

# EPIDEMIOLOGY AND MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS IN ST. PETERSBURG AND LENINGRAD OBLAST



## IMPROVEMENT OF THE PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED INFECTIONS IN ST. PETERSBURG AND LENINGRAD OBLAST Short report on Russian-Swedish projects

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### INTRODUCTION

Since the Soviet Union collapsed in December 1991, Russia, as many other previous Soviet Republics, was revising its way of living. The period of introduction into the market economy proved to be very difficult, resulting in poverty, unemployment and social insecurity. High abortion rates, constantly decreasing birth rates, diminishing middle age for men and women, frightening rates of HIV/AIDS and sexually transmitted infections (STIs) epidemics are factors that placed the country in a highly unfavorable situation regarding reproductive health. Only recently has the Russian government prioritized reproductive health and socially important diseases, including HIV/STI.

Reproductive health includes many components. Reproductive tract infections, and particularly STIs, are two of the most important areas of reproductive health. In Russia, management of STIs is far less than optimal, which could be characterized by inadequate epidemiologic surveillance, diagnostic services, patient management and adjacent areas. Poor STI services lead to negative social consequences. Sweden has a long-lasting tradition of work in the area of reproductive health, particularly in the area of STIs. Since Russia has become a separate state, Sweden, like many other Western countries, offered financial help, know-how transfer and exchange of experiences in the form of different joint projects.

This paper presents a short review of the current situation on STI diagnosis and patient management in St. Petersburg and Leningrad Oblast. The paper also presents the achievements of the project that has already affected the current situation or will contribute to future development. The review is primarily based on evidence collected from the St. Petersburg and Leningrad Oblast project, though data from sister projects were also used.

### SITUATION ANALYSIS

#### Evaluation of the epidemiologic situation

STIs constitute an important threat to public health in many countries, both directly as a result of

their ability to cause complications as well as their potential ability to increase the transmission of HIV. The World Health Organization (WHO) has estimated a worldwide incidence of 340 million curable STI episodes every year, with many millions of incurable viral STIs, including an estimated 5 million HIV infections occurring annually [1].

In Russia, there are four reportable bacterial STIs: syphilis, gonorrhea, chlamydial infection and trichomoniasis [2]. While the estimated incidence of these infections in St. Petersburg has declined during the past decade [3], the reported incidences in 2005 were 48.3, 39.8, 171.7 and 140.7 per 100 000 population for *T. pallidum*, *N. gonorrhoeae*, *C. trachomatis* and *T. vaginalis* infections, respectively. However, the reliability of these data from Eastern Europe is doubtful, largely because of inadequate diagnostic testing [4], incomplete epidemiological surveillance [5] and the development of self-treatment. During the same period, nearly 3 million non-treponemal and 28 000 treponemal serological tests, 1 million microscopic and culture tests for gonorrhea, 800 000 tests for trichomoniasis and 73 000 tests for chlamydial infection were performed at various dermatovenereological institutes in St. Petersburg [6]. It is alarming that the ratio between the number of reported syphilis and gonorrhea cases has drastically changed from 1:33 to 1.2:2, respectively, during the past 10 years [7].

#### Factors affecting epidemiologic data and diagnosis

**Sampling.** The pre-analytical stage, i.e. sample collection, storage and transportation, has a crucial impact on the results of the laboratory diagnosis of STIs. Many of the STI diagnoses in Eastern Europe, including Russia, rely on microscopic examinations of genital smears [8, 9, 10]. During our projects, we organized a number of courses in which physicians were trained on how to use bed side microscopy to examine the genital tract. Samples brought by the physicians attending our training courses for bed side microscopy [11, 12] showed highly uneven quality. For instance, from 500 male urethral samples,

350 contained epithelial cells. Most of the samples were obtained using the Volkman spoon and therefore 65% were regarded as too thick. In two thirds of the samples from female urethra there was no material from the urethra detected on glasses presented by physicians attending training courses in bed side microscopy [11]. Surprisingly, those physicians who could not find urethral samples on their glasses were never questioned from the laboratories serving them. It could be presumed that in the case of absence of cells on the microscopic slide, the laboratory provided a negative outcome.

