

Verification Report

Organization:		Clinic of reproductive medicine "Nadiya"	
Address:		19-A Maxima Kryvonosa 03037, Kyiv, Ukraine	
Order number (WIS):		124618/130383	
Type of audit/assessment:		Verification of date	
Audit date:		11.04.2016	
Reporting date:		21.04.2016	
Utilized Checklists and objective audit records:		CL 27 01 001e	
Representative of organization:		Medical Director Viktor Veselovskiy	
Auditors (verifiers)/Assessors:			
Name of Team leader:	Nataliia Danko	Name:	Glukhova Olga

1 Scope of use

According to the request of the Clinic of Reproductive Medicine "Nadiya" Quality Austria conducted independent verification of the data submitted in the report document - "The results of the clinic," Nadiya" for 2015".

The amount of data of verification is limited by the text and the data contained in the report document "The results of the Clinic "Nadiya" for 2015" which is submitted for consideration. These data refer to the results of the treatment carried out in the period from 01.01.2015 on 31.12.2015.

The structure of the report "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015" and completeness of its data corresponds to what will be published on the website of Reproductive Medicine Clinic "Nadiya" or in the open media. Report of Reproductive Medicine Clinic "Nadiya" will be referred to and attached to the results of verification report of the Quality Austria.

2 Declaration of Independence

Reproductive Medicine Clinic "Nadiya" takes all responsible for the information which is contained in the report "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015".

Quality Austria was not involved and did not contributed to the drafting of the document "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015", and

acts as an independent verifier, checking the adequacy of the contents of this document.

Quality Austria is responsible for verification report content and its conclusions which are based on the report "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015".

3 Verification methodology

Verification methodology is based on audit procedures in accordance with ISO/IEC 17021 and control mechanisms in accordance with the guiding principles of mathematical statistics, the relevance, completeness and responsiveness.

To check the information and data were done:

- Survey of personnel responsible for the collection and preparation of data.
- Verification of documents and records.
- Data verification and checking directly the sources formation of the data.
- Check and eliminate nonconformities in the report documents.

4 Verification

Check of the report of basic health indicators in 2015, prepared for publication was associated with:

- Checking the sequence, interaction and performance criteria for medical processes of the Clinic;
- Verification of the identification and traceability procedures for patient's data and their treatment outcomes;
- Verification of the data of embryological department and department of assisted reproductive technologies conformity assessment contained data in the information database on the number and type of cycle, to data contained in the final format of medical records on paper records and Clinics report, prepared for publication;
- Analysis of Clinic medical paper records (medical records, medical histories, stimulation sheets, etc.);
- Analysis of Clinic medical records on electronic media;
- Monitoring software used to create the data base clinic. Samples for key performance indicators were checked. Activities clinic to ensure the reliability of the software and safety information in electronic data bases of Clinic. In particular, for verification was evaluated Clinics' program "Medialog", where patient data, results of various treatment programs are stored;
- Verification of Call-center activities in part of providing feedback from patients and collecting data on the whole chain of treatment, including obtaining data for report based on treatment outcomes;
- Verification of Registry activities in conducting contractual work with patients and storage of medical records;

- Verification indication of characteristics and trends of medical processes in the analysis by Clinics' top management.

5 Overall impression

Based on the report "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015" were traced the origin and formation of the document data from the original sources - Clinics' databases, formed by various departments, including embryological department and assisted reproductive technologies department. Made the appropriate data sampling and reproduced the mechanism of final report document formation.

Clinical results for 2015 presented in this report correspond to the content of electronic databases, archive medical records on paper records, test day -11.04.2016.

During the verification the audit team confirmed proper storage conditions for health records in electronic and paper form. Records corresponding to different types of cycles (cycles of IVF on their own egg cells, transfer "frozen and unfrozen" embryos in non-donor cycles, donor cycles) have been checked and traced back to the outcomes of treatment (the number and frequency of pregnancies). The data for each protocol (cycle) of treatment consistent with requirements for the various indicators of clinical outcomes.

6 Conclusions

As a results of the verification audit team Quality Austria believes that the report "The results of the Clinic of Reproductive Medicine "Nadiya" for 2015" contains accurate information. Data of the report prepared in accordance with the principles of relevance, completeness and responsiveness. The report presents the clinical outcomes of activities Clinic of Reproductive Medicine "Nadiya" for 2015.

Quality Austria
Trainings-, Zertifizierungs-
und Begutachtungs GmbH

The commissioned auditor


Nataliia Danko (electronically prepared)