAI) and the Clinical Disease Activity Index (CDAI): a review of their usefulness and validity in rheumatoid arthritis. Clin. Exp. Rheumatol., 23(Suppl. 39): S100–S108.

Addendum 3

A.3.3. ALGORITHM OF DIAGNOSTICS OF TUBERCULOSIS

Algorithm of patient management with regard to detection and prevention of tuberculosis in administration and conduct of anti-TNF therapy.

I. Questioning of patients as to symptoms suspicious with regard to tuberculosis.

Indications of tuberculosis (TB) of various localization

TB Localization	TB Indications
TB of lungs	Cough, excretion of saliva, intoxication syndrome (febrile or subfebrile body temperature, loss of body mass, paleness, weakness, loss of appetite), spitting of blood, pain in thorax, pathological changes in lungs on X-ray of thorax
TB of various localization	Intoxication syndrome, symptoms attributable to organs involved in pathological process
Extra-pulmonary TB	
TB of bronchi, trachea, and upper respiratory tract	Intoxication syndrome, cough, excretion of phlegm, excretions from nose, local pathological changes in mucous membrane of these organs when subjected to bronchoscopy or ENT examination
TB of larynx	Intoxication syndrome, cough, excretion of phlegm, husky voice, local pathological changes in mucous membrane of larynx when subjected to bronchoscopy or ENT examination
TB of pectoral lymph nodes	Intoxication syndrome, cough, excretion of phlegm, expanded shadow of lung roots on X-ray of thorax, affection of bronchi when subjected to bronchoscopy
Tubercular pleurisy	Intoxication syndrome, pain in thorax, lack of breath, dry cough, presence of exudate in pleural

TB Localization	TB Indications
	cavity
TB of nervous system and brain-tunic	Intoxication syndrome (from acute to moderate), meningeal syndrome (from acute to moderate), pathological changes in liquor, local disease centre symptoms of brain affection
TB of bones and joints	Intoxication syndrome, local pain in bones and joints, cold abscesses in soft tissues, pathological changes in bones and joints when subjected to X-ray examination
TB of urogenital system	Intoxication syndrome, disuretic syndrome, pathological changes in urine analysis, pathological changes in urinary system organs when subjected to X-ray examination, local pathological changes in mucous membrane of urinary bladder when subjected to cystoscopy
TB of peripheral lymph nodes	Intoxication syndrome, expansion of peripheral lymph nodes, ulcers over expanded peripheral lymph nodes
TB of intestines, peritoneum	Intoxication syndrome (from acute to moderate), diarrheal syndrome, expansion of mesenteric lymph nodes when subjected to USE, syndrome of intestine obstruction
TB of skin	Intoxication syndrome (from acute to moderate), scrofuloderma, lupus erythematosus,
TB of eye	Intoxication syndrome (from acute to moderate), frontal uveitis, peripheral uveitis, chorioretinitis
TB of ear	Intoxication syndrome, excretions from ear, reduction of audition, local pathological changes by ENT examination
TB of adrenal gland	Intoxication syndrome, Addison syndrome, pathological changes in adrenal glands when subjected to X-ray and US examination
Miliary TB	Intoxication syndrome (acute), miliary rash in lungs when subjected to X-ray examination

II. Examination for tuberculosis of lungs and primary diagnostics of tuberculosis of lungs at the facilities of general medical network:

Symptom complexes requiring compulsory examination for tuberculosis

Bronchial and pulmonary symptoms	Intoxication symptoms lasting >2 weeks
Dry cough or cough with excretion of phlegm >2 weeks	Febrile, subfebrile body temperature
Pain in thorax attributed to respiration	Loss of weight, loss of appetite, increased perspiration
Spitting of blood, pulmonary hemorrhage	Weakness

To be conducted in three stages:

1. Gathering of complaints and anamnesis.
2. X-ray examination of thorax organs.
3. Triple examination of phlegm for acid-fast bacteria (AFB).

In case of complaints with suspicion of tuberculosis (*cough for ≥3 weeks, with excretion of phlegm*, which is accompanied by loss of body mass; fatigue; fever; sweating during the night; pain in thorax; loss of appetite; spitting of blood), the patient is administered X-ray/fluorography examination in 2 projections (frontal and lateral). If X-ray/fluorography shows no changes, the patient is administered triple examination of phlegm for AFB. If X-ray and fluorography examination is for some reason unavailable, the patient having symptoms with suspicion of tuberculosis is administered triple examination of phlegm for AFB.