It is generally agreed that diagnosis of the cervicitis in women is done when the cervical discharge is present at pelvic examination, together with more than 10 leukocytes (PMNL) present per microscopic field at magnification of 1000  $\times$ . Cervical discharge or enlargement of the number of leukocytes alone is not enough for a positive diagnosis of cervicitis [13]. However, for 25% of the physicians participating in bed side training, detection of cervical discharge or laboratory-reported elevated number of leukocytes alone was enough for initiating treatment for cervicitis. Additionally, 30% of the patients were diagnosed with cervicitis based on incorrect collected samples, i.e. instead of cervical sample — vaginal sample, bearing clusters of leukocytes, was evaluated.

*Transport.* Instead of samples, patients are sent to the diagnosing laboratory for sampling in a number of cases. This might be one factor contributing to the “reduction” of the prevalence of gonococcal infection [7]. Sample transport for diagnosis of syphilis is well established, whereas the sample transportation system for gonococcal and chlamydial infection is not organized at all.

Diagnosis of *Trichomonas vaginalis* infection is primarily based on microscopic testing of stained genital samples [10] performed by laboratory personnel. As a result of low quality of equipment (i.e. microscopes), diagnosis of “atypical trichomonas” (smaller in size and without flagella) is reported [11]. In St. Petersburg and Leningrad Oblast, as well as in Estonia and Lithuania, “atypical” trichomonas is the major diagnosis. Although we asked on numerous occasions our Russian physicians to demonstrate “typical” trichomonas, we were mostly invited to see “atypical” forms, which were never confirmed by our teachers because diagnostic criteria could not be matched. Finding “atypical” forms is often followed by “specially designed” treatment [14]. This phenomenon, however, is not known in Western countries.

When culture is not applicable, wet-smear testing is the most traditional method of testing for *T. vaginalis* [15]. Because motility diminishes with time, microscopy for *T. vaginalis* should be performed as

soon as possible after sampling. If samples would be tested as a wet smear bedside, it would allow preventing trichomonas from exposure to varying temperatures during transportation. Being sensitive to temperature conditions, trichomonas lose their viability. Consequently, if tested at the laboratory as a wet smear, they could not any longer be characterized as trichomonas.

Very few laboratories in St. Petersburg and Leningrad Oblast perform cultures of gonococci [16]. When trying to explore the usage of culture, even using special transport media, gonococci are often lost, and consequently, not isolated.

*Sample registration in diagnosing laboratories.* Samples arriving from the clinical sites have to be registered at the laboratory before they enter laboratory routines. During our study [16], we revealed that many laboratories had no unified data collection system, nor did they have standard protocols for laboratory results. Furthermore, laboratory protocols were not adjusted to clinical needs.

*Disposables and medium.* Laboratory personnel performing microscopy perform a tremendous job. The majority of the laboratories use thick, very old, scratched glasses that have been washed hundreds of times. This makes their work extremely difficult and reduces the reliability of their results. Washing quality may affect quality of staining (e.g., microorganism attachment and pH changes can result in incorrect coloration).

The use of glass tubes in cultural diagnosis of gonococcal infection results in uneven distribution of medium, which leads to variable thickness of the medium through the tube. This, in turn, causes sub-optimal growth of the micro-organism [17].

Growth of micro-organisms often requires use of a specially adopted medium. Gonococci are very sensitive to the medium and to the micro-organisms that may live in that medium. Therefore, to isolate gonococci special antibiotic supplements suppressing the growth of other bacteria are used [17]. Testing the medium of Russian origin, the latter was found to be comparatively sensitive in the isolation of gonococci [16]. However, not many laboratories have understood the importance of using antibiotic supplements in the isolation of gonococci. Sub-cultivation of gonococci in order to receive pure colonies for final identification still remains a problem.

