# European Union survey on organization and quality control of cervical cancer screening and HPV vaccination programs

# Introduction to the Survey

The purpose of this project is to collect information regarding the organization of cervical cancer screening and HPV vaccination programs in European countries as well as quality control efforts within these programs. This survey is part of the European Union PREHDICT study which seeks to determine optimal strategies for cervical cancer screening and HPV vaccination in European countries (more information <u>here</u>). As a first step, we need to understand how organized cervical screening and HPV vaccination programs operate, in particular how they perform quality control to ensure effectiveness of programs in preventing cancer.

For this purpose, we are requesting your participation in this survey. If you cannot fill out some sections, note the reason in the space provided. We understand that programs may be undergoing changes so in filling out the survey, please answer according to how the program currently works. In general, we are interested in national level information. However, if program implementation differs significantly across regions in your country, please describe differences and provide details on region-specific programs.

Thank you for agreeing to participate in this survey and taking the time to respond to all the questions included. The results will be instrumental in characterizing current quality control efforts in screening programs and providing recommendations on quality control for the benefit of EU member countries. The information provided by you in this questionnaire will be used for research purposes and results will be presented by country, not by individual responder.

Your response and any attachments should be sent to Miriam Elfström at <u>Miriam.Elfstrom@ki.se</u>. Do not hesitate to call or email with questions or concerns:

Joakim Dillner, M.D., Professor Department of Medical Epidemiology and Biostatistics Karolinska Institutet, Stockholm, Sweden

Phone: +46 768 871 126 Joakim.Dillner@ki.se Miriam Elfström, MPH, Project Leader Department of Medical Epidemiology and Biostatistics Karolinska Institutet, Stockholm, Sweden

Phone: +46 8 5248 7999 Miriam.Elfstrom@ki.se



# PREHDICT ORGANIZATION & QUALITY CONTROL QUESTIONNAIRE

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# 1) Screening program organization, infrastructure, & operational costs

#### Organization of the screening program – program status<sup>1</sup>

- 1) Is cervical cancer screening offered to women through a publicly mandated program? (Note: program screening requires public responsibility, coordination, supervision) (Respond Yes or No)
  - a) If yes, please provide the relevant information for the following (i-vi):
    - i) The law, official regulation, decision, directive or recommendation that provides the public mandate to implement the program (*Please describe*)
    - ii) The authorized screening test (Please list)
    - iii) The authorized examination interval (Please describe)
    - iv) The eligible group of persons (target age range, and further eligibility criteria, if any) (*Please describe*)
    - v) The source of public financing for participation in screening (Please list)
    - vi) The level or amount of co-payment required from the participant, if applicable (Please give amount)
- 2) Is the program "organized", i.e. does it:
  - a) Provide for a national or regional team responsible for implementation (coordinating service delivery, quality assurance, and reporting of performance and results)? (*Respond Yes or No*)
    - i) If yes, please give the name of the institution/organization and level (national, regional, local, other) where team(s) is/are based (*Please describe*)
  - b) Require service providers to follow comprehensive guidelines, rules and standard operating procedures? (*Respond Yes or No*)
  - c) Define a quality assurance structure and mandate supervision and monitoring of most steps in the screening process (invitation, testing, diagnosis and follow-up of screen-positives)? (*Respond Yes or No*)
  - d) Require ascertainment of the population disease burden to monitor and evaluate the program? (*Respond Yes or No*)
- 3) Is the program population-based, i.e., is each eligible person in the target population identified and personally invited (written invitation) to attend a given round of screening? (*Respond Yes or No*)
  - a) If yes, please respond to the following questions:
    - i) What is the target population and what are the exclusions (if any)? (*Please describe*)
    - ii) What institution or organization is responsible for sending invitations and what database(s) is/are used as the source(s) of data for invitations? (*Please describe*)
    - iii) What implementation phase is the program currently in? (Mark X next to the phase the applies to your program)

-Rollout complete - at least 90% of eligible target population has been personally invited (written invitation) at least once

-Rollout on-going - personal invitations have been sent to less than 90% of the eligible target population

-Piloting - routine screening has not yet started but population-based screening is being piloted

<sup>&</sup>lt;sup>1</sup> For definitions see von Karsa et al. 2008

-Planning phase - policy to implement population-based screening has been officially adopted and planning has started -Other (*Please explain*)

b) If no, and only part of the eligible population is invited, please explain the procedure:

