

**Updated protocol for the planned EUROCHIP-3 work
BULGARIA
AUGUST 2010**

In the last 20 years, the incidence and mortality from cervical cancer in Bulgaria have risen constantly, which is in sharp contrast to the steady decline in most European countries. Up to the late 1980s mortality rates from cervical cancer in Bulgaria were comparable to the rates of many EU countries. A dramatic increase in mortality rates is observed during the political and socio-economic reforms of the last two decades. Thus in 2007, 1097 new cases of cervical cancer, were registered. Cervical cancer is responsible for 7.3% of all cancer cases in females, after breast cancer, non-melanoma skin cancer, colorectal cancer and corpus uteri cancer. In 2007, as well as in the last 20 years, approximately 30% of the new cervical cancer cases are in advanced (III + IV) stages.

This situation of increasing incidence and mortality rates is due to the fact that the State funded health care system existed before 1989, has been dismantled. The population based screening programme of the past has been replaced by opportunistic screening that requires substantial personal initiative of both the providers and the clients. Currently, Bulgaria has no national programme for cancer prevention, however, there are ongoing efforts to develop one. There are some local initiatives for free of charge preventive check-ups that are undertaken rarely and unsystematically.

The absence of institutionally structured preventive programmes creates significant barriers in access to regular smear tests. A study on psychosocial aspects of cervical cancer screening in Bulgaria has shown that the most important barriers women face are the unwillingness of doctors to offer and to perform Pap smears, the unpleasantness of the gynecological visits, and the lack of information.¹

Previous research under EUROCHIP 2 project has shown that in Bulgaria there is lack of instructions and organization for implementation of organized population based screening programme (see Annex 06, part 1, Final Scientific Report, EUROCHIP II)². Currently, guidelines for good practice, based on the European guidelines for quality assurance in cervical cancer screening, have been worked out but not implemented in practice, yet³. The above mentioned research has shown that there are a lot of problems regarding quality control at cytological laboratories, as well. Although the research was limited at two main laboratories in the country (see Annex 06, part 2, Final Scientific Report, EUROCHIP II), it was the first survey on "certain components of the internal quality control through re-screening and a comparability test and of the external quality control through a qualification test and a smear exchange test".

In June 2009, when WP4 participants of EUROCHIP-3 were proposing their action plans, the situation in Bulgaria was quite optimistic regarding cervical cancer screening and especially the implementation of a population-based screening program, in comparison to the

¹ Avramova L, Alexandrova A, Balabanova D, Bradley J, Panayotova Y, Todorova I: *Cervical cancer screening in Bulgaria: Psychosocial aspects and health systems dimensions*. Sofia: Health Psychology Research Center & Engender Health; 2005 (in Bulgarian)

² available at: http://www.tumori.net/eurochip/material/Report/EUROCHIP-2_Final_report/Annex_06_EUROCHIP-Bulgaria.pdf

³ Guidelines were prepared by Bulgarian experts, including Zdravka Valerianova, Nikola Vassilev and Victor Zlatkov, under the 'STOP and GO for a Check-Up' project.

situation today. At that time it looked that there were enough political will and public awareness in the country and the only missing piece was the implementation of the (proposed in 2007) program. Moreover, in May 2008 the “STOP and Go for a Check-up” project⁴ was approved and funded by the European Social Fund, Human Resource Development Program (№ BG 051PO001– 5.3.02.-0001-C0001).

The ‘STOP and GO for a Check-Up’ project has been initiated and developed by the Programs & Projects Management Directorate of the Bulgarian Ministry of Health. It took the project managers a lot of time and effort to convince the Ministry of Health and other authorities about the merits of the programme and to raise political support for it. Many organisations and specialists in oncology and public health were involved in the development of the project including the Bulgarian Cancer Registry, Bulgarian Association of Oncogynecology, leading specialists in oncology, etc. The application was submitted to the Human Resources Development Program of the European Social Fund and it was approved with a budget of 19 558 281.73 leva (about 10 million Euro) starting date in May 2009 and ending date in September 2010. It is important to note, that this is the first project of national scope after 1989 that aims to make changes in cancer prevention as a whole with the end point being the start of a national population-based screening programme for breast, cervical and colorectal cancers.