*Test systems and laboratory quality control.* Internationally, each new diagnostic kit before its introduction into the market should undergo certain routine testing against an internationally recognized “gold standard”. This situation, however, does not apply in

the majority of test systems produced in Russia (and other East European countries). We observed varying test quality [18], both in different producers [19] and in different series of the same kit [16]. Absence of a quality control system does not allow even the most intriguing studies to be internationally accepted. Further, when patients test themselves at different laboratories, they may receive completely different results, which could eventually lead to improper treatment.

Quality control in most of the clinical microbiologic laboratories does not exist. An officially existing quality control system does not meet the international standard. We could not find clinical microbiologic laboratories in St. Petersburg or Leningrad Oblast that would be measuring performance of their thermostats, refrigerators, pipettes, etc., or controlling the quality of media. Controls are usually run using the same method, which means that the control result would most likely correspond to the manufacturer's recommendations, but the overall quality of performance remains unknown. Moreover, there are no reference strain collections to be used for growth control of micro-organisms.

External quality control faces the same problem as in other East European countries. There is no central institution that provides relevant control samples and that evaluates the performance of test methods using internationally accredited methods. There are, however, a Central Institute of Dermato-venereology and a Federal Technical Regulation and Metrology Agency. These are organizations that are trying to do some work in the area of quality control though this attempt is insufficient as an effective system of external quality control.

*Need of a reference laboratory.* Discussions regarding the need of a reference laboratory have occurred recurrently and on different levels. However, the term "reference" is often mixed with the expression "normally functioning". It is clear that such a big country as Russia needs a reference centre that could have a network of regional centres. A similar system exists at the Central Institute of Dermato-Venereology in Moscow. However, probably because of a lack of experience and knowledge (and perhaps finance), this institution does not yet perform Reference laboratory activities. Russian microbiologic laboratories would highly benefit from the introduction of a laboratory quality control system. In that respect, the recent acceptance of the International standard ISO/FDIS 15189: Medical laboratories — Particular requirements for quality and competence (ISO 15189:2003) by the Russian Microbiology Society is highly promising [20].

*Patient management.* Usually, it is the physician's responsibility to determine which infection the pa-

tient needs to be tested for. As most of the patient categories pay for their treatment themselves, it is largely up to them to decide which tests have to be used. Even when the patients are consulting the same institution, several tests could be suggested, depending on whether the institute is municipal or privately own [21]. The treating physician informs the patients of the available methods, suggesting which methods he or she feels could benefit the patients. Often in the case of the municipality, the working physician tries to save the institute money, whereas the opposite occurs in the private sector where the private physician often recommends using the most advanced techniques. Our questionnaire-based study demonstrated that the majority of physicians were not aware of the quality of the tests being used by a specific laboratory. The knowledge generally limits to the fact that nucleic acid tests are better than antigen detection assays or similar.

Patients are often tested for several infections, such as *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Ureoplasma urealyticum*, *Mycoplasma hominis*, *Mycoplasma genitalium*, genital herpes, *Candida spp.*, *Trichomonas vaginalis*, and *Gardnerella vaginalis*. Multiple findings result in the use of so called "complex therapy", which involves using multiple antibiotics and immunomodulators [22]. Finding just one of the above-mentioned organisms could be a sufficient reason to initiate partner tracing and treatment. Just imagine all the "possibilities" provided by the combination of false-positive and false-negative results obtained if the patient were to consult several laboratories providing diagnostic services of varying quality.

Despite the availability of international recommendations, a number of divergent treatment schemes are still in use, schemes that are often very complex, costly and not evidence-based.