#### Organization of central screening office

- 1) At what level is the screening program administered? (*Please choose: National, Regional, Local, or Other. If you choose Other, please explain*)
- 2) What are the aggregate annual costs of the screening program in Euros or in the currency of your country, broken down by the following items? (*Enter cost after each item and note currency*)
  - a) Program implementation
    - i) Invitations (Cost and currency)
    - ii) Smear-taking (Cost and currency)
    - iii) Processing and interpreting samples/slides (i.e. laboratory costs including mail/transportation costs) (*Cost and currency*)
    - iv) Follow-up and treatment (Cost and currency)
    - v) Registration and communication of results (Cost and currency)
    - vi) Monitoring and evaluation of the program (Cost and currency)
    - vii) Total cost cannot be itemized, but includes (Please specify and give cost and currency)
  - b) Office(s) of the organized screening program
    - i) Personnel salary and wages (Cost and currency)
    - ii) Equipment (Cost and currency)
    - iii) Supplies (Cost and currency)
    - iv) Facilities and administration (Cost and currency)
    - v) Total cost cannot be itemized, but includes (*Please specify and give cost and currency*)
  - c) Other costs, including (Please specify items, cost and currency)
  - d) Total cost cannot be itemized, but includes (Please specify total cost and list)
- 3) How many staff members are required to run the office of the organized screening program?
  - a) Program management (Please note number of staff)
  - b) Research staff (Please note number of staff)
  - c) Other (Please note number of staff)
- 4) Are staff responsibilities documented? (If so, please attach a description of position titles and responsibilities when sending in the completed survey) (Respond Yes or No)
- 5) Is there a program mission statement and are there program guidelines? (If so, please attach copies when sending in the completed survey) (Respond Yes or No)

#### Communication in the program

1) What systems are used to communicate between the different parts of the screening program – administration, sample-taking, labs, diagnosis, treatment, follow-up, evaluation etc.? (*Please exemplify*)

# 2) Screening program quality control and effectiveness

1) Is there a screening quality assurance/quality control program in place? (*Respond Yes or No*) (If available, please attach copy of standard operating procedure(s) for measuring quality)

#### Scope of the screening program quality control (QC) efforts

- 6) At what administrative level is the QC program implemented? (*Please choose: National, Regional, Local, or Other. If Other, please explain*)
- 7) Are individually identifiable data collected systematically? (*Please respond Yes or No and add comments in the space provided if necessary*)
  - a) Cytology (Respond Yes or No, and add additional information if needed)
  - b) Histology (Respond Yes or No, and add additional information if needed)
  - c) HPV tests (Respond Yes or No, and add additional information if needed)

#### Data reporting

(If responded yes to question 2 above under "Scope of the screening program quality control effects", continue with the following questions)

- 1) How are cytology and histology data stored? (*Please explain and if routines differ across units within the country, please explain this as well*)
  - a) Are data regarding opportunistic and organized tests stored in the same manner? (Please explain)
- 2) How are data reported? (*Please choose: Reporting on paper & centralized digitizing; Reporting electronically;* Combination of paper reporting & electronic reporting; or Other. If Other, please explain)
- 3) Who is responsible for submitting screening data? (*Please describe*)
- 4) Who is responsible for compiling screening data? (*Please describe*)
- 5) Is there a system in place for data quality control checking? (Respond Yes or No)
- 6) What data quality control measures are evaluated?<sup>2</sup> (Mark X next to those that apply)
  - Comparability refers to the standardization of coding and classification systems

- Completeness – refers to the extent to which data on screening samples taken in the population are recorded in a registry database

- Validity refers to the accuracy of the diagnoses recorded in the registry
- Timeliness refers to the rapidity at which a registry can collect, process, and report sufficiently reliable and complete data
- 1. What is the frequency of data reporting?
  - a) Cytology labs (Please choose: Monthly, Quarterly, Annually, or Other. If Other, please explain)
  - b) Histology labs (Please choose: Monthly, Quarterly, Annually, or Other. If Other, please explain)
  - c) HPV labs (Please choose: Monthly, Quarterly, Annually, or Other. If Other, please explain)

#### Data analysis and programmatic use of data

1) Is there a system in place for analyzing screening data? (Respond Yes or No)

(If responded yes to previous question, continue with the following questions)

2) How often are screening data analyzed and data compiled? (*Please choose: Monthly, Quarterly, Annually, or Other. If Other, please explain*)

<sup>&</sup>lt;sup>2</sup> For definitions see Parkin and Bray, 2009.