Taking into account the situation in the country regarding cervical cancer screening and the already existing scientific research, including previous study within the EUROCHIP 2, it looked quite evident to the Bulgarian team in EUROCHIP-3, that activities should be connected with the “STOP and GO for a Checkup” project. Therefore, we proposed an action plan with the following main activities (see Annex 10 ??...):

- ❖ To support in all possible means the development of a Screening registry;
- ❖ To design and carry out a survey on adherence to the project screening activities;
- ❖ To disseminate EU Guidelines and survey results to the public, medical groups, and decision-makers.

According to the initial time-line of the “STOP and GO for a Check-up” project all the preparatory activities should be fulfilled until February 2010. The Screening registry was planned to be created and tested at the end of 2009. Inviting women and performing screening tests were planned for March and April 2010. Unfortunately, due to many different circumstances, including numerous political changes in the country, the initial schedule was not followed and project managers had to ask twice for extension of the project. Currently, the STOP and GO for a Check-up project has deadline in October 2011, but the main activities have not been started yet.

All these circumstances set the Bulgarian team in an uneasy situation of not being able to carry out the initial action plan, proposed to the EUROCHIP 3, WP4 leaders in June 2009. Looking at the current situation, and after a discussion with the EUROCHIP 3 leaders in Sofia, we are now proposing the following plan for action:

⁴ The official name of the project is *National Campaign for Early Diagnostics of Cancer*. It has been accepted and signed by the Minister of Health and the Minister of Labor and Social Policy, under the operative program Development of Human Resources of the EC (BG051PO001 -5.3.0)

1. Develop and carry out a survey among the cytological laboratories throughout the country regarding their resources and quality control.

Although there was a study on cytological laboratories under the EUROCHIP 3 project, it has a limited scope in regard to the number of laboratories and their resources and activities laboratories. Currently there are 13 laboratories throughout the country, based at the oncological dispensaries and one laboratory, based at the National Oncological Hospital. There is no National referent laboratory. Currently, these laboratories are working separately, they are not obliged to report their results to a higher level, there is no screening registry and not unified methodology for control.

However, these laboratories are expected to be in charge for the cytological testing for the "STOP and GO" project and in the future, for the population-based screening program. Under the "STOP and GO" project, these laboratories would be provided with software, their staff should be trained for registration of the smears according to the requirements of the screening registry and asked to handle with at least 50 000 smears that the project foresees.

Therefore, it would be really important to compare the capacity and practices in all the laboratories, as well as to provide their staff with feedback on their situation. For that reason, we propose to organize and carry out a study among the staff of all 14 laboratories, in order to assess their current state and to obtain detailed and updated information on the main problems. This study would provide the management of the "STOP and GO", as well as the Ministry of Health with updated and reliable information on the capacity and quality that these laboratories could currently provide and what should be done in the coming future in order to follow the European recommendations.

This study would give missing at present information on a crucial element of a screening system – the current state of cytological laboratories in Bulgaria, their problems and needs. A report on the main difficulties and recommendations for overcoming them would be prepared and disseminated.

METHODS: For the aims of this study, a detailed questionnaire would be developed, based on the European guidelines for quality assurance in cervical cancer screening. Questionnaire would focus on the physical and human resources of the labs, their documentation, reporting system, protocols, time management, administration, quality control and linkages within the health system. Information collected from the study would be analyzed. Recommendations would be prepared. At the end of this phase, a round table would be organized for dissemination of the results among the lab staff and health authorities.

TIME LINE:

Activity	Starting date	Final date	Notes
Questionnaire preparation – paper based and electronic version	Sept 2010	Nov 2010	Questionnaire was approved by the Bulgarian group of experts (Annex 1)
Contact Lab directors and sending the preferred version of questionnaire	Dec 2010	Feb 2011	
Return of the questionnaires	Feb 2011	April 2011	
Analysis and Recommendations	April 2011	May 2011	
Round table to disseminate results	-	June 2011	

- 2. Prepare and carry out a survey among women diagnosed with cervical cancer in the last 3 years (2008-2010). The aim of this survey is to obtain better information on:**
- a. Women’s Pap smears history prior the diagnosis**
 - b. Main barriers for not getting regular Pap smears throughout the country**