## SOLUTIONS PROPOSED BY THE PROJECT

### Optimization of laboratory diagnosis

*Organization.* During the entire project, we paid special attention in closely monitoring laboratory routines used in the diagnosis of STIs. A detailed assessment of the laboratory services in St. Petersburg and Leningrad Oblast was conducted with the help of collaborators from the St. Petersburg Dermato-venereology dispensary (Tatjana Smirnova, Irina Litvinenko, Olga Gaivaronskaya), the Leningrad Oblast Dermato-venereology dispensary (Boris Nikiforov) and the Leningrad Oblast Health Committee (Elena Voronina). The situation regarding the STI laboratory services was completely unknown in St. Petersburg, before the inventory was conducted [7, 10]. The inventory allowed the establishment of

the laboratory network that included people with the same interest (i.e. laboratory diagnosis of STIs). With the network, it became possible for professionals to exchange their knowledge and experiences.

There is only one institution in St. Petersburg and Leningrad Oblast, which is the City Dermato-venereology dispensary that participates in a Federal STI program. Having the list of laboratories and knowing what services they are providing, the dispensary could become a coordinating centre working to find practical solutions for improved sampling and to introduce suitable technologies, algorithms, etc. The number of workshops and discussions organized with network participants always permitted easy access to the people working in a specific field (e.g., diagnosing of gonococcal infection) and to forward these individuals recommendations for improvement. All network members were receiving elaborated written materials and guidelines.

In St. Petersburg as well as in Eastern Europe discussions are frequently held regarding the Reference laboratory, including its functions, aims and general organization. Some problems are created because of a communication barrier between the municipality-owned institutions and federal institutions. Our close collaboration with the microbiology laboratory of the **D.O. Ott Institute of Obstetrics and Gynecology** showed that the microbiology laboratory was frequently acting as a **reference** regarding the diagnosis of *C trachomatis* infections. The laboratory can also validate tests and conduct investigations on *N gonorrhoeae*, *T vaginalis* and *M genitalium*, so it could easily become a reference for those infections as well. The latter laboratory has, for example, performed, and currently works, on validating Russian-produced nucleic acid amplification tests [19], participated in other international programs and test validations requested by the test producers. However, as mentioned above, there are some communication difficulties between municipal and federal institutions. In many cases the communication problems are solved on a personal but not on an administrative level.

**Bed side microscopy.** A number of courses on bed side microscopy were held in Sweden, St. Petersburg and Leningrad Oblast. The main faculty member, Anders Hallén, a dermato-venereologist from the Academic Hospital, Uppsala University, was helped by Lithuanian dermato-venereologists: Andrius Vagoras of Vilnius University and Rita Butylkina of the Kaunas Public Health Center in Kaunas. In Leningrad Oblast most of the 19 regions were visited with the help of the Leningrad Oblast chief dermato-venereologist, B. Nikiforov, Leningrad Oblast Health Committees Mothers and Child Health Department head specialist, O. Siskina, and later by the newly elected specialist and head of that department N. Pankov. More than

30 working stations were supported and at least one installed in each of the regions. In the Vsevolozsk and Vyborg regions of the Leningrad Oblast the majority of gynecologists, venereologists, urologists and general practitioners were trained to use bedside microscopy as a part of their daily routines [12]. A number of applicants from different regions of the Oblast have been trained. In St. Petersburg, the youth centres have become the main users of the method [13]. Most venereologists and gynecologists working with young people in the city are using bedside microscopy. In addition, new trainees will be using this method in the near future. The D. O. Ott Institute of Obstetrics and Gynecology has become a training centre for bedside microscopy. Equipped and trained by the project, the training centre has established a 144-hour training course, after which a certificate is issued.

During the project, educational materials have been prepared on the subject of bedside microscopy [13, 23–26]. One of the books being used [24] was highly acknowledged internationally, i.e. in 2004, the book received a special price at the International Book Exhibition in Frankfurt. Two of the educational books [13 and 23] were legalized by the Russian Association of Medical Laboratory Diagnosis and by the Federal Health Care and Social Welfare Agency's North-West district. One book [23] will be distributed to all the laboratories through the Federal Technical Regulation and Metrology Agency.