- 3) Does the program produce a report? (Respond Yes or No)
  - a) If yes, how often? (Please choose: Bi-annually, Annually, or Other. If Other, please explain)
  - b) How is the report published? (Please explain)
- 4) As a result of collecting and analyzing screening program data, have changes been made to the screening program, and when were they made? (For example, changes may have occurred in the following areas: lab practices, clinical staff practices and training, invitation and individual follow-up protocols, data collection protocols etc. Please specify as many explicit examples as possible.)
- 5) If changes need to be made to the screening program, who makes the decision and how are they implemented? (*Please explain*)

#### Screening method used and indicators of sample quality

- 1) Who takes the samples? (Mark X next to those that apply)
  - General practitioner
  - Primary care nurse
  - Midwife
  - Gynecologist
  - Other (Please describe)
  - A mix of health care providers (Please describe)
- 2) What screening method is used? (Mark X next to those that apply)
  - Conventional cytology
  - Liquid based cytology
  - HPV testing
    - Primary HPV testing alone
    - Primary testing alongside cytology
    - HPV testing for triage of abnormal cytology
      - LSIL
      - ASCUS
    - -HPV testing for test of cure in treated women
    - Other (Please describe)
  - -Combination of methods (Please describe)
  - Other (Please describe)
- 3) What coding system for cytology and histology results is used by your system?
  - a) Cytology results (Please describe)
  - b) Histology results (Please describe)
- 4) If SNOMED coding is used, what is the protocol for translating the codes and who is responsible for the translation? (*Please describe*)
- 5) What specific indicators for sample quality are measured and how are they recorded in reporting? (Mark X next to those that apply)
  - a) Cytology
    - Sample adequacy indicators
    - Much blood
    - Many leukocytes
    - Few epithelial cells
    - Poor fixation

- Mechanical damage
- Thick sample layer
- No endocervical cylinder cells
- No squamous cells
- Few squamous cells and many endocervical cylinder cells
- Other (Please describe)
- b) Histology
  - Specimen type
  - Histological grade of lesion
  - Circumference and localization of the lesion
  - Uni/multifocal
  - Distance to the endocervical, ectocervical margins
  - Stroma involvement
  - Micro invasion
  - Other (Please describe)
- 6) How are these cytology and histology quality control measures used in program management? (*Please describe*)
- 7) What is the recommended follow-up of poor-quality smears? (Please describe)
- 8) What proportion of smears is re-taken as a result of poor quality? (Please describe)
- 9) Has your screening program produced evidence supporting the use of specific quality indicators that result in a reduction in invasive cervical cancer cases? (*Respond Yes or No*)
  - a) If yes, please describe:

#### **Programmatic indicators**

- 1) Invitations and sample-taking:
  - a) How do you ensure that the correct women are having smears within the recommended timeframe? (*Please describe*)
  - b) How do you avoid excessive sample-taking? (Please describe)
  - c) Who communicates with women regarding their test results? (Please describe)
- 2) Who oversees and carries out the referral process? (Please describe)
- 3) Coverage and compliance:
  - a) How is screening program coverage calculated in your program? Specifically:
    - i) What is used as the numerator? (i.e. number of women screened at least once in defined interval) (*Please describe*)
    - ii) What is used as the denominator? (i.e. number of resident women in target population) (*Please describe*)
    - iii) Is coverage calculated by 5-year age groups? (Respond Yes or No)
    - iv) Is coverage calculated separately for subgroups of women? (Respond Yes or No)
      - (1) If yes, please mark X next to all subgroups accounted for in coverage calculations:

-Invitation status -Personally invited -Not personally invited

#### -Unknown

#### -Program status of test performed -Within organized program -Outside organized program -Unknown

- b) How is screening compliance calculated in your program? Specifically:
  - i) What is used as the numerator? (i.e. number of invited women in given period who were screened) (*Please describe*)
  - ii) What is used as the denominator? (i.e. number of invited women in that period) (*Please describe*)
  - iii) Is a cut-off period used after the end of the respective screening period to assess compliance? (i.e. if women are to be screened every 3 years, compliance can be calculated based on a time period of 3 years and 6 months) (*Respond Yes or No*)
  - iv) If yes, what cut-off period is used? (Please describe)
- c) What is the population coverage of the screening test in the target age groups in your country? (*Please describe*)
- d) Are opportunistic and organized sample-taking integrated into the screening program monitoring and invitation system? (*Please describe*)
- e) What proportion of samples is taken outside the organized program? (*Please describe*)
- 4) Turnaround time:
  - a) What is the median time from when the smear was taken to when the woman receives the result? (*Please note, we are interested in the actual recorded time from smear taking to notification of results, not the recommended time*) (*Please give average number of days*)
  - b) What is the median time from abnormal sample to colposcopy in your country? (*Please note, we are interested in the actual recorded time from abnormal sample to colposcopy, not the recommended time*) (*Please give average number of days*)

