

## Organization of medical equipment service in the region

*This paper presents the results of the research of medical equipment servicing in the region based on the survey by questionnaire of the head doctors and service organizations managers in the Vologda Oblast. Due to the fact that regional medical institutions haven't their own technical services, the author has analyzed the key indicators of the institutions' development registered in the Vologda Oblast and engaged in the service of medical equipment. The author has identified the factors constraining the development of regional infrastructure of the medical equipment service as well as he has identified the areas of the public authorities' activity to ensure the effective work of medical equipment under the limited finance conditions.*

*Public health, service, region, medical equipment, service organization, engineering service, health-care agency.*



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Community health is an important condition for social and economic progress of the region and it depends on many factors. One of the main factors is health care. This sector is aimed to ensure the preservation and improvement of health by force of highly skilled therapeutic and prophylactic mutuality which is currently impossible without the use of modern types of medical equipment<sup>1</sup>. Health-care agencies commonly use complex high-tech medical equipment to heighten the

interest both to the sphere of production and to the field of maintenance (service)<sup>2</sup>. In this aspect, there are such important questions as ensuring of equipment operation and safe application of the worn and outdated medical equipment which is exploited by many Russian medical institutions.

In 2009 the Roszdravnadzor officers checked the use of diagnostic equipment purchased by more than 1550 health-care agencies within the framework of the national

<sup>1</sup> Medical equipment includes the following medical products: instruments, apparatus, equipment, facilities, installations, kits, systems with software tools, devices, mechanical and other tools designed for individual or compatible medical application and which should be provided with maintaining production service according to the maintenance documentation (Maintenance of medical equipment: guidelines: approved by the letter of The Department of State Control over Drugs and Medical Equipment of the Ministry of Health of the Russian Federation, 27.10.03 № 293-22/233).

<sup>2</sup> Maintenance of the medical equipment (ongoing and planned) includes identifying and preventing of medical equipment failure by force of timely completion of works to ensure their functionality during the planning period (OST 42-21-9-80 "The system of maintenance and repair of medical equipment. Basic provisions").

project “Health” [3]. The audit showed that 660 health-care agencies (43% of the total audited institutions) didn’t use that medical equipment. 1197 incidents of idle medical equipment were registered. The reasons were the following: medical staff wasn’t trained to use the medical equipment in 443 cases (37% of the total number of registered downtimes); there were no consumables for medical equipment in 156 cases (13% of the total number of registered downtimes); the equipment was broken during three months and more in 300 cases (25% of the total number of registered downtimes). Moreover, 94 medioprofilactic institutions (6% of the total number of audited organizations) couldn’t organize the out-of-warranty maintenance of their medical equipment. Thus, today the population of medical equipment is not used in corpore because of ill-timed medical equipment service.

We analyzed the logistical support of diagnostic and treatment process in the health-care agencies of the Vologda Oblast in 2009 [4]. According to the statistics those medical institutions<sup>3</sup> exploited 67759 units of medical equipment in 2008.

Municipal hospitals were well provided for the domestic medical equipment and regional hospitals were well provided for import medical equipment. More than half of medical equipment had 100% of physical depreciation and obsolescence. It clearly reflects degree of inadequate approaches to the financial support of the health system and malfunctioning of hospital equipment system based on these approaches[5]. Extremely high level of ageing of medical equipment which is forced to use by health workers leads to a number of serious negative effects and reduces the final efficiency of the health system [5].

<sup>3</sup> The survey involved 40 head doctors from the health-care agencies (including 9 regional, 5 municipal and 26 district hospitals); it is 68% of the total number of heads of medical institutions.

The supplies of expensive laboratory and diagnostic medical equipment are prevalent in the structure of medical equipment in the health-care agencies of the Vologda Oblast. Therapeutic, surgical and sterilizing instruments are purchased to a lesser extent. The medical equipment of regional health-care agencies is operated by 91 – 96% because only part of medical equipment is in working condition. The share of operated medical devices can be increased by timely and quality technical service and training of medical personnel in proper use of new medical equipment. For example, according to the monitoring of failures and malfunctions of medical devices, which was carried out by the State health-care agency “Vologda Regional Hospital № 1”, medical equipment downtime was caused by medical personnel’s mistakes (60%), faulty maintenance (25%) and factory defects (5%).