The chief venereologist of Leningrad Oblast, B. Nikiforov, has described the importance of the method as “the unique possibility to evaluate the quality of sampling and to monitor the quality of treatment”. Physicians using bed side microscopy get more patient respect and appreciation because they can diagnose urogenital infections and allied conditions during the first visit and the patient does not need to wait for an answer to be treated [12]. Our evaluation has also demonstrated that the number of diagnoses made by using bedside microscopy increases yearly, demonstrating the physicians' interest in this approach.

During the training sessions, a number of peculiarities in diagnosis and general management of the reproductive tract infections were discovered. (This issue is described in detail in the beginning of this paper). Use of bedside microscopy encouraged physicians to improve the quality of their work. Patients showed their appreciation, i.e. physicians who did not use microscopy were asked why they did not use this method by patients who have been consulting physicians using the microscope. According to existing legal regulation, physicians are not allowed to make a final diagnosis before laboratory analysis has been made. Consequently, all samples are still sent to the laboratory for confirmation. However, physicians who use the microscope (i) put more pressure

on their laboratories when the laboratory and their own results do not agree; (ii) the laboratories admitted that sample quality has improved; and (iii) close contact between the treating physician and the laboratory was established, especially regarding ambiguous or difficult cases.

Method evaluation by patients (in progress) has indicated positive reactions. Physicians using microscopy bedside were given higher scores by the patients. In addition, the patients felt that the quality of such service provided by physicians using bedside microscopy is much higher as compared with that provided by physicians who do not use the microscopy themselves in the sense that the method saves time and counseling is more effective.

Laboratory personnel also attend the course given at the Ott institute. The protocol for microscopic evaluation of genital smears used by the laboratory is non-standardized and contains information, which for the physician is difficult to interpret (e.g., finding gonococci-like Gram-negative microorganisms). Therefore, we have elaborated the unified protocol, which allows standardization of the microscopic examination and includes clinically relevant information.

*Optimization of sampling.* Today, nearly 100 physicians from St. Petersburg and Leningrad Oblast have experienced bedside microscopy and consecutively have seen the quality of their own sampling. Their initial view on sampling quality has changed. Our trained physicians are often under observation by their colleagues, working at the same working place. The latter get word of laboratory comments about improved sampling quality, patient comments, and finally, observe their colleagues being able to immediately examine the patient's material before it is sent to the laboratory for analysis. This fact increases interest in bedside microscopy.

Concerning the last step of the project, our intention is to establish an Internet-based course, allowing the faculty being present in the training centre and the trainees in any region in Russia.

*Epidemiological studies.* During the project, a number of epidemiological studies had been conducted [27]. Training for bedside microscopy involved collection of patient samples (improvement of sampling techniques achieved). First, using optimized diagnostic tools, the epidemiological studies allowed us to learn the epidemiological status of certain risk groups [27]. Second, patients from whom samples were obtained for the purpose of collecting epidemiological data [27] or evaluation of diagnostic methods [12, 18, 19] were asked to answer a standard questionnaire, which later was developed into the standard history of the disease (anamnesis) protocol. With this standardized questionnaire, we could study

behavioral factors [27], as well as knowledge of STI/HIV prevention of those persons involved in our studies (risk groups) [28]. For the first time, patients were independently responding to a standardized questionnaire. Both physicians and patients were learning this new type of dialogue. Third, we also designed a standard protocol for physical examination. This protocol allowed the following: (a) it saves physicians time (the standard protocol was designed with ready pre-printed questions with squares for physicians to place their response with a cross in the correct square); and (b) if the patient would visit another physician later on, the latter physician would have the same, easy readable protocol. Fourth, we supplied physicians with disposable sampling tools (plastic bacteriological loops). Thus, physicians participating in the study could optimize their sampling skills and learn about the advantages gained from using very smooth disposable tools. At the same time, they could gain new skills in bedside microscopy. Parenthetically, during the training phase, the DO Ott Institute microbiology laboratory marked a significant decrease in the "prevalence" of chlamydial infection!