#### Cost of screening quality control program

- 1) What are the costs of maintaining the quality control program? (Enter cost after each item and note currency)
  - a) Data collection (Cost and currency)
  - b) Data analysis (Cost and currency)
  - c) Slide review (Cost and currency)
  - d) Lab staff training and certification (Cost and currency)
  - e) Lab certification
    - i) Cytology (Cost and currency)
    - ii) Histology (Cost and currency)
    - iii) HPV testing (Cost and currency)
  - f) Other (*Please specify and give cost and currency*)
  - g) Total cost cannot be itemized, but includes (*Please specify and give cost and currency*)

#### 3) Screening program monitoring system

1) Is there a comprehensive mass screening registry in place? (Respond Yes or No)

(If responded yes to previous question, continue with the following questions)

#### Program monitoring indicators

- 1) What screening program monitoring indicators are currently collected in your program? (Mark X next to all that apply and provide the %, number, and incidence (respectively) of samples that have the diagnosis)
  - Profile of cytological diagnoses
    - Inadequate samples
      - % inadequate due to poor operator technique
      - % inadequate due to cervical pathology, physiological changes
    - Adequate samples
      - -Bethesda classification system
        - -Atypical squamous cells
          - -Atypical squamous cells of undetermined significance (ASC-US)
          - -Atypical squamous cells cannot exclude HSIL (ASC-H)
        - -Low grade squamous intraepithelial lesion (LGSIL or LSIL)
        - -High grade squamous intraepithelial lesion (HGSIL or HSIL)
        - -Atypical glandular cells not otherwise specified (AGC-NOS)
        - Atypical glandular cells, suspicious for AIS or cancer (AGC-neoplastic)

- Other classification system (Please list the diagnosis used and the % of adequate samples that have those diagnoses)

-Number of biopsies and associated histopathological diagnoses.

-Number of treatments administered

- -Cancer case monitoring
  - -Cancer incidence per 100,000 women (within recommended screening ages)
    - -Total -By stage -By histological type
  - Interval cancers

-Cancer in situ incidence per 100,000 women

- Cancer incidence of women outside of recommended screening ages
  - -Younger
  - Older

-Cancer incidence of women without screening within recommended timeframe (i.e. 3 years, 5 years etc.)

-Cancer mortality per 100,000 women by histological type

- 2) Is your country currently monitoring whether treatment impacts fertility? (Respond Yes or No)
  - a) If treatment impact on fertility is monitored, how is this coded and reported? (Please describe)

#### Costs of the screening program monitoring

- 1) What is the cost of establishing screening registries in your country? (Enter cost after each item and note currency)
  - a) Staff training (e.g. data management and analysis, IT) (Cost and currency)
  - b) Data infrastructure (Cost and currency)
  - c) Reporting systems (Cost and currency)
  - d) Other (*Please specify and note cost and currency*)

- e) Total cost cannot be itemized, but includes (Please specify and note cost and currency)
- 2) What is the cost of maintaining screening registries in your country?
  - a) Staff support (Cost and currency)
  - b) Data infrastructure (Cost and currency)
    - i) Data collection and reporting (Cost and currency)
    - ii) Database (Cost and currency)
    - iii) Data cleaning and quality control (Cost and currency)
  - c) Reports and publications (Cost and currency)
  - d) Other (Please specify and note cost and currency)
  - e) Total cost cannot be itemized, but includes (Please specify and note cost and currency)

#### 4) Cervical cancer audits

1) Are systematic audits of cervical cancer cases conducted? (Respond Yes or No)

(If responded yes to previous question, continue with the following questions)