According to the European guidelines for quality assurance in cervical cancer screening (second edition, 2008):

“If registration of opportunistic smears is not available, information on opportunistic screening can be collected using questionnaire or interview surveys. When diagnosing a cancer case, information on previous smears, including opportunistic smears should be checked. Re-reading of the previous smears can be performed at this phase to give feedback on potential false-negative result. This activity will serve more an educational rather than an epidemiological purpose, unless controls and blind review of the slides are added. If there is no register-based source, the completeness of such activity cannot be assured.”⁵

In the Bulgarian context currently it is not possible to ask for re-reading of previous smears, because of the lack of screening registry. However, it would be really useful to test if women diagnosed with cervical cancer had their smears in the last years. Therefore, we would ask several obstetricians, working at the cancer prevention offices in the oncological dispensaries in the cities with higher cervical cancer incidence rates, to cooperate for getting information from women newly diagnosed with cervical cancer. We would provide them with a short questionnaire and they would ask and help women to fill it. These local obstetricians would gather information from women for six months (January 2010 – May 2011). In addition, few personal interviews would be performed in order to give better understanding on the patient way throughout the system. Information would be analyzed and used for the final report.

Getting this kind of information would be important input to the existing information on cervical cancer prevention in the country. There is no study on women’s history in Bulgaria. The results and some of the interviews might be used for a material in CancerWorld /ESO.

TIME LINE:

Activity	Starting date	Final date	Notes
Questionnaire preparation	-	Jan 2011	Questionnaire was approved by the Bulgarian group of experts and Ahti Antila (Annex 2)
Contact obstetricians in the dispensaries - sending the questionnaire and instructions for the survey	Feb 2011	March 2011	
Return of the questionnaires	-	June 2011	
Analysis and Recommendations		August 2011	
Reporting results		September 2011	

⁵ Web page p.39

3. Dissemination of the Bulgarian guidelines for good practice, based on the European guidelines for quality assurance in cervical cancer screening among the health specialists involved in the cervical cancer prevention within the oncological dispensaries.

In the first action plan for EUROCHIP 3 we were planning to cooperate with the “STOP and GO” management for dissemination of full translation of the European guidelines for quality assurance in cervical cancer screening in Bulgarian. Meanwhile, it became clear that under the “STOP and GO” project it won’t be possible to fund the translation of the Guidelines due to some limitations of the contract with the European Social Fund. However, there are already worked out guidelines for good medical practice, prepared for the purposes of the “STOP and GO” and based on the European guidelines. This document might be disseminated instead of the Bulgarian translation among health authorities and medical specialists.

The Bulgarian guidelines for good practice would be disseminated and discussed at the Round table, organized for discussing the results of lab survey.

**Annex 1 - Questionnaire for Cytology Laboratory Directors
Assessment of the Quality Control and Competency of the Staff⁶
Bulgaria 2010**

Information for participants:

Dear Colleagues,

You are invited to participate in a study, directed to the laboratories involved in the cytology testing within the oncological network throughout the country. This study is part of the EUROCHIP-3 project and funded by the EC. EUROCHIP is focused on the main elements of cancer control: primary prevention; early detection (screening), treatment, follow up and registration of cancer cases. The EUROCHIP aim is to cooperate for improvement of the cancer control organization in individual countries and to propose steps for better prevention and control. More information on the project and its aims could be find at the project website: <http://www.tumori.net/eurochip>.

Within the Eurochip project every participating country has a local group of experts, working in cooperation with the Ministry of Health and other institutions. In Bulgaria, the main partner is the Bulgarian National Cancer Registry.

The aim of the study you are invited to participate, is to gather up-to-date information on the laboratory conditions and practices, regarding cytology diagnostics for cervical cancer. MENTION WHICH SAMPLES ARE TO BE INCLUDED FOR THE CURRENT QUESTIONNAIRE. Results would be summarized and presented to the health authorities and general public. Recommendations for improvement would be proposed. Within the International Cervical Cancer Prevention Week (23-29 January 2011) you would be invited at a round table to discuss the results of this study.