The system of regional state-owned enterprises “Medical Equipment” had been operated until 1992 in Russia. Those enterprises maintained the centralized deliveries of new medical equipment in accordance with the health-care agencies’ applications. They also serviced the equipment. However, the volume of the planned budgetary funds allocated for the purchase of medical equipment later and services reduced and effective functioning of this system was breached.

As a result the system of regional state enterprises has ended and maintenance of medical equipment in the health-care agencies in out-of-warranty period is realized on the basis of a contract with a licensed contractor or by own technical service. Nowadays 94% of medical equipment in the Russian health-care agencies on average is serviced by the service organizations and 6% of equipment is served by the engineering and technical services of the medical institutions and service subdivisions of the companies which produce the medical equipment [6].

Table 1. Comparison of forms of medical equipment service

|               | Service organization  | Technical service of the medical institution  |
|---------------|---|---|
| Advantages    | <ol style="list-style-type: none"> <li>1. Competitive environment allows to choose cheaper services</li> <li>2. Independent solution of human, technical and logistical issues, responsibility for harm to patients and medical staff by malfunction of medical equipment.</li> <li>3. Service organization's staff training is held in the field required by the regional health-care agency.</li> </ol> | <ol style="list-style-type: none"> <li>1. Training of engineering staff is held on the base of certain medical equipment that is operated in this health-care agency.</li> <li>2. High reliability and quality of the duties reduce the cost of work performed.</li> </ol>                    |
| Disadvantages | <ol style="list-style-type: none"> <li>1. High-cost services at the expense of the upkeep of the management contractor apparatus.</li> <li>2. Unreasonably high service prices owing to the monopoly position of the contractor (in the case of complex medical equipment).</li> </ol>  | <ol style="list-style-type: none"> <li>1. The service of all the operated medical equipment is impossible (in the major medical institution).</li> <li>2. Sometimes the use of repair resources is insufficient.</li> <li>3. The costs of technical service organization are high.</li> </ol> |

The main advantages and disadvantages of the medical equipment service [7] are presented in *table 1*.

The main condition for the service of medical equipment is acquisition of license by a service organization in the Office of Licensing and Legal Service of the Federal Service on Surveillance in Healthcare and Social Development. The licenses are issued by Roszdravnadzor to service 23 types of medical equipment. A service organization must obtain a license to maintain the medical equipment (duration – 5 years) and a health-care agency must obtain a medical license to confirm the competence of technical service).

According to the Federal Law № 128-FL of 08.08.2001 “On licensing of certain types of activity” [9], licensing authorities form the open and generally accessible government information resources that contain the information from the register of licenses. Information from the site of Roszdravnadzor ([www.roszdravnadzor.ru](http://www.roszdravnadzor.ru)) allows us to make a list of the registered in the Vologda Oblast organizations that maintain the medical equipment. They are CJSC PF “Vologdamedtehnika” (Vologda), CJSC “Medprombyt” (Cherepovets), LLC “Vologda. Medicine.Service” (Vologda), LLC “Delrus-B” (Vologda), LLC “Medtehnika 35” (Vologda), LLC “TD “MedGasService” (Kaduy), LLC

“ECO Group” (Vologda), LLC “Antey-Pharma” (Vologda), LLC “Medpharma-Vologda” (Vologda).

The results of the head doctors survey which was carried out in the state health-care agencies in the Vologda Oblast in 2011 show that service of medical equipment is implemented generally by the regional service organizations both during the warranty and post-warranty periods. The medical institutions haven't their own technical services (*tab. 2*).