Careful gathering of disease anamnesis is of big importance because tuberculosis features gradual onset. Even in case of acute manifestation of disease (febrile body temperature, spitting of blood, and pulmonary hemorrhage) it is possible to ascertain that several weeks (months) before that manifestation the patient experienced weakness, increased perspiration, reduction of appetite, loss of body mass.

Further it is necessary to establish presence of tuberculosis in anamnesis of the patient or his/her family members and contacts with persons ill with tuberculosis.

Three variants of tactical measures for facilities of general medical network in detection of tuberculosis:

If AFB are detected in at least 1 analysis of phlegm, and X-ray changes are found in the patient's lungs, he is sent to an anti-tuberculosis centre for further examination to confirm the diagnosis of tuberculosis.

In case no AFB are detected in any of the 3 phlegm smears examined, and X-ray shows infiltrative or local disease centre changes in lungs, then test therapy is conducted using antibiotics of wide spectrum for up to 2 weeks. In this case it is not allowed to use agents having anti-tuberculosis activity (streptomycin, kanamycin, amikacin, capreomycin, rifampicin, mikobutin, fluorchinolone group agents). In case of inefficiency of the therapy with antibacterial agents of wide spectrum, the patient has to be sent to an anti-tuberculosis centre for additional examination. If infiltrative changes in lungs are resolved the patient is given the diagnosis of non-hospital pneumonia.

In case no AFB are detected in any of the 3 phlegm smears examined but in lungs X-ray shows dissemination, round shape formation, cavity, expansion of pectoral lymph nodes, pleurisy, the patient has to be sent to an anti-tuberculosis centre for further examination

including instrumental diagnostics for morphological, cytological, and microbiological verification of the diagnosis.

III. Prophylactic X-ray examination.

It is to be performed once a year in case symptoms with suspicion of tuberculosis are absent.

If X-ray shows changes, then the examination is to follow the algorithm described above.

Diagnosis of tuberculosis is established on the basis of the following:

- positive result of microscopy of phlegm smear or material of bioptates (in case changes are detected after X-ray or bronchological examination);
- positive cultural analysis of phlegm or material of bioptates (in case changes are detected after X-ray or bronchological examination);
- positive result of morphological analysis for tuberculosis of bioptates of affected organs or tissues;
- X-ray changes in lungs which are confirmed by inefficacy of antibiotics of wide spectrum, by anamnesis and clinical data;
- data of genetic methods for identification of tuberculosis mycobacterium which are confirmed by X-ray, anamnesis, clinical data.

IV. Examination for extra-pulmonary tuberculosis.

1. Gathering of complaints and anamnesis.

2. X-ray examination of thorax organs.

3. Analysis of biological material from the prognostic localization area of tuberculosis for microscopy of smear (print, bioptate) by Ziehl-Nielsen method for AFB, cultural analysis for tuberculosis mycobacterium, and histological examination.

V. Prophylactics of development of active tuberculosis on the background of anti-TNF therapy.

- Preventive treatment is conducted in case indications of active tuberculosis are absent.
- Isoniazid 0,3 g once a day during 6 months once a year on the background of anti-TNF therapy.

Scheme of monitoring of the patient with suspicion of tuberculosis

Careful gathering of TB anamnesis, physical examination and X-ray examination of thorax organs is required just before the beginning of therapy		
□		□
Changes are present: Consultation with phthisiatrist		No changes: Isoniazid is administered 300 mg a day during 6 months simultaneously with vitamin B_6 100 mg/day on the background of which therapy with TNF blockers is conducted. In case isoniazid is contra-indicated (epilepsy and other diseases accompanied with inclination to convulsions, previously experienced poliomyelitis, disturbance in functions of kidneys and liver, overt atherosclerosis), chemical preventive treatment of tuberculosis is not conducted during the period of therapy with TNF blockers. Decision as to administration of INF for the patients of this category is taken in a consultation held by rheumatologists and phthisiatrists

A.3.4. MORE COMPLICATED THERAPY, prophylactics and treatment

Requirements to the facilities providing primary medical care:

Personnel resources.

Primary medical and sanitary care for RA patients is provided by ambulant and out-patient as well as in-patient facilities of the state health care system, in most cases locally. Primary medical and sanitary care for patients with rheumatic diseases at the ambulant and out-patient facilities is exercised on the basis of interaction of primary health care link doctors: divisional therapeutists, general practice doctors, family doctors, and rheumatologists.

Clinical observation of RA patients by the primary link doctors is possible in case of low level or absence of disease activity and if patient undergoes disease modifying therapy administered by rheumatologist.

Therapeutic care for patients with rheumatic diseases within the system of primary medical and sanitary care is arranged in a district (ambulant clinic, divisional hospital, out-patient clinic, district hospital, central district hospital), in cities (city out-patient clinic, consultation and diagnostic centre, infirmary, city hospital).

A.4.1.2. MATERIAL AND TECHNICAL BASIS

Material and technical basis is formed in accordance with the regulations of the Health Care Ministry of Ukraine relevant to conditions of activities of the primary link doctors.

Requirements for the facilities providing secondary medical care:

Personnel resources

Specialized rheumatologic care is arranged in the health care facilities of Ukraine (region hospital, city hospital, hospital with an appropriate specialized rheumatologic department, rheumatologic centre).

On the secondary level medical care for RA patients is given in out- or in-patient conditions by the rheumatologists who passed specialization in rheumatology in the volume specified by law, in accordance with the following regulations: Health Care Ministry order of 12.10.2006 № 676, Health Care Ministry orders of 15.12.1993 № 243, and of 05.12.1991 № 173 as well as recommendations of the Assoiciation of rheumatologists of Ukraine. BA therapy may be conducted both in in-patient conditions and on the basis of the rooms of biological therapy. When necessary doctors of other specializations may be involved.

Material and technical basis

Rheumatologic department is a structural subdivision of a multi-profile hospital.

In ambulant and out-patient clinic rheumatologist's room is arranged in accordance with the current staff-related regulations.

The rheumatologic department is to be equipped with the following:

- manipulation room and room for intraarticular manipulations to be equipped under the principle of a 'minor operating room';
- ward (beds) and equipment for intensive therapy.

Rheumatologic room should have in its disposal a room for consultative reception of patients, conduct of treatment and diagnostic procedures (sampling of biological liquids/blood, urine, articular liquid/for subsequent analysis, intraarticular manipulations, etc.)

Equipment of the treatment room for intraarticular manipulations at an out-patient clinic or rheumatologic department.

Separate premises meeting aseptic parameters, with clean dressing room, and pre-treatment room (for patients to change their clothes).

Item No.	Description of equipment and tools	Min. quantity required
1.	Bactericidal lamp	1
2.	Table (couch) 75–85 cm high (for manipulations with lower limbs of the patient)	1
3.	Stepladder to the table (for patient)	1
4.	Small table (for manipulations with upper limbs of the patient)	1
5.	Chair for the patient	1
6.	Small table for steam sterilizer with sterile material	1
7.	Cabinet with first-aid kit	1
8.	Cabinet for medical agents, tools, etc.: sterile (single-use) syringes 2; 5 and 20 ml with needles 0,5–16 and 0,8–40 mm, atraumatic single-use needles with diameter 1,2–2,0 mm, rubber gloves, bactericidal plaster	1
9.	Stand with test-tube for synovial liquid	1
10.	Vessel for discharge of synovial liquid	1
11.	Oilcloth cushions (to put under limbs) (15x30 cm, 25x40 cm)	2 per size
12.	Kit of medical agents: - bottles with 70–90% alcohol, iodine solution - ampoules with physiological solution and anesthetics (2% lidocaine 0,5% novocaine) - bottles (ampoules) with medical agents (diprospan, depo medrol, metipred, flosteron, hydrocortisone-acetate, etc.)	1

Instrumentation equipment

Electrocardiograph
Echocardiograph
Capillaroscope
X-ray apparatus
Ultrasonic apparatus
Arthroscope
Laboratory equipment
Blood pressure meter
Infusomat

Equipment for qualified emergency care
Computerized tomograph (magnetic resonance tomograph)

DRAFT OF A STANDARDIZED CLINICAL PROTOCOL OF MEDICAL CARE FOR PATIENTS WITH RHEUMANOID ARTHRITIS

The draft is compiled by: V.N.Kovalenko, N.M.Shuba, O.P.Bortkevich, E.A.Garmish

Abstract. Pursuant the need to update the existing recommendations, this paper presents a draft of the Protocol of medical care for the patients with rheumatoid arthritis in accordance with the current regulations of the Health Care Ministry of Ukraine.

Keywords: rheumatoid arthritis, protocol of medical care.

PROJECT OF COMPATIBLE CLINICAL PROTOCOL OF MEDICAL CARE TO THE PATIENTS WITH RHEUMATOID ARTHRITIS

The project prepared by: V.M. Kovalenko, N.M. Shuba, O.P. Bortkevych, O.O. Garmish

Summary. Because of the necessity to update the existent recommendations, there is performed the Project of Protocol of medical care providing to rheumatoid arthritis' patients in concordance with the new requirements of Ministry of Health of Ukraine.

Key words: rheumatoid arthritis, protocol of medical care providing.

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