Your participation in the study is anonymous. Data would be presented in a summarized form, without mentioning specific laboratories and names of the staff.

You could choose to fill either a hard copy, or electronic version of the questionnaire. If you want to be provided with an electronic version, please contact our coordinator, Yulia Panayotova at the following e-mail adress: jupanajo@gmail.com. In case you prefer the hard copy, please send the filled form back not later than Dec. 15th at the following address: Sofia, 6 Plovdivsko Pole Str. National Oncological Hospital, Dr. Valerianova.

Thank you for cooperation! We highly appreciate your participation!

Sincerely,

Zdravka Valerianova, PhD, Director of the National Oncological Hospital

⁶ This questionnaire is based on the European guidelines for quality assurance in cervical cancer screening, (Arbyn M, Anttila A, Jordan J, Schenck U, Ronco G, Segnan N, Wiener H, Herbert A, Daniel J, von Karsa L (eds). European Commission (2008) *European Guidelines for Quality Assurance in Cervical Cancer Screening - second edition. Office for Official Publications of the European Communities, Luxembourg*)

Human Resources:

- ❖ When the laboratory has been established? year
- ❖ How many people are working currently in the lab?
- ❖ What is their qualification? How many:
 - Patho-anatomists –
 - Cyto-technicians –
 - Biomedical scientists –
- ❖ Are there part time members of the staff?
 - Yes
 - No
- ❖ How many?
 -
- ❖ What are their specialties?
 -
- ❖ Is the staff involved in testing of different types of specimens?
(Are these people involved only in cervical pathology?) which types of specimens?
Yes/No;
if yes >YOU SHOULD SPECIFY WHICH SAMPLES ARE TO BE INCLUDED TO FILL-IN THE
QUESTIONS AFTER THIS (GYNAECOLOGICAL/CERVICAL SMEARS ('pap smears'));
WHAT ABOUT IN TOTAL?) Note that a laboratory can have many different kinds of
cytological or histological samples, not only the pap smears
- ❖ How many people were working in the lab in the following years? For pap-smears; in
total (--- or do you want to ask only for pap smears....?)
 - 1970:
 - 1980:
 - 1990
 - 2000
 - 2005
- ❖ What is the structure of lab professionals (hierarchy) Yulia, how to answer to this?
Note that also working time consumption could be asked (how many of those staff;
how many full-time, how many part-time; if part-time what is the work time
proportion) Specify: For pap-smears; and in total?
 - Director
 - Senior pathologist(s)

- Consultant Cytopathologists
 - Senior laboratory technicians
 - Staining technicians
 - Biologists and/or laboratory technicians
 - Secretary
 - Other (please, specify)
- ❖ Is there continuous education for the lab staff? Note can vary by profession, ask to describe that, too, using the above positions). Also, specify internal or external education (for the latter, where?)?
- Yes
 - No
- ❖ Which of the following ... is available to the staff in the lab?
- up-to-date cytology textbooks
 - subscription or online access to one or more of the cytology journals
 - participation in regular meetings on review cases (specify if cytological; or cyto-pathological samples included)
 - attending workshops and symposia
 - regional inter-laboratory slide review sessions
 - performance evaluations
 - participation in proficiency testing
 - teaching cytotechnology students, pathology residents and fellows

You could ask whether there are multihead microscopes available regular meetings on review cases, or if they are used for the final cytological diagnosis (consultation between cyto-pathologist and cytotechnician).

WORKING CONDITIONS:

- ❖ Do you have a specific building for the lab?
- Yes /No
- ❖ Was the building constructed for this purpose?
- Yes /No /I don't know
- ❖ Whose property is the building?
- Governmental Municipal Private Other (please specify)
- ❖ In how many rooms the facility is located?
-

- ❖ Are there separated:
 - Screening room - Y/N
 - Sample-preparation room - Y/N
 - Secretarial room - Y/N
- ❖ Are all of the facility enough:
 - Lighted - Y/N
 - Ventilated - Y/N
 - Quiet - Y/N
 - Spacious - Y/N
- ❖ Is the lab equipped with effective exhausted system? - Y/N
- ❖ Is the lab equipped with enough storage containers? - - Y/N
- ❖ What type of staining do you use?
Automatic / Manual

MICROSCOPES:

- ❖ How many microscopes do you have?
- ❖ Please specify their type (mention also if you have multihead microscopes – with how many heads):
.....
.....
- ❖ Are all of them working properly?
- ❖ How often do you check them for adequacy of the stage and objectives
 - Every ... days
 - Monthly
 - Yearly
 - Less than once an year
- ❖ Do you have computerized system for recording cytological results?
 - Y/N
- ❖ If, NOT How do you record your results?