#### **Protocol for audits**

- 1) Are all cases of cervical cancer included regardless of age, stage at diagnosis, place of diagnosis? (*Respond Yes or No*)
- 2) What is the protocol for audits in your country? (*Please describe and provide a copy of the audit protocol if possible*)
- 3) Do audits in your country include a comparison group (i.e. controls)? (Respond Yes or No)
- 4) How often are audits of cervical cancer cases completed? (Please describe)
- 5) Who is responsible for conducting the audit? (*Please describe*)
- 6) How are the results of the audit disseminated? (Please describe)
- 7) Is there a protocol for how results should be disseminated? (*Respond Yes or No*) (If there is a protocol, please attach a copy when returning the completed survey)
- 8) Are the results of the audit made public? (Respond Yes or No)
  - a) If yes, please describe how the results are made public (i.e. are they presented on a government or healthcare webpage, and/or are they published in scientific papers?):

#### Measuring the impact of audits

- 1) Are the results of the audits used programmatically (Respond Yes or No)
  - a) If yes, how are the results used? (Please describe)

#### Data collected for audits

- 1) Is there a separate audit database? (Respond Yes or No)
- 2) Are there audit data collection forms? (Respond Yes or No)

- 3) Are there audit data coding guides? (Respond Yes or No) (If yes, please provide copies when returning the completed survey)
- 4) Which characteristics of cases are collected? (Mark X next to all that apply)
  - Screen detected cancer
    - Cancer diagnosed at referral for colposcopy
    - Cancer diagnosed during follow-up by repeat cytology

-Interval cancer

- Previously screened as recommended
- Not previously screened at recommended frequency

-Lapsed attender

- Previously screened as recommended
- Not previously screened at recommended frequency

-Never invited (subgroups by < 25, 25-64, 65+)

- Never attended
- -Lost to follow up
  - Abnormal cytology
  - Referral indicated and not attended
  - Follow up not attended after treatment for CIN
- a) How are the collected characteristics coded? (Please describe)

#### Cost of completing an audit

- 1) What is the cost of completing an audit? (Enter cost after each item and note currency)
  - a) Data collection (Cost and currency)
  - b) Data analysis (Cost and currency)
  - c) Staff (Cost and currency)
  - d) Publication and dissemination (Cost and currency)
  - e) Other (Please specify and note cost and currency)
  - f) Total cost cannot be itemized, but includes (Please specify and note cost and currency)

### 5) HPV vaccination program details and implementation

#### Program organization and target population

- 1) Is the vaccination program organized? (Please respond: Yes, organized or No, opportunistic)
  - a) If responded yes to the question above, when did the organized vaccination program start? (*Please list year and month, if different across regions please describe any differences*)
  - b) If responded no to the question above, how is vaccination offered? (Please describe)
- 2) What is the organized vaccination program target population?
  - a) Gender (Mark X next to gender(s) that apply)
    - Males
    - Females
  - b) Target vaccination age (Please provide target age(s))
- 3) Was/is there an organized catch-up vaccination effort? (Respond Yes or No)

- a) If yes, what was/is the targeted gender and age-range? (Please provide target age(s))
- 4) Which vaccine(s) is used in the organized program? (*Please choose: Bivalent, Quadrivalent, or Both bivalent* and quadrivalent)
  - a) Does the vaccine used by the program differ across regions or districts in your country? (*Please describe*)
- 5) What vaccination delivery strategy is used for the organized program? (*Please choose: School-based; Physician administered; Mass-vaccination; or Other. If Other, please describe*)

# 6) Vaccination monitoring and evaluation program

- 1) Is there a centralized vaccine registry for the organized vaccination program? (Respond Yes or No)
- 2) Is there a vaccine safety system in place for reporting of adverse events following vaccination? (*Respond* Yes or No)

#### Vaccination coverage and uptake

- 1) How is vaccination coverage calculated in your program? (Please describe and attach your standard operating procedure for calculating coverage)
- 2) How are vaccination schedules that extend over reporting periods accounted for in calculating vaccine schedule completion and overall coverage? (*Please describe*)
- 3) Is reporting of uptake stratified by the number of doses given? (Respond Yes or No)
- 4) How does your program account for receipt of the 2<sup>nd</sup> or 3<sup>rd</sup> vaccine outside of the recommended vaccination schedule in reporting? (*Please describe*)
- 5) Have you prepared for, or already conducted, a response to low vaccination coverage? (Respond Yes or No)
  - a) If yes, what response have you planned for or performed? (Mark X next to all that apply)
    - Investigation of structure and logistics of HPV vaccination program implementation
    - Breakdown of the statistics of vaccination coverage geographically and socio-economically
    - Investigation of attitudes towards vaccination among populations with low vaccination coverage
    - Targeted and tailored information campaigns to groups with low vaccination coverage
    - Other (Please describe)