*Evaluation of the diagnostic systems used.* It was impossible during the project to limit our project area to the St. Petersburg and Leningrad Oblast. These two regions are a part of Russia and therefore some questions could not be solved just locally because of, for example, legal aspects. At the same time, by evaluating quality of diagnostic tests used in all of Russia, we extended the geography of the project to the whole country.

Presently, we are running several studies designed to evaluate the nucleic acid amplification tests (NAAT) in Russia that are made by the main NAAT manufacturers in this country [19]. This will be the first attempt with respect to the quality evaluation of Russian-produced diagnostic kits using internationally accepted evaluation methodology, i.e. evaluation against Western quality assured systems. This evaluation is done through an extensive collaborating effort among the following institutes: Microbiology laboratory of DO Ott Institute, St. Petersburg (A. Savicheva), Swedish National Reference Laboratory for Pathogenic Neisseria, Örebro University Hospital, Sweden (M. Unemo), University Hospital of North Norway, Tromsø, Norway (Skogen V.), Department of Bacteriology, Mycology and Parasitology, Statens Serum Institute, Copenhagen, Denmark (J-S. Jensen), Centers for Disease Control, Atlanta, USA (R. Ballard) and Uppsala University (M. Domeika). This study is also an integral part of another project "Quality assurance and synchronization of the STI/HIV Control and Prevention in Russia" run in collaboration with the Central Institute of Dermato-Venereology, Moscow (A. Kubanova).

*Standards of laboratory diagnosis of STIs.* Today, standards of STI diagnosis in Russia essentially do not exist. During our inventory studies on laboratory facilities and services, we learned about the gaps in STI diagnosis [10, 16]. We arranged a series of seminars and meetings with the laboratory workers of St. Petersburg and Leningrad Oblast. From these seminars and meetings, we decided to produce the STI diagnostic protocols. However, from our collaborators in the project "Quality assurance and synchronization of the STI/HIV Control and Prevention in Russia", we received indications of the need of such protocols for the entire country. Furthermore, these indications came from other Eastern European countries as well, which resulted in the organization of the International Network for Sexual and Reproductive Health. The existence of this organization was announced during the 22<sup>nd</sup> IUSTI Conference in Versailles in 2006. During the workshops, experts from Eastern European countries were working closely with their Western colleagues, who were representatives from reference laboratories throughout the world. The aim of this work was to prepare recommendations adapted to the peculiar needs of Eastern Europe, with later adoption and implementation into laboratory practice of specific countries, including Russia. The main representatives from the Russian site are Professor E. Sokolovskiy (Pavlov State Medical University, St. Petersburg), Professor A. Savicheva (DO Ott Institute of Obstetrics and Gynecology, RAMS, St. Petersburg) and representatives from the Central Institute of Dermato-venereology that include A. Kubanova (Director Professor) and Professors N. Frigo, S. Rotanov, T. Pripitnevich and O. Dolia. The first part of the international guideline for the Diagnosis of *Neisseria gonorrhoeae* infections has already been published [30] and the second part has been accepted for publication [17]. The guideline for the diagnosis of syphilis is also ready and will be presented soon. The Russian version should be legalized and it is hoped that it will appear during the autumn of 2007. Thereafter, regional legalization procedures will be initiated.

*Laboratory quality control.* During the project, 14 selected laboratories in St. Petersburg and in Leningrad Oblast were working on elaboration of the Russian version of the Laboratory Quality Control Manual according to the "International standard ISO/FDIS 15189: Medical laboratories — Particular requirements for quality and competence (ISO 15189:2003)". A number of seminars and workshops were arranged in Russia, Lithuania and Sweden. The faculty was led by microbiologist Eva Hjelm (Uppsala Academic Hospital, Uppsala, Sweden). This manual allows step-by-step introduction of the laboratory quality control requirements in the clinical microbiology laboratories. Thus, the manual ap-

plies to a much broader area than STIs. Laboratories, project participants, were involved in preparation of their own LQC documentation according to standard requirements. Recently, the Russian Society for Medical Laboratory Diagnosis ratified this international standard [20]. This will allow us to finalize the quality control manual, making it available for all Russian clinical microbiology laboratories seeking to establish quality control.