On paper (text book) on journal Other (specify)
- ❖ Who have access to these documents?
.....

Archiving

- ❖ Who is responsible for administration and archiving of request forms, samples and written and/or computerized reports.

- ❖ Is there any national legislation, these procedures must comply with?
Y/N/ don't know
- ❖ Are there any procedures assuring patients' data security?
Y/N/ don't know
- ❖ For how long are the request forms or their electronic equivalents stored?
 - not stored
 - 6 months
 - 1 yaer
 - 5 years
 - 10 years
 - Other (please, specify)

- ❖ For how long are the slides stored?
 - not stored
 - 6 months
 - 1 yaer
 - 5 years
 - 10 years
 - Other (please, specify)

- ❖ How are different procedures allocated to the staff? Who is responsible for/doing:
 - Description of the specimen -
 - Staining -
 - Primary assessment of the specimen's quality -
 - Primary screening -
 - Re-screening -
 - Additional assessment of the positive smears -
- ❖ Is every specimen accompanied by request form?
 - Y/N
- ❖ Is there unified request form that you use? (Please, attach one to the questionnaires)
 - Y/N

- ❖ (Labeling) Do you give unique identification number to every sample?

- ❖ What protocol do you use for staining?
 - the standard Papanicolaou protocol....
 - Other (please, specify)
 - Don't know

- ❖ Is there any control of staining procedure?
Y/N

Assessment of the Sample

- ❖ What kind of specialist is doing the primary screening?
 - Which classification system do you use in the lab?
.....
- ❖ According to your knowledge, is there a national standard classification system?
 - Y/N/Don't know
- ❖ If "yes", which is that system? Ако отговорът на предния въпрос е „да“, коя е тази система?
 - PAP
 - Bethesda
 -
 - Other (please, specify)
 - Don't know
- ❖ Could the system used in the lab be transformed to Bethesda?
 - Y/N/Don't know
- ❖ Do you include information on the quality of the cervical sample?
Y/N/Don't know Specify the reported classes for this: _____
- ❖ Do you include recommendations for further action (repeat smear, colposcopy, etc.) in the protocol?
 - Y/N/Don't know
- ❖ Is the identity of the cytotechnologist/cytopathologist available on the document, issued from the lab?
 - Y/N/Don't know

Samples for second screening assessment

- ❖ What type/kinds of samples are referred for re-screening? (**more than one answer is possible**)
 - Samples with inadequate/unsatisfactory quality
 - Samples with any cellular abnormalities leading to a specific recommendation
 - Samples with previous recommendations for a repeat or reference for gynaecological, colposcopic and histological examinations
 - Quality control related slides.
- ❖ What is qualification of the person who performs re-screening in your lab?
 -

Workload requirements – primary screening

- ❖ How many pap smears per day is a normal workload in your laboratory (as a whole)?
.....
- ❖ How many pap smears per person daily is a normal workload (specify separate if some are working part-time)?
.....
- ❖ How many slides per woman are tested? What does this question mean?
.....
- ❖ What is the average time (in minutes) for the reviewing one pap smear by the cytotechnologist?
.....
- ❖ How many pap smears per year have been tested in this lab in the following years? (if data available)
 - 1970:
 - 1980:
 - 1990:
 - 2000:
 - 2005:
 - I don't know
- ❖ Are there any standards for the workload of laboratory specialists in the country?
 - Y/N/ Don't know
- ❖ How many hours is the standard working day in the lab? If full-time?
.....
- ❖ Does it often happen that a staff member works more than two hours without a break?
- ❖ How are the records of the primary screening assessment kept?
- ❖ Who has access to these results?
- ❖ Are some of the following items included in the patients' records?
 - Patient identification data
 - Name, address and ID number of the laboratory
 - Date of sampling; sample-taker; sample-taking unit
 - Date of arrival of the smear in the laboratory
 - Indication for examination: screening, follow-up or clinical indication
 - Type of examination: cytological, histological or virological
 - The results of the laboratory examination in accordance with the current standard classification system.