CJSC PF “Vologdamedtehnika” was retaining leadership from 2007 till 2010. But at the same time the number of the organizations served by that company decreased by 15%. The other regional service organizations increased the volume of medical equipment services. It is evidence of the competitive environment's development in the regional market. As a result, a medical institution can choose the most optimal conditions to maintain the medical equipment.

The regional service organizations are able to service the medium- complex medical equipment. It is necessary to conclude the contracts with authorized distributors of such producers as LLC “SpektrAp”, LLC “GM and Helskea”, CJSC “TKF MONO-M”, etc. to maintain the complex systems. These contracts lead to considerable expenses.

Table 2. Maintenance of the medical equipment in the health-care agencies in the Vologda Oblast in 2007 – 2010, per unit

| Service organization                       | Number of the health-care agencies which are served |      |      |           | 2010 as compared with 2007, in % |
|--|---|------|------|-----------|----------------------------------|
|  | 2007  | 2008 | 2009 | 2010      |                                  |
| <i>Warranty maintenance (service)</i>      |   |      |      |           |                                  |
| CJSC PF "Vologdamedtehnika"                | 27  | 26   | 24   | <b>23</b> | 85                               |
| LLC "Delrus-B"                             | 15  | 16   | 15   | <b>16</b> | 107                              |
| LLC "Medpharma-Vologda"                    | 1   | 3    | 6    | <b>6</b>  | By 6 times                       |
| LLC "Medtehnika 35"                        | 3   | 4    | 6    | <b>4</b>  | 133                              |
| LLC "ECO Group"                            | 3   | 4    | 4    | <b>3</b>  | 100                              |
| LLC "Vologda. Medicine. Service"           | 0   | 0    | 0    | <b>1</b>  | –                                |
| LLC "TD "MedGasService"                    | 0   | 1    | 1    | <b>0</b>  | –                                |
| CJSC "Medprombyt"                          | 0   | 0    | 1    | <b>0</b>  | –                                |
| LLC "Antey-Pharma"                         | 0   | 0    | 0    | <b>0</b>  | –                                |
| <i>Post-warranty maintenance (service)</i> |   |      |      |           |                                  |
| CJSC PF "Vologdamedtehnika"                | 26  | 26   | 23   | <b>22</b> | 85                               |
| LLC "Delrus-B"                             | 8   | 8    | 12   | <b>14</b> | 175                              |
| LLC "Medtehnika 35"                        | 1   | 2    | 3    | <b>4</b>  | By 4 times                       |
| LLC "Medpharma-Vologda"                    | 1   | 1    | 2    | <b>3</b>  | By 3 times                       |
| LLC "ECO Group"                            | 2   | 2    | 3    | <b>2</b>  | 100                              |
| CJSC "Medprombyt"                          | 2   | 2    | 1    | <b>1</b>  | 50                               |
| LLC "Vologda. Medicine. Service"           | 0   | 0    | 0    | <b>1</b>  | –                                |
| LLC "TD "MedGasService"                    | 0   | 1    | 1    | <b>0</b>  | –                                |
| LLC "Antey-Pharma"                         | 0   | 0    | 0    | <b>0</b>  | –                                |

The public opinion poll of the leaders of these organizations<sup>4</sup> has been conducted in 2011. It is aimed to identify the existing problems in the maintenance of medical equipment and find the areas for further development.

According to the statute of licensing [10], specialized service enterprises can service the medical equipment when the right to maintenance is received from the producer. This requirement allows the service organization to receive the service documentation, spares and consumables from the producer or his authorized representative. Only two organizations are the authorized distributors of the producers. They are CJSC PF "Vologdamedtehnika" (CJSC "AMIKO", NIPK "Electron", Chirana Co., Dr ger Co., CJSC "Rentgenprom", CJSC "DIACON", etc.) and LLC "Medpharma" –

<sup>4</sup> The leaders of five service organizations were polled (62.5% of the total number of organizations maintaining the medical equipment). LLC "Medtehnika" 35 doesn't service the medical equipment.

Vologda (LLC "MEDIN", B. Braun Medical Co., Chirana Co., etc.).