### **Optimization of the STI patient management**

*STI management groups.* To optimize the organization of the STI management, a team of professionals (venereologists, gynecologists, microbiologists, general practitioners, urologists, etc.) was assembled in both St. Petersburg and Leningrad Oblast. Such team, the STI group, is the most efficient (according to the Swedish model) way of planning prevention strategies and organizing patient management (including laboratory diagnosis) in a specific region. STI management groups were legalized by the St. Petersburg and Leningrad Oblast Health Committees. STI groups were trained during multiple workshops in Sweden and in Russia. The two latter groups were actively participating in all project planning activities, strategy elaboration, and especially, in the implementation phase of the project. However, the biggest value of the groups is the informal connection that developed during the years of the project. Group members were having a number of professional contacts even outside the project: for example, discussing different patient cases, diagnostic and treatment failures, planning studies and research. Such an integrated form of networking was actually the goal of this project.

Interestingly, such an integrated approach seems to find high acceptance. Perhaps that is why we are discussing at the conference today the "birth" of the new "Association of the Protection of the Reproductive Health" in Russia, which is the highest expression of the need to face the problem from the inter-professional perspective [30].

*STI patient management standards.* As mentioned above, a unique legalized patient management algorithm (standard) in St. Petersburg and Leningrad Oblast, as well as for the whole Russia does not exist. We choose to use a Swedish model in which each county has prepared its own local "STI patient management folders". The Russian version of such folders was prepared in collaboration with venereologists, gynaecologists, microbiologists and general practitioners using STI treatment guidelines of the International Union against STI (IUSTI) and, to some extent, the Centers for Disease Control (CDC), UK and Canadian as a base. The elaborated Russian STI folder contains brief information on clinical manifestations, principals

of diagnosis, patient management algorithm, as well as relevant information on the law of communicable diseases, local epidemiology, and finally, a list of the youth clinics and laboratories that were recommended for diagnosis and treatment of STIs [32]. The folder also contains separate patient information sheets, with the aim of unifying information given to the STI patients. The folder was prepared in a free map format, allowing an immediate substitute of pages should a revision be needed and making the upgrading of the guidelines highly dynamic. Folders were legalized by the St. Petersburg and Leningrad Oblast Health Committees, after which a number of folder presentation seminars were arranged in most of the regions of the Leningrad Oblast. In St. Petersburg folder presentations were done during the meetings of the professional societies. Over 3000 folders were distributed to the STI patient managing physicians. Folders were also placed on the Internet and printed in two editions [33, 34]. Later, STI patient management folders were legalized by the Health Ministry of Mordovia and by the Archangelsk and Kaliningrad Health committees.

Further, methodological guidelines for the management of STI patients [24] were also elaborated and published.

*Information materials for the patient.* Several information brochures for the patient were prepared, published and distributed. All patients participating in our studies (epidemiologic or method elaboration) also received information about different STIs, their clinical manifestations and prevention methods [35].

### Presentation of the project achievements

*Project conferences.* Each St. Petersburg and Leningrad Oblast project year was closed by a yearly conference. Presentations from sister project teams (Lithuania, Estonia, Belorussia and Moscow) were always invited, which facilitated the sharing of experiences and exchanging of ideas. Conferences were always attended by specialists from other Russian regions as well, which served to broaden the contact network of the project. During the past few years, bilingual (Russian-English) conference books were issued in order to have a great "Project business card" that facilitated international presentation of the project results. Conference books were also made available on the project's Home page [36, 37].

*Presentations in other Russian conferences.* The project manager and other members of the project team are actively participating in other Russian conferences organized by professional societies and institutions. Project results are always attracting huge attention, which often results in signing contracts between the interested parties from the other administrative regions and the project managers. This in turn leads to further implementation of the project materials.

*Presentation at the international conferences.* Project participants had a number of opportunities to present the project results for an international society by attending a number of conferences (such as IUS-TI, ISSTD and EADV). The results are presented in the form of posters or oral presentations.

## TO CONCLUDE

*Optimization of the diagnosis of STIs.* **Evaluation of the STI laboratory services** in St. Petersburg and Leningrad Oblast made it possible to create evidence, and consequently, to perform evidence-based evaluation of such services. It also allowed creating an inter-laboratory network, namely the mechanism to further implement the project's achievements.

**Elaboration of methodological guidelines and laboratory quality control materials** of STI diagnosis created all the prerequisites for improved diagnosis, which is being realized through that network. Such guidelines and other methodological materials allow the standardization of laboratory procedures and enhance the quality of laboratory services.

**Optimized sampling and laboratory diagnosis** will gradually have an influence on STI epidemiologic data and on the epidemiologic situation *per se*. It will reduce the importance or prevalence of some infections. At the same time, the number of reported cases of other infections might increase.

The **introduction of laboratory quality control** opened up new possibilities for laboratories to re-examine their quality control routines, identify weaknesses and call attention to new ways for improvement.

**Evaluation of the diagnostic test systems** used in Russia permits learning about the performance of those tests from an international perspective. Such evaluation allows for international comparisons and internal medico-political decisions in choosing the most effective diagnostic systems.

**Legalization of guidelines, methodologies, etc.**, at the level of Health Committees and Professional Associations brings materials closer to the practical user and assures sustainability. Tight collaboration with the Federal Technical Regulation and Metrology Agency, Russian Association of Laboratory Medicine and Educational-Methodological Board for Medical and Pharmaceutical Education, opened up perspective of the introduction of the projects results in to the postgraduate education, and easy know how transfer through the existing distribution channels.

*Optimization of STI patient management.* Patient management starts at the moment where the patient is diagnosed as having an infection. Diagnosis of STIs should be quick, inexpensive and

reliable. **Bedside microscopy** is useful in obtaining answers to many clinical situations at an extremely low price (little time loss for patient and physician, no expensive reagents and no repeated visits). It helps to break the chain of infection at an early stage (patients could be treated and informed that they are infected at their first visit. In this case, the patient is recommended to avoid sexual contact before the treatment is completed). Consequently, bedside microscopy creates all the necessary prerequisites to optimize patient management. Courses in bedside microscopy that are organized within the project and **centers of excellence established in Leningrad Oblast and St. Petersburg**, including the **training centre at DO Ott Institute of Obstetrics and Gynecology, RAMS** demonstrated that the approach is effective and acceptable by both physicians and the patients.

**Standard methodological materials and standardized protocols** prepared for microscopy of genital smears both in case it is used in clinic and in the laboratory allow unifying testing and presentation of the test results. The result then responds to the need of the physician, which positively affects the quality of the diagnosis.

**Standard protocols examining patient risk factors** are time saving and retrieving one and the same information, regardless of the medical institution that the patient may visit. Moreover, standard protocols facilitate information exchange between the treating physicians, which is important if the patient changes physician.

**Standard patient management algorithms and patient management guidelines** that have been elaborated during the project make it possible for the standardization of patient management routines and facilitate locating information regarding treatment. They also allow the possibility of presenting unified information to the patient regarding disease and measures to eradicate the disease. If consultation of other specialists or laboratories is needed, these are also presented in the STI management algorithm.

## FINAL CONCLUSION

The project run in Leningrad Oblast and St. Petersburg **created a network among specialists** and professional activities that are related to infections of reproductive health, including STIs. Project participants identified a number of inadequacies in STI management and had a possibility to participate in resolving these deficiencies. The number of standard protocols and methodologies prepared during the project created the necessary prerequisites to improve the situation. Project sustainability is assured through the legalization of the standards and methodologies

at different administrative levels and educational institutions. Project achievements will be internationalized through the **International network for Sexual and Reproductive Health**. Establishment of the **Russian Network for Protection of Reproductive Health** will assure that the improvements reach other regions of Russia and will put pressure on the local and central health administration.

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