- Judgment of the quality/adequacy of the preparation
- Advice for repeat sample or referral
- Date of the final report
- Name of the person or persons who evaluated the sample

❖ Who is responsible for the information in the records and its completeness?

- Director
- Senior pathologist
- Consultant cytopathologists
- Senior laboratory technicians
- Staining technicians
- Biologists and/or laboratory technicians
- Secretary
- Other (please, specify)

❖ Who confirms the result of the pap smear test?

..... What does this question mean? Does it mean who makes the final diagnosis?? (i.e. cytopathologist for abnormal smears; cytotechnician for the most of normal results??)

❖ When the pap smear test results should be reported?

- In 24 hours
- In 48 hours
- Up to 5 days
- Up to 10 days
- Up to one month
- Other (please, specify)

❖ To whom does your laboratory report the results of the pap smear tests?

-

❖ Do you report the negative results to women? If not, does someone else report?

How?

- Y/N

❖ How do you report the positive results to women? +How? (by a letter; also by phone/face to face...?)

-

❖ According to the current organization of the lab, is it possible to:

- link multiple test results for the same patient

Y/N/I don't know

- Provide easy access to details about previous cervical cytology and histology of the patient
Y/N/I don't know
- Provide a mechanism for ascertaining and recording clinical outcome after cytology tests
Y/N/I don't know
- Provide the data necessary for evaluation of the screening program.
 - Y/N/I don't know

Quality management/ quality assurance

- ❖ Is there a person who is trained in collecting and managing documents, process descriptions and manuals?
 - Y -> (is this person from the laboratory staff or is external quality manager?)
 - N
- ❖ Do you use any handbooks with practical guidance on quality assurance?
 - Yes (Please, specify)
 - No
- ❖ Are any of the following documents available in the laboratory?
 - Overview of the screening laboratory
Y/N
 - Description of personnel organisation (including levels of competence and responsibilities of each person, lines of communication and structure of management documents
Y/N
- ❖ What kind of methodology for internal quality control of cytology do you use?
 - Methods based on re-screening of slides
 - Methods based on monitoring screening detection and reporting rates,
 - Methods based on correlation of cytology with clinical/histological outcome
 - Other methods (please, specify)
 - We don't use any methods for internal quality control
 - I don't know

If you do not use re-screening, please skip the next question. If you use rescreening, which of the following **re-screening procedures** are in use?

- rapid reviewing of smears initially reported as negative or inadequate,
- rapid preview/pre-screening of all smears,
- random re-screening (full re-screening of a 10% random sample of smears reported as negative or unsatisfactory),
- targeted re-screening of specific patient groups,

- seeding abnormal cases into the screening pools,
 - seeding abnormal cases into the re-screening pools,
 - retrospective re-screening of negative cervical cytology specimens from patients with a current high-grade abnormality (targeted reviewing)
 - automated re-screening of smears initially reported as negative
- ❖ Is the lab certified according to national safety standards?
 - ❖ Which standard? And when approved a) for the first time. And b) most recently

External quality control of screening skills

- ❖ Which of the following procedures have been applied to your laboratory?
 - Proficiency testing
 - Accreditation
 - Recertification
 - External quality assurance via test cases
 - Monitoring laboratory and personal reporting rates for high-grade and low-grade cytological abnormalities and comparing results with national standards

Responsibilities for quality control

The laboratory manager is responsible for the quality system and for the approval of working guidelines and procedures.

Communication

- ❖ Does your laboratory exchange information and follow-up data with other laboratories?
- ❖ Do you communicate with sample takers?
Y/N
- ❖ Do you inform sample takers on their percentage of less-than-satisfactory or unsatisfactory cell samples?