However, the regional service organizations have the problems with the provision of spares and consumables. The leaders of the organizations providing maintenance and repair of medical equipment (CJSC PF "Vologdamedtehnika" and CJSC "Medprombyt") point out the following reasons:

- a) producers of medical equipment set high spares prices, so sometimes it is unreasonably to repair the equipment;
- b) spares are sold only in large lots but a service organization usually doesn't need such number of spares;
- c) foreign producers of medical equipment refuse to ship the spares because they are interested in maintenance and repair by themselves;
- d) there are no catalogs of spares and consumables that's why sometimes the orders are drawn incorrectly;
- c) long delivery terms of spares and consumables.

Table 3. The number of medical equipment service contracts which were signed in 2010

| Service organization             | Health-care agency |           |          |       | Total      |
|----------------------------------|--------------------|-----------|----------|-------|------------|
|                                  | regional           | municipal | district | other |            |
| CJSC PF "Vologdamedtehnika"      | 11                 | 38        | 25       | 131   | <b>205</b> |
| CJSC "Medprombyt"                | 11                 | 22        | 0        | 34    | <b>67</b>  |
| LLC "Delrus-B"                   | 5                  | 25        | 6        | 4     | <b>40</b>  |
| LLC "Medpharma-Vologda"          | 3                  | 4         | 0        | 0     | <b>7</b>   |
| LLC "Vologda. Medicine. Service" | 3                  | 1         | 0        | 2     | <b>6</b>   |

One of the ways to solve this problem is to create the regional basic organization of the Russian Association of Enterprises to sale and repair medical equipment<sup>5</sup> in such areas as service of the centrally received medical equipment, post-warranty maintenance, supply of spares and consumables [11].

Another important issue is the loss of services efficiency and quality due to the lack of maintenance documentation as well as refusal of the companies which produce medical equipment to provide it. It is possible to change contracts for the supply of medical equipment and include a requirement to provide maintenance documentation with a service instruction for medical personnel and a registration certificate of medical device to solve this problem.

We have analyzed the activity of service organizations in the Vologda Oblast to identify the trends in the development of the regional market which services the medical equipment. CJSC PF Vologdamedtehnika was in the lead (205 contracts) by the indicator "The number of medical equipment service contracts which were signed" in 2010 (*tab. 3*). The company took such position because it was created on the basis of the regional state-owned enterprise Medtech. That's why it kept not only maintained production facilities and skilled electricians in the stuff, but also strong links with the regional medical

institutions. In addition, this organization had an atypical structure of medical equipment service for the Vologda Oblast. The qualified electricians, electrical engineers and the engineers maintained X-ray machines and laboratory equipment carried out the service on the basis of the central production sector CJSC PF "Vologdamedtehnika". In addition, each of the central regional hospital had a specialist from CJSC PF "Vologdamedtehnika" which maintained the sophisticated medical equipment.

However, the head doctors from the district hospitals in the Vologda Oblast (according to a survey in 2011) note that competition in medical equipment service is virtually absent in the districts. The poll results of the managers from the service organizations also confirm this information (Only two organizations CJSC PF "Vologdamedtehnika" and LLC "Delrus-B" have the contracts with the district health-care agencies).

According the information from the official website of the Committee of Public Order of the Vologda Oblast, the average contract price for medical equipment service was 285 thousand rubles for the period from May to November in 2010.

Staffing is an important component of the organization of medical equipment service. Only the specialists which are 18 and elder are admitted to service medical equipment if they have appropriate vocational training [1]. The technical service must have the specialists to service all types of medical equipment specified in the license.

<sup>5</sup> In November 2010 the self-regulatory organization RAPMED consisted of 84 Russian service organizations; 8 of them were located in the North-West Federal District.

Table 4. Staffing of the service organizations in the Vologda Oblast in the first quarter of 2011

| Service organization           | Average age | Number of technical services employees |            |           |
|--------------------------------|-------------|--|------------|-----------|
|                                |             | Permanent employees                    | By-workers | Total     |
| CJSC PF Vologdamedtehnika      | 47          | 28                                     | 13         | <b>41</b> |
| CJSC Medprombyt                | 25          | 15                                     | 4          | <b>19</b> |
| LLC Delrus-B                   | 45          | 9                                      | 2          | <b>11</b> |
| LLC Medpharma-Vologda          | 28          | 3                                      | 1          | <b>4</b>  |
| LLC Vologda. Medicine. Service | 30          | 2                                      | 0          | <b>2</b>  |

Table 5. Qualification of the service technicians which maintain medical equipment

| Service organization           | Technical education |           | Qualification rate of access | Certificate of education |
|--------------------------------|---------------------|-----------|------------------------------|--------------------------|
|                                | Higher              | Secondary |                              |                          |
| LLC "Delrus-B"                 | 19                  | 0         | 15                           | 15                       |
| CJSC PF "Vologdamedtehnika"    | 11                  | 30        | 5                            | 41                       |
| LLC "Vologda.Medicine.Service" | 4                   | 0         | 2                            | 4                        |
| CJSC "Medprombyt"              | 2                   | 9         | 2                            | 0                        |
| LLC "Medpharma-Vologda"        | 2                   | 0         | 2                            | 2                        |

Staffing of the service organizations is characterized by the indicators from *table 4*.

CJSC PF "Vologdamedtehnika" has the largest technical service department (41 persons); the average age of its personnel is 47 years. This fact demonstrates the rich professional experience of the staff. LLC "Delrus-B" and have 19 people in its technical service department; there are 11 people in the technical service of LLC "Medprombyt". The average age of employees in these companies is 25 and 45 years, respectively.

Table 5 shows the proficiency level of the service technicians which maintain medical equipment. Taking into account the average age and educational level of the service technicians from the regional service organizations we can note that nowadays primarily young people with higher technical education are hired for the positions of electricians and engineers. This fact is explained by the opening of a new specialty "Engineering in Medicobiologic Activity" at Vologda State Technical University in 2001.

According to the estimate of the managers from the regional service organizations, average capacity utilization is 74%. Capacity utilization is above the average rate in CJSC PF

"Vologdamedtehnika", LLC "Medfarma-Vologda", LLC "Medprombyt" have; it is down the average rate in LLC "Delrus-B" and LLC "Vologda. Medicine. Service" (*tab. 6*).

An important advantage of the service organization in comparison with its competitors is availability of metrological and transport services as well as the quality management system.

Metrological service is the service that is established in accordance with the law to ensure traceability and implement metrological control and supervision [12]. Metrological service staff carries out a test<sup>6</sup> and calibration<sup>7</sup> of measuring instruments. Only two service organizations in the Vologda Oblast (CJSC PF "Vologdamedtehnika" and LLC "Medprombyt") have metrological services in their structure which are accredited by the Federal Agency for Technical Regulation and Metrology (Rosstandart).

<sup>6</sup> Test is ascertainment of measuring instruments' aptitude to be used on the basis of experimentally determined metrological characteristics and confirming of their compliance with regulatory requirements.

<sup>7</sup> Calibration a set of operations that correlate the value of a quantity obtained with this instrument and the respective value of a quantity defined by the standard to determine the actual metrological characteristics of measuring instruments.

Table 6. Capacity utilization of the companies and availability of services

| Service organization           | Capacity utilization, % | Availability of service/ system |                           |                   |
|--------------------------------|-------------------------|---------------------------------|---------------------------|-------------------|
|                                |                         | Metrological service            | Quality management system | Transport service |
| CJSC PF "Vologdamedtehnika"    | 85                      | yes                             | yes                       | yes               |
| LLC "Medpharma-Vologda"        | 85                      | no                              | yes                       | yes               |
| CJSC "Medprombyt"              | 80                      | yes                             | yes                       | yes               |
| LLC "Delrus-B"                 | 60                      | no                              | yes                       | yes               |
| LLC "Vologda.Medicine.Service" | 60                      | no                              | no                        | no                |

The effectiveness of the medical equipment service<sup>8</sup> is provided by fulfilling of the requirements of the existing quality management system. Nearly every service organization in the Vologda Oblast has a quality management system (with the exception of LLC "Vologda.Medicine.Service"). Technical service plans and implements activities to bring the quality management system in accordance with applicable national and international standards for quality management systems, as well as it monitors the maintenance of medical equipment.