#### Indicators used for evaluating the impact of HPV vaccination

- 1) What indicators will be/are used for monitoring and evaluating the impact of vaccination? (Mark X next to all that apply)
  - -HPV prevalence in the population
    - Vaccine types
    - Non-vaccine types

-HPV immunity in the population

- Prevalence of abnormal pap smears
- Participation in organized screening by vaccinated women
- HPV typing of precancerous lesions (specifically CINII-III and AIS)
- Cervical cancer incidence
- HPV typing of cervical cancer cases

- Incidence and typing of other HPV-related cancers
- Incidence of other HPV-related diseases
  - -Condyloma
  - -Cancer in situ (vagina, vulva, penis, anus, tonsil)
  - -Recurrent respiratory papillomatosis

-Cervical cancer mortality and mortality from other HPV-related cancers (vagina, vulva, penis, anus, tonsil)

- Frequency and duration of hospitalization for cervical cancer and other HPV related disease
- Frequency of surgical intervention for cervical precancerous lesions
- Other (Please describe)

# 7) HPV vaccination program costs

#### Costs of program implementation

- 1) What was the cost of launching the vaccination program in your country? (*Please note cost and currency*)
- 2) What is the cost of the vaccine program administration? (Please note cost and currency)
- 3) What is the cost of administering the vaccine in your country? (Please note cost and currency)
- 4) Total cost cannot be itemized, but includes (Please specify and note cost and currency)

#### Costs of monitoring and surveillance programs

- 1) What is the cost of establishing vaccination registries in your country? (Enter cost after each item and note currency)
  - a) Data infrastructure (Cost and currency)
  - b) Reporting systems (Cost and currency)
  - c) Other (Please specify and note cost and currency)
  - d) Total cannot be itemized, but includes (Please specify and note cost and currency)
- 2) What is the cost of maintaining vaccination registries in your country? (Enter cost after each item and note currency)
  - a) Staff (Cost and currency)
  - b) Data reporting, cleaning (Cost and currency)
  - c) Data analysis (Cost and currency)
  - d) Other (*Please specify and note cost and currency*)
  - e) Total cannot be itemized, but includes (Please specify and note cost and currency)
- 3) What is the cost of laboratory-based monitoring? (*Enter cost after each item and note currency*)
  - a) HPV prevalence in the population (Cost and currency)
  - b) HPV typing of CIN II, CIN III, and AIS (Cost and currency)
  - c) HPV typing of HPV-associated cancers (Cost and currency)
  - d) HPV typing of low-grade lesions (Cost and currency)
  - e) Other (Please specify and note cost and currency)
  - f) Total cannot be itemized, but includes (*Please specify and note cost and currency*)
- 4) Is it possible to link HPV vaccination data with health registers? (Respond Yes or No)
  - a) If so, what is the cost of linking HPV vaccination data with health registers? (Enter cost after each item and note currency)

- i) Cervical cancer screening registry (Cost and currency)
- ii) Cancer registry (Cost and currency)
- iii) Cause of death registry (Cost and currency)
- iv) Drug prescription registry (Cost and currency)
- v) Inpatient and hospital-based outpatient care registry (Cost and currency)
- vi) Other (Please specify and note cost and currency)
- vii) Total cost cannot be itemized, but includes (Please specify and note cost and currency)

#### Please do not hesitate to contact us with questions:

Joakim Dillner, M.D., Professor Department of Medical Epidemiology and Biostatistics Karolinska Institutet, Stockholm, Sweden

Phone: +46 768 871 126 Joakim.Dillner@ki.se

Miriam Elfström, MPH, Project Leader Department of Medical Epidemiology and Biostatistics Karolinska Institutet, Stockholm, Sweden

Phone: +46 8 5248 7999 Miriam.Elfstrom@ki.se

#### **Completed surveys**

Thank you for your participation in this survey. The completed survey form along with attachments should be sent by email or post to:

Email: Miriam.Elfstrom@ki.se

Post: Attn: Miriam Elfström Karolinska Institutet Department of Medical Epidemiology and Biostatistics Box 281, 171 77 Stockholm, Sweden