CHIP
COPENHAGEN HIV PROGRAMME

Annual Report 2010

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CHIP
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GLOBAL EXCELLENCE IN HEALTH

Content

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Foreword

During the fall 2010, Rigshospitalet – Copenhagen University Hospital has developed its vision and goal to become the international hospital of Denmark by 2020. The strategy focuses on specific elements: Global Excellence, Partnership, Research, Productivity & Resource Optimising and the Good Working Life.

The Global Excellence strategy will assist Rigshospitalet to offer patients a highly specialised treatment on an international level and aims to ensure that Rigshospitalet will be among the 10 best research hospitals in Europe by 2020. The global excellence strategy is a collaborative effort between the Capital Region of Copenhagen and the Copenhagen University with the aim to support competent academic groups with a recognised high international research profile. Ten Global Centres of Excellence were announced in October, of which Rigshospitalet houses six – and we are very proud that Copenhagen HIV Programme is one of the six Global Excellence in Health Centres. The strategy implies that these centres of excellence will act as lighthouses to inspiration for other groups striving to reach an international level of their research.

CHIP has a long history of top-end research in HIV, but we find it very inspiring that CHIP has been able to extend its activities to include research in H1N1 influenza as well

Jannik Hilsted, MD
Chief Medical Officer, Rigshospitalet

as the innovative set-up of monitoring viral infections in transplant patients to ensure optimal treatment and improved organ survival in the recipient as effectuated in the MATCH initiative described elsewhere in this annual report. We are convinced that CHIP will fulfil the expectations inherent in being awarded the Global Excellence in Health status.

From the Director

The future mission and vision for CHIP
CHIP aims to perform front-line research that informs the clinical handling of persons suffering from infectious diseases in general and specifically HIV, while the scientific methodology applied has to be state-of-the-art. All proposed projects are evaluated against these overall aims and only research ideas that fulfill both will be considered for further development.


Jens D. Lundgren

The international research funding structures potentially available to support the projects that CHIP is involved with are extraordinarily competitive. We are reliant on this income stream to maintain our infrastructure in the current form. The aims for the projects CHIP wants to develop are therefore formulated both to ensure that we spend our energy on addressing the best possible research ideas, but equally that this is a necessity to maintain our continued existence.

When the financial situation is such that international funding bodies have reasonable excess resources to continue to fund research grants to support groups such as CHIP, these principles are fairly easy to uphold. At least I am happy to say that this has been possible to do within CHIP over the last many years. The challenge facing CHIP's management team will be to ensure that this can continue in the years to come.

Consequently, we are spending significant resources currently to renew the strategic plan for CHIP and plan to complete this process in 2011.

One strategic decision has however already been taken, namely that CHIP needs to place more emphasis on infections other than HIV. The name CHIP encompasses HIV and a large section of research within CHIP will remain focused on this virus, including the ongoing effort to disseminate the results of our research in training and outreach, not least in developing e-learning and e-tools. But our aim has all along been to also focus on other pathogens. This is exemplified in the ongoing CHIP research