Y/N
- ❖ Do you send a copy of the cervical smear results to the woman's GP?
Y/N
- ❖ Do you send cytological and histological records to the regional or national screening/cancer registry?
Y/N
- ❖ How often?
 - Twice in a year
 - Yearly
 - Every two years
 - More rare (please, specify)
 - Do not send
 - I don't know

- ❖ Do you have to inform women of their results of the smear?

Y/ N

The following questions are in regard to the STOP and Go for a checkup project?

- ❖ Do you think that the laboratory has (available) capacity for testing more pap smears than now?

Y/ N

- ❖ How many additional pap smears could be tested in the lab monthly?

○

- ❖ If it is a matter of choice, would your lab participate in a population based screening program? Why?

Yes - > why?

No - > why?

- ❖ If a population based screening program is implemented in the country, do you think that your lab would meet the European requirements for quality assurance??

Y/ N

Thank you very much for your participation!

We highly appreciate your opinion!

.....

We haven't included any questions on funding. Probably we might add something ...

The following questionnaire aims at collecting data about you, for sample characterization purposes only. They will be used for statistical procedures and anonymity and confidentiality are guaranteed.

I. Demographic questions:

Age: _____ years

Sex: Male Female

Specialty: _____

How long have you been practicing in cytological lab? : _____ years

How long have you been practicing in this laboratory? : _____ years

Annex 2

Dear Mrs/Ms,

You are invited to participate in a study on cervical cancer in Bulgaria. This study is part of the EUROCHIP-3 project, funded by the EC. EUROCHIP is focused on the main elements of cancer control: primary prevention; early detection (screening), treatment, follow up and registration of cancer cases. The EUROCHIP aim is to cooperate for improvement of the cancer control organization in individual countries and to propose steps for better prevention and control. More information on the project and its aims could be find at the project website: <http://www.tumori.net/eurochip>.

Within the Eurochip project every participating country has a local group of experts, working in cooperation with the Ministry of Health and other institutions. In Bulgaria, the main partner is the Bulgarian National Cancer Registry.

The aim of the study in which you are invited to participate, is to evaluate the history of Pap-smear of women recently diagnosed with cervical cancer. You would be asked to answer few questions on your experience with Pap smears in the previous years, and subsequent treatment, if any. Your physician would ask you to complete a short self-administered anonymous questionnaire, provided by our research team. Your experience and opinions are very valuable and they can help us learn more about the research topic.

Your contribution to this research is voluntary and you can choose not to participate if you don't want to. There are no direct benefits to you for participating in the study. Your participation in the study is anonymous. Data would be presented in a summarized form, without mentioning names of participants. You must be at least 18 years old to be in this research project.

Thank you for cooperation! We highly appreciate your participation!

1. When were you diagnosed with cervical cancer?
2. At what stage was the cancer at diagnosis?
3. What was the exact diagnosis (e.g. try to collec data if it was a squamous-cell carcinoma; or adenocarcinoma; -- or do you get that kind of info otherwise??
4. Have you ever been tested for cervical cancer using PAP-smears?

YES

NO

5. How often do you used to go for PAP-smear in the past? (Needs more detailed formulation,. So that it would be clear if it was just for the current diagnostic episode; or as a preventive action before the current diagnosis (see below).
6. When was your last PAP-smear prior the diagnosis? (see the comment above... can you specify/structure the question in more detail?)
7. Have you ever had abnormal results from your Pap-smear tests?

NO -> Go to Q7

YES -> How many times?

When was the last time you had abnormal results from your Pap-smear test?

What were the recommendations of your physician?

- No treatment + another PAP-test in 3/6 months
- Prescribed treatment and new PAP-test in 3/6 months
- Colposcopy
- Biopsy
- Surgical treatment and follow-up

Did you follow physician's recommendations? Do you need this?

YES

NO

When was the first time? What was the recommendation?

8. Have you ever heard of screening programs for preventing cervical cancer?

YES

NO

If yes: when? Where? From whom?...

9. Do you think they are effective?

10. Would you participate in such program, if available?

11. Would you recommend regular PAP-smears or participation in screening programs to your relatives and friends?

YES

NO

For further information on project aims and results, you could contact ...

If you do not mind, you could also leave your contact information. Our team might want to contact you for few more additional questions.

Demographic data:

Age:

Sex:

Education:

Current occupation: