Original Articles

DOI 10.18019/1028-4427-2019-25-2-140-148

Organizational issues in management of patients with chronic osteomyelitis and the solutions offered by osteology infection clinic

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Objective To search organizational solutions for improving quality of care for patients with chronic osteomyelitis (COM) based on many years' experience of osteology infection clinic of the FBGI Russian Ilizarov Scientific Center "Restorative Traumatology and Orthopaedics". **Material and methods** 10 124 patients who received treatment for COM at the osteology infection clinic between 2011 and 2018 were enrolled in the study and causes of the condition identified. A staged organizational and functional model of specialized medical care was offered to launch osteology infection clinic with structural units, facilitate processing of the hospital database information and develop clinically based system for assessing quality of care. **Results** Review of the findings suggests that both medical and socioeconomic implications are involved in the treatment of COM and support needs to be considered for the patients. **Conclusion** Organizational and technological aspects are essential for management of patients with COM.

Keywords: chronic osteomyelitis, controlled Ilizarov external fixation, osteology infection clinic, organizational and functional model

Chronic osteomyelitis (COM) is a common and severe infectious suppurative disease in Russia[1] and abroad [1, 2]. COM is a multifactorial condition that requires organizational and technological solutions and multidisciplinary approach to facilitate complex specialized treatment.

The incidence of COM is increasing because of the prevalence of high impact injuries and inadequate or inappropriate bone fixation with IM nails, plates and implants [3–5]. The question of creating a barrier between implanted material and pathogenic microorganism has remained a keystone of fundamental and applied principles of surgery [6]. The treatment concepts of COM remain complex due to changes in the spectrum of pathogenic microorganisms and enhanced resistance to antimicrobial therapy including agents of recent generations. Continuous massive application of antimicrobial agents results in disturbed immune status, adverse events in vital organs and systems [6–8]. The current approach to treatment of patients with COM established in the Russian Federation includes two-stage spectrum of actions aimed at eradication of suppurative infectious process first to be followed by elimination of sequelae and orthopaedic reconstruction. Most of COM cases are treated in non-specialized hospitals [8].

COM is presented in a rather complicated and ambivalent manner in the insurance medicine from organizational point of view on the health care system. It happens for the reasons as follows:

– statistical data on suppurative infectious complications following musculoskeletal surgical procedures are falsified due to fear of economic and legal sanctions. The topic of infection after implantation is unlikely to be popular among administrators of any level and often kept silent;

– an adequate care is difficult to budget through standard coverage per case because development of infection is primarily deemed as a non-standard course of postoperative period and can involve different types of expenditures and length of hospital stay;

– COM patients are economically irrational with free market of medical services and being filtered off with the majority of hospitals under objective, readily formalized reasons;

[1] Federal Clinical Guidelines "Acute hematogenous osteomyelitis in children". Russian Association of Pediatric Surgeons. Voronezh, 2015.

Gubin A.V., Kliushin N.M. Organizational issues in management of patients with chronic osteomyelitis and the solutions offered by osteology infection clinic. *Genij Ortopedii*, 2019, T. 25, No 2, pp. 140-148. DOI 10.18019/1028-4427-2019-25-2-140-148. (In Russian)

– projects for thorough coverage of treatment of several types of infection were initiated in well-financed regions that showed more realistic statistical data. Labor COM related costs are difficult to calculate in a systemic manner with the regions due to a diversity of clinical patterns.

A unique 50 year practical experience and the world's largest population (more than 20 000 patients) successfully treated at the Kurgan Ilizarov Center for COM allowed for developing our own organizational and technological approach to the solution of the condition. A specialized osteology infection clinic (OIC) was initiated at the Russian Ilizarov Scientific Center "Restorative Traumatology and Orthopaedics" (RISC "RTO") in 2011 to improve outcomes, reduce treatment length and total permanent disability rating. The OIC and has been fully functioning since 2016.

The purpose of the work was to analyze results of medical care rendered to patients with COM at the specialized OIC.

