1 November 2011

HIDES 2 (HIV Indicator Diseases Across Europe Study)

Call for Collaboration

Background:
Most patients infected with HIV across the European continent remain undiagnosed; although this percentage varies markedly from 15-80% across the continent. Undiagnosed HIV is harmful to the person infected as appropriate health interventions are then delayed until the HIV infection is diagnosed. It is also detrimental to society as persons unaware of their HIV infection may transmit more frequently to others than persons that are aware of their HIV status.

An important public health issue is hence how to diagnose more HIV-infected persons earlier in the course of their infection through earlier testing. Following the recommendations from the HIV in Europe 2007 Conference (see www.hiveurope.eu), the HIDES study aims at developing focused HIV testing in patients presenting with certain clinical conditions and/or diseases.

The study has 2 overall aims:

1. **Implement surveys to assess HIV prevalence for one or more diseases and/or conditions within a specific segment of the population not yet diagnosed with HIV and that present for care with the specific disease/condition.**

The implementation will be based on the following list of 11 diseases associated with high-risk behaviour or immune deficiency. The survey can be implemented in patients (between 16 – 65 years):

1. Presenting for care of malignant lymphoma, irrespective of type
2. Presenting for care of cervical or anal dysplasia or cancer, (Cervical CIN II and above)
3. Presenting for care of Hepatitis B or C virus infection (acute or chronic – and irrespective of time of diagnosis relative to time of survey),
4. Presenting with ongoing mononucleosis-like illness
5. Presenting with unexplained leukocytopenia or thrombocytopenia lasting at least 4 weeks
6. Presenting with seborrheic dermatitis / exanthema
7. Presenting with pneumonia, admitted to hospital for at least 24h
8. Presenting with unexplained lymphadenopathy
9. Presenting with peripheral neuropathy of unknown cause (diagnosed by neurologist)
10. Presenting with primary lung cancer
11. Presenting with severe or recalcitrant psoriasis (newly diagnosed)

2. **Launch, implement and evaluate an audit system of the performance of HIV testing of persons presenting with a condition which has already been established as an indicator for HIV testing.**

Audits will be performed in the following diseases:

1. Tuberculosis
2. Non-hodgkin's lymphoma
3. Anal cancer
4. Cervical cancer
5. Hep B and C
6. Candida esophagitis

Procedures:
Each centre/clinic will:

1. Concerning the surveys:

Assess HIV prevalence for one (or more) of the specific diseases or conditions listed above, for the segment of the population presenting within that specific clinic or centre. The clinic or centre can perform more than one survey on more than one of the above listed indicator diseases. It is a possibility to involve local GP practices in the recruitment of patients into the surveys.

Each survey should be implemented within a segment of the population that is logical and easy to identify within a specific setting. The survey should be implemented on consecutive patients not yet known to be HIV-infected. The patients should present with one of the 11 conditions listed above. Each centre or clinic should enrol at least 100 patients per disease but preferentially 200-400 patients before end of 2012.

The survey will be complete after a minimum of 100 patients per site (presenting with one of the 11 selected diseases above) have accepted an HIV test. The data submitted will include the age of the patient, gender, ethnicity and the result of the HIV test.

2. Concerning the audits:

One audit assesses HIV test prevalence for one specific disease/condition for a specific segment of the population within a specific setting (see Aim above for diseases to be studied). The setting can perform more than one audit on other diseases or conditions.

Clinics/departments can participate in the study by reviewing retrospectively, how many of the patients presenting with one of the ID and who were not yet know to be HIV positive, were offered and accepted an HIV test. Within a period of one year all consecutive patients (or >100 consecutive patients).

If surveys are done in cervical/anal dysplasia/cancer, centers are encouraged to also perform an audit within this disease preceding the start date of the survey.

Audits should be carried out in countries where testing of the disease/condition is part of national testing policy/recommendations.

Reimbursement:
Surveys fulfilling the minimum criteria will be reimbursed at the rate of 13 Euro per patient survey completed and data keyed in online. For patients with a HIV positive test result, additional data is needed and will be reimbursed with 40 Euro per HIV positive patient.

Audits are reimbursed with 200 E pr 100 patients (one time entry into online system when information available).

Study group and data transmission:
Upon survey and/or audit submission, the principal investigator will become part of the HIDES study group and be involved in the analyses and reporting of the results as well as listed on any publication or presentation of the data.

All data can be entered electronically.

Ethical Considerations:
The study will be implemented transnationally and it is therefore the responsibility of each investigator to ensure that the appropriate local and national ethical and data sharing regulations are met. The Coordinating Centre will submit an application to the Danish national data-sharing agency, but this will be applicable only for centres in Denmark.

The centre implementing the survey will need to ensure that patients who test positive are then referred appropriately for care, treatment and counselling according to their national and local guidelines.

If you would like assistance in preparing documents for your local and national ethical approval process, please contact CHIP (contact information below).

For audits, ethical approvals are not acquired in many countries, since they will not include blood samples.

Please complete the below form if you are interested in collaborating on HIDES 2 and return it to the coordinating centre, Copenhagen HIV Programme, study coordinator Dorthe Raben dra@cphiv.dk . Based on the applications received, centres will be awarded funding to begin implementing the project.

Coordinating Centre: Copenhagen HIV Programme
University of Copenhagen
Panum Institute, Building 21.1
Blegdamsvej 3B
2200 Copenhagen N
Denmark
www.cphiv.dk

For more information, please contact:

Coordinator: Dorthe Raben
T: 45 3545 5757
F: 45 3545 5758
dra@cphiv.dk

HIDES 2: HIV Indicator Diseases Across Europe
Call for Collaboration

1. Name of centre or clinic:_____
   Department if applicable: _____
2. Person responsible for survey:_____
   Position:_____
3. Mailing address:_____
   City:_____
   Country:_____
   Telephone:_____
   FAX:_____
   Email:_____

My clinic/department/hospital is interested in participating in HIDES 2 by performing the following surveys and/or audits:

Surveys:

		Estimated time to enrol 100 patients
1. Malignant lymphoma		
2. Cervical or anal dysplasia or cancer		
3. Hepatitis B or C		
4. Ongoing mononucleosis-like illness		
5. Unexplained leukocytopenia or thrombocytopenia		
6. Seborrheic dermatitis / exanthema		
7. Pneumonia – admitted to hospital		
8. Unexplained Lymphadenopathy		
9. Peripheral neuropathy of unknown cause		
10. Primary lung cancer		
11. Severe or recalcitrant psoriasis		

Estimated time for ethical approval process _____
No need for ethical approval because _____

Audits :

1. Tuberculosis	
2. Non-hodgkin's lymphoma	
3. Anal cancer	
4. Cervical cancer	
5. Hep B and C	
6. Candida esophagitis	

Ethical approval needed (yes/no) _____
Estimated time for ethical approval process _____

Please return the form to: Copenhagen HIV Programme, University of Copenhagen, Panum Institute, Building 21.1, Blegdamsvej 3B, 2200 Copenhagen N, Denmark , fax: 45 3545 5758, mail: dra@cphiv.dk