The quality of repair work is confirmed by the warranty obligations:

- a) the medical devices, which don't reach the end of their service life, are provided with the guarantee for 3 months;
- b) the medical devices reached the end of their service life are provided with the guarantee for 1 month.

Various forms of contact with the consumers are used during maintenance of medical equipment. Organization of service support in the areas of medical equipment placement is very important as a form of professional relationship. This form is popular because modern medical facilities are difficult to transport and dismantle. The results of researches [13] show that 90% of medical equipment services are

<sup>8</sup> The poll of the head doctors from the health-care agencies in the Vologda Oblast in 2011 has showed that they rate the quality of medical equipment service provided by the regional service organizations to 3.92 points on a five-point scale.

carried out in the health-care agencies and only 10% of services are carried out in the production workshops of service organizations. Sometimes some spares required for the equipment can be produced in these workshops. If it's impossible to produce spares in the workshops they can be ordered from the company which produces the medical equipment. Almost all service organizations in the Vologda Oblast have transport service (with the exception of LLC "Vologda.Medicine.Service") to deliver the medical equipment.

The results of the questionnaire in 2011 allow us to obtain such qualitative information as opinions and expert assessments by the head dictators (33 pers.) of Vologda hospitals and managers of service organizations (5 pers.) about the factors which hinder the development of regional infrastructure of medical equipment service<sup>9</sup> (tab. 7).

92% of experts note that the main factor constraining the development of the infrastructure of medical equipment service is a lack of financial assets. The low efficiency of existing mechanisms for public purchases in the medical equipment service takes the second place (34% of experts point out this factor).

<sup>9</sup> The infrastructure of medical equipment service is a set of specific, interrelated and complementary elements which are necessary and sufficient to detect and prevent failures and malfunctions of medical equipment in the region through timely execution of works ensuring their functionality during the planning period (Shcherbakova A.A. The essence and structure of the regional infrastructure and medical equipment service / A.A. Scherbakova // Problems of the territories' development. – 6 (52). – 2010. – Pp. 61-66.).

Table 7. The factors which hinder the development of the infrastructure of medical equipment service

| №  | Factor   | Number of experts, pers. |                       | Total  |    |
|----|--|--------------------------|-----------------------|--------|----|
|    |  | Medical institutions     | Service organizations | People | %  |
| 1. | Lack of financial assets   | 30                       | 5                     | 35     | 92 |
| 2. | Low efficiency of existing mechanisms for public purchases                     | 9                        | 4                     | 13     | 34 |
| 3. | Imperfection of acquis communautaire   | 8                        | 4                     | 12     | 32 |
| 4. | Low qualification of engineers maintaining the medical equipment in the region | 11                       | 1                     | 12     | 32 |
| 5. | Lack of monitoring system of medical equipment state                           | 6                        | 1                     | 7      | 18 |

Thus, we can conclude that the infrastructure of medical equipment service in the Vologda Oblast isn't developed well. So, today it's necessary to elaborate the measures that will ensure trouble proof and safe operation of the medical equipment in the health-care agencies in our region and improve structural, organizational, financial effectiveness of healthcare. The state authorities and health management should have an important role in solving of these problems. The can obliged the head doctors of the medical institutions to pay

due regard to medical equipment service. Also, the priority areas of work in this area in limited financial support will be the following:

- a) more rapid implementation of the Automated information system for monitoring of medical devices (It is going in test mode in 60 regions of the Russian Federation);
- b) creation of the technical services based on the regional and municipal health-care agencies;
- c) purchase of unified medical equipment to reduce the time of its technical service.

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