ORGANIZATIONAL TASKS

Organizational and functional model of specialized and high-technology medical care was offered for patients with COM treated at the OIC. The model included: a) the system of structural organization of OIC with database information from clinical departments; b) the system of quality medical care delivery.

1. The system of structural organization of OIC with database information from clinical departments

Experience of specialized OIC and clinical departments in treatment of patients with COM between 2011 and 2018 was reviewed.

Several items have been formulated to minimize professional risks and achieve optimal conditions for clinic functioning:

– **structure** (structural organization facilitates infection control to prevent the spread of infection. Cross colonization is ruled out for the patient all along the way from an isolated admission unit to a specialized clinical department and then to a ward with identified nosology and type of infection and finally to a modern operating room constructed with clean air technology) (**Fig. 1**);

– **location** (OIC occupies a separate building housing three clinical departments, scientific and clinical laboratories isolated from infection free units);

– **specialized clinical departments** (according to a type of orthopaedic and trauma pathology: periprosthetic joint infection is treated at department № 1, spinal infection at department № 2 and posttraumatic and hematogenous osteomyelitis at department № 3);

– **fundamentals** (Ilizarov effect[2], integrated and radical approach, technological consistency engaging specialists of "clean" departments, employing combined techniques);

[2] G.A. General biological capability of tissues respond to gradual stretching by growth and regeneration (Ilizarov Effect): Diploma OT 355 (USSR). № 11271. Applied 25.12.85. Published 23.04.1989. Bulletin «Discoveries. Inventions». 1989; 15 : 1. (Priority dtd 24.09.1970)

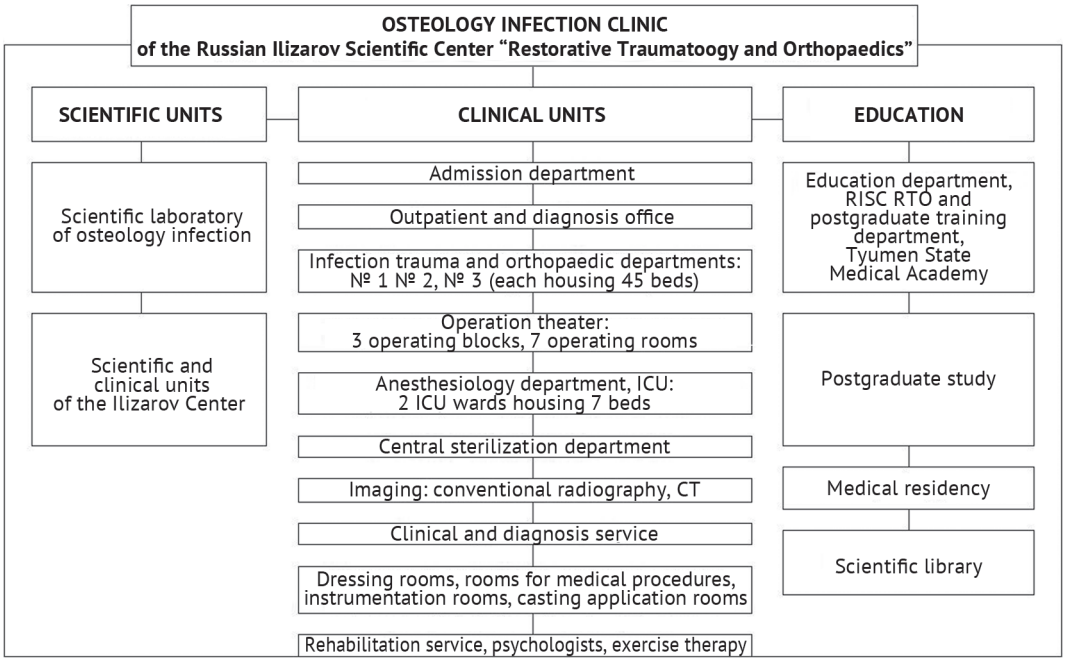

Fig. 1 Structure of osteology infection clinic

– **scope** (any localization, any phase of inflammation process including acute infection, enhanced volume of surgical intervention with maintained quality of treatment);

– **personnel strategy** (highly qualified and experienced personnel including paramedical staff; combined research and clinical practice; educational activities).

TREATMENT OF PATIENTS

Total 10 124 patients with COM were treated at OIC between 2011 and 2018 with average 1 265 patients per year (**Fig. 2**).

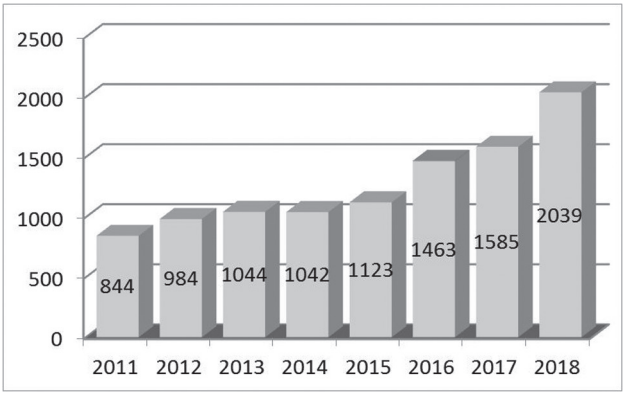

Fig. 2 Patients treated at OIC between 2011 and 2018

It should be noted that 9 142 (90.3 %) patients sought medical care at OIC due to failures of previous treatments performed at different hospitals of the country. **Figure 3** shows distribution of patients coming from different Federal Districts of the Russian Federation.

3 796 (37.5 %) patients underwent 3 to 5 different surgical interventions and over prior to admission to OIC (Table 1).

Table 1

Operative interventions that patients had prior to admission to OIC

Type of surgical intervention	%
Sequester- and necrectomy	69.1 %
Incision and drainage of abscess	15.2 %
Muscle and skin plasty	0.7 %
Bone and autologous grafting	0.3 %

All patients had singular (46.6 %) and multiple (36.1 %) sinuses or wounds with purulent discharge (17.3 %) on admission. Treatment was aggravated by comorbidities (**Fig. 4**).

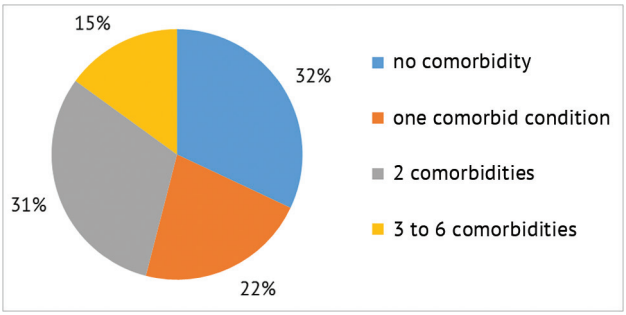

Fig. 4 Comorbidities of patients treated for COM between 2011 and 2018

Fig. 3 Distribution of patients by Federal Districts of the Russian Federation

The increasing burden of comorbidities is seen in patients in recent years (Table 2).

Table 2

Comorbidities detected in patients who were admitted to OIC in 2018

Comorbidity	Number of cases	%
Cardiovascular impairment	1077	51.85
Pulmonary disease	873	42
Viral hepatitis	298	14.35
Diabetes mellitus	169	8.3
Connective tissue disease	173	9
HIV	32	1.6
All patients suffering from traumatic spinal cord injury had chronic diseases of the genitourinary system	–	100

Chronic osteomyelitis of all limb segments is treated at OIC including conditions combined with different orthopaedic and trauma pathologies, osteomyelitis of pelvis and spine [7]. The number of patients with periprosthetic joint infection grows year on year and currently accepted technology and the Ilizarov method are used to address the condition [5]. Patients of the Ilizarov Center developing infection in 'clean' departments are early transferred to OIC for timely and effective treatment.

Despite severity of the pathology and comorbidities high-level surgical activity persisted throughout formative years (**Fig. 5**). With increasing rate of surgical activity the inpatient length was noted to decrease (**Fig. 6**).

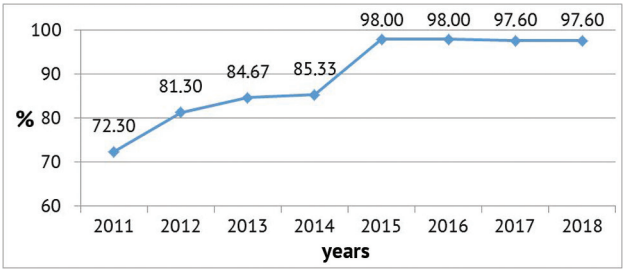

Fig. 5 Surgical activity in OIC

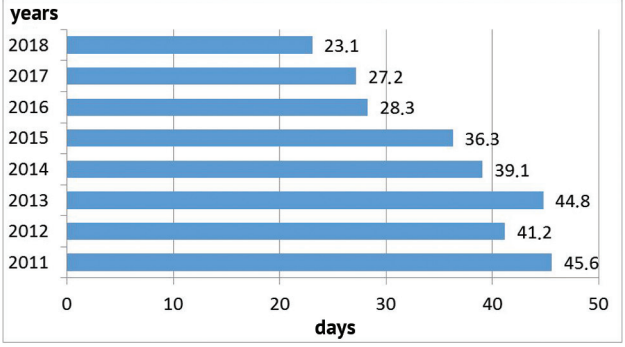

Fig. 6 Average length of inpatient treatment between 2011 and 2018

Improved and maintained performance of specialized inpatient facility can be ascribed to structural, diagnostic and technological possibilities of OIC, consistency of treatment phases provided by structural units of the Center and OIC from admission to complete rehabilitation. The Center ensures a closed cycle of treatment process facilitating the consistency irrespective of a unit where the patient commences the treatment. A variety of diagnostic modalities are available for the confirmation of infection, during the preoperative workup and at stages of restorative treatment [10, 11, 12, 13, 14]. Computed tomography, plain radiography with and without contrast to identify sinus tracts are employed at OIC. High-resolution multislice computed tomography helps to show morphological characteristics of a study area in patients with COM and accurate detection of pattern and volume of the involved bone and surrounding soft tissues to develop optimal surgical strategy [15]. Antibiotic resistance testing is essential for microbiological culture analysis in addition to microflora identification and antimicrobial susceptibility testing. A role of bacterial biofilms in maintaining and functioning of osteomyelitic nidus is investigated together with morphologists [12]. Immunological tests allow for assessment of antigenic homeostasis. Serum lysozyme's levels, cell-mediated and antibody-mediated immune responses are most informative. The results of the tests are evaluated in dynamics: on admission, postoperatively, at stages of restorative treatment with transosseous osteosynthesis technique (compression, distraction, fixation) and after frame removal. The use of immunological parameters in clinical practice allow prognosis of reparation in patients with COM, determination of treatment strategy aimed at timely eradication of inflammatory process [13]. Pathomorphological tests allow grading of inflammatory process and quality control of surgical debridement. Biochemical methods allow assessment of changes in internal environment: extent of disturbed homeostasis and dynamics in adaptation process following skeletal intervention [11]. Evaluation of reparative capabilities using parameters of metabolic status is helpful in identifying an optimal treatment option for patients with COM.

2. System of quality medical care

The system of quality medical care includes supply, control and assessment of quality corresponding to patient's needs and modern level of diagnosis, treatment, rehabilitation and prophylaxis of diseases [16]. Accomplishing the Ilizarov Center's mission of 'providing patient's transition to a higher quality level of support and motion with surgery' we set core values on delivery of quality health services:

– **conditions of treatment**: creating comfortable conditions for the patient at OIC with brand new system of clean room technology. Patients share rooms with regard to the same-type pathogen identified. Friendly, trustworthy environment, and highly qualified medical staff are important for COM patients to facilitate inpatient adaptation and growing confidence in recovery;

– **adequate, accessible and safe treatment**: new treatment technology based on Ilizarov Effect and many years' experience of COM treatment is applied at OIC providing high rate of successful results, safety of medical manipulations and is being accessible for all patients including most severe cases;

– **access to timely medical care**: the importance of appropriate and timely care cannot be understated for COM patients. By delaying medical care, the patient makes it more difficult due to involvement of vital organs and systems;

– **individual approach to the patient**: localization of purulent nidus, extent of involved bone and soft tissues, type of infection are identified for every clinical case. Attending physician reviews important medical information of the patient, lab results and imaging reports and gets opinions from colleagues to determine optimal treatment strategy;

– **psychological status of the patient**: a staged psychotherapeutic model aimed at improvement of psychopathological reactions caused by surgical intervention was offered at OIC departments to provide constructive conflict management strategies [17] (Table 4).

As shown in Table 4, the findings reflect the efficacy of psychotherapeutic program developed for COM patients and it can be advocated for therapeutic and rehabilitation practice to be integrated in specialized orthopaedic and trauma inpatient unit.

– **succession and consistency**: program of successive management, prophylactic medical examination and phasing of treatment was introduced into clinical practice of OIC with regard to patients' age and severity of condition. Appropriate treatment can be provided for patients at any age, from a very young to a very old age [18];

– **patient satisfaction with treatment** is an overall correlation between efforts of OIC medical staff and expectations of the patient from the treatment delivered. Patient satisfaction is evaluated with questionnaires, and their comments and wishes are always recognized.

– **continuous improvement of treatment technology**: the importance of teamwork and effective collaboration between orthopaedic surgeons and researchers is vital to successful application of technology in treatment of patients with COM.

Quality Management System has been introduced and maintained at OIC and the RISC "RTO". Documentation plays a critical role as part of Quality System. Guidelines for Inpatient Medical Records in RISC "RTO" have been developed and approved by CEO's Order № 32 dtd 08.02.2013. Unified statistical reports are submitted by heads of the units showing leading departments. Quality of medical care is evaluated at OIC departments once a month to comply with relevant state of documentation requirements in relation to clinical information, diagnoses and medical procedures. The criteria are formulated according to severity of the disease based on standards and protocols of treatment. **Figure 7** presents diagram of quality medical care providing to patients at OIC. External audit is employed to demonstrate compliance with external criteria. Supervision of medical care is crucial to ensure compliance with high-quality standards of care, clinical effectiveness, patient satisfaction, overall quality of services, correct diagnosis and adequate treatment.

In Quality Management System, our teams use mutually reinforcing techniques in a cycle of planning, implementing, evaluating, and revising to improve the quality of clinical and administrative processes.

Table 4

Evaluation of efficacy of psychotherapeutic assistance to COM patients (n = 241) [17]

Clinical types of mental disorders	"Complete" recovery		"Practical" recovery		"Incomplete" recovery	
	abs.	%	abs.	%	abs.	%
Adjustment disorder	83	84.69	15	15.31	–	–
Neuroses, among them:	44	58.67	31	41.33	–	–
emotional exhaustion	28	37.33	17	22.67	–	–
obsessive-compulsive disorder	8	10.67	7	9.33	–	–
hysteric neurosis	8	10.67	7	9.33	–	–
Neuroticism	20	48.78	14	34.15	7	17.07
Personality disorder	11	40.74	8	29.63	8	29.63

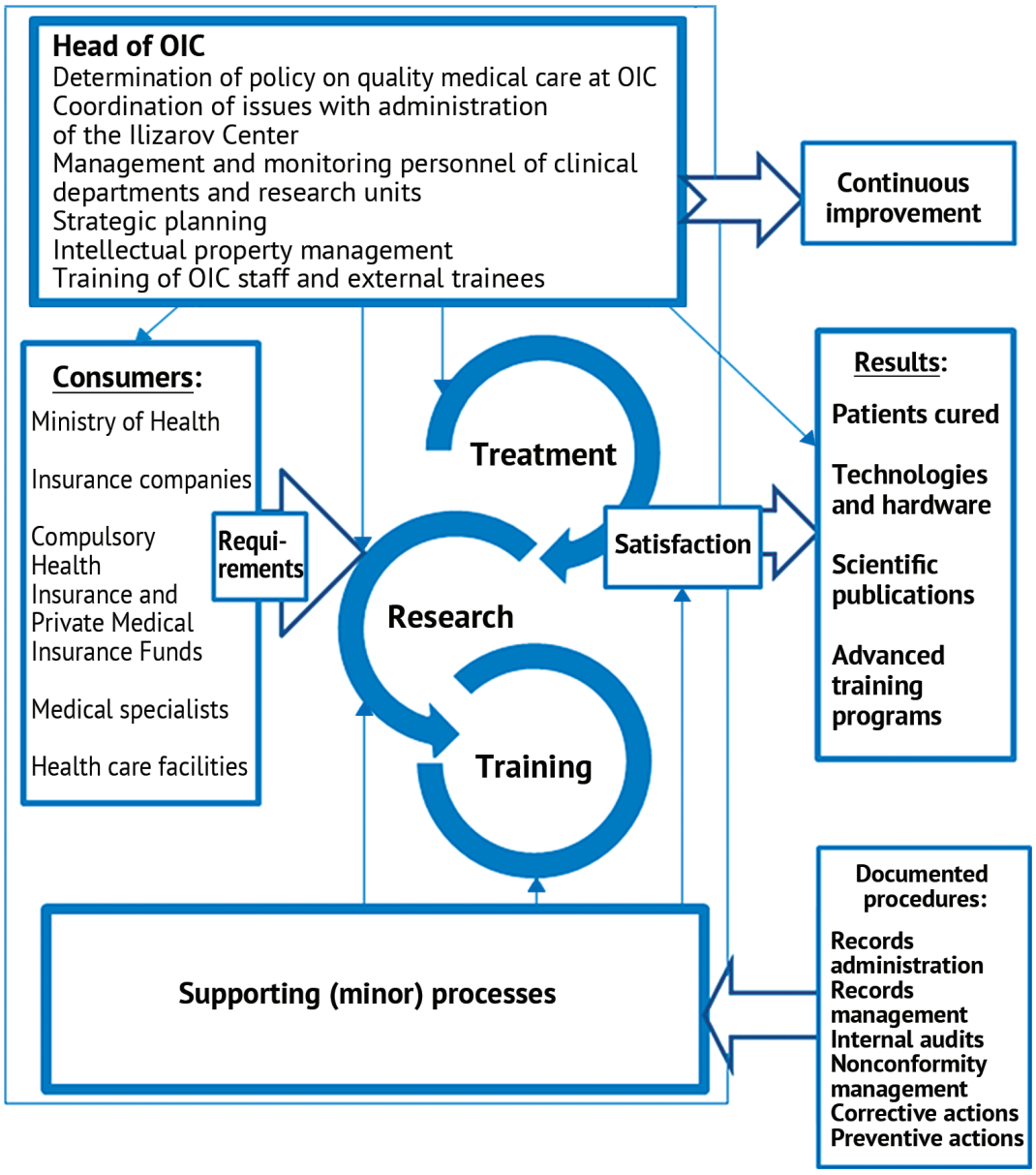

Fig. 7 Diagram of organizational and functional system of quality medical care

EDUCATIONAL ACTVITIES

Educational activities of the staff of OIC are well known far beyond Russia. The staff of the clinic largely contributes to the success of training programs they develop in cooperation with the Center's education department. They share the exceptional expertise and experience in Ilizarov treatment of challenging cases through surgical assistance, case presentations and interactive

discussions, pre- and postoperative discussions, lectures and hands-on workshops. The faculty offers Advanced Bone Infection Programs to provide a broad range of clinical experience and hospital practices, special training and knowledge to orthopaedic specialists.

DISCUSSION

Review of literature and experience of OIC show that COM having a multifactorial origin is a considerable healthcare burden. Creation of hygiene and sanitary conditions is important for diagnosis and treatment providing quality medical care for patients with purulent complications of musculoskeletal pathologies. Construction of separate health facilities for treatment of purulent diseases of locomotor system was not warranted by the Russian healthcare system prior to establishment of OIC in Kurgan. These patients are normally treated in regional and municipal general hospitals, specialized infection surgical and trauma departments located in the neighborhood of 'clean' wards with a high risk of nosocomial infection. However, observations and experimentations presented at the 10th meeting of All-Russian Society of Epidemiologists, Microbiologists and Parasitologists on Provision of Epidemiological Welfare for the Russian Population (2012), international meetings on nosocomial infection (2003, 2010) led many experts to incriminate patient related and environmental factors as major sources of infection. Infectious diseases are commonly transmitted through direct person-to-person contact. The practice of aseptic technique is an infection prevention method that is recognized as an important factor in the prevention and transmission of healthcare associated infections. Aseptic technique improves patient safety intraoperatively and postoperatively preventing or reducing the risk of prolonged length of stay, polyfocal osteomyelitis that would require several operative interventions. High prevalence of nosocomial infection is seen in patients with HIV infection, hepatitis B virus, hepatitis C virus infections and comorbidities. However, the incidence of hospital-acquired infection recorded in Russia is low due to absence of clearly defined diagnostic criteria, barriers to compliance and poor design of facilities, supply and exhaust ventilation in clinical departments, required quantity of surgical blocks, sterilization units, dressing rooms, etc.

Medical care for population (nearly 50 %) in the rural areas and small towns can be often insufficient and inappropriate. High rate of poor outcomes of COM is caused by inadequate equipment, scarce experience of the staff at municipal healthcare facilities and also by ineffective organization of health care delivery to the cohort of patients, adverse selection and referral practices of local and regional governments employing high-technology services of regional and federal specialized hospitals [6, 19, 20]. The system accepted in the Russian Federation to treat patients with COM includes two staged management and is aimed at eradication of suppurative inflammatory process followed by elimination of the sequelae. The treatment option can last for years and result in disappointing outcomes for the patient and the government.

Technology developed at OIC to address COM is completely different from conventional methods and based on controlled transosseous osteosynthesis with the Ilizarov fixator providing 97.6 % of successful results regardless of an extent of pathological process and age of the disease. The practice addresses both orthopaedic reconstruction of the involved segment and eradication of suppurative infection at one stage avoiding high doses of antibiotics. For good reason, foreign orthopaedic surgeons have a particular interest in our technology (the Ilizarov method is applied in 96 countries) that has been shown to be highly successful in limb salvage [7, 10, 21, 22].

CONCLUSION

1. Treatment of COM is a serious challenge for health care system. The rising number of joint-replacement procedures, spine instrumentation, population aging and somatic preoccupation, the threat of antimicrobial resistance can be expected to cause a rise in the incidence of infections.

2. The scenario requires organizational and technological approach to the solution of the disease.

3. Evidence from Russian specialized centers with the focus on COM cases is essential for COM statistics rather than that of standard reports.

4. Quality Management System is useful for objective assessment of medical care provided to patients with COM.

5. Specialized centers (departments) can be established to address COM in hospitals with high surgical activity and extensive experience with a diversity of musculoskeletal conditions treated using different techniques including considerable expertise in controlled transosseous osteosynthesis with the Ilizarov fixator.

6. Emergency medical care (incision and drainage of suppurative foci, antibacterial and symptomatic therapy) must be provided in acute conditions at non-specialized trauma and orthopaedic departments. Infected cases in remission with the need of orthopaedic reconstruction are to be treated at specialized infection units.

7. Specialized infection departments can be practical for the hospitals with massive usage of orthopaedic implants (centers and institutes of orthopaedic, trauma and joint replacement surgery) to provide timely and appropriate care recruiting specialists who performed previous treatments. The approach will facilitate technological succession and clearly identified motivation for the institution and specialists.

8. Government funded programs are needed for subsidizing diagnosis, treatment and rehabilitation as well as integrated multicenter multidisciplinary research on COM.

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Received: 11.02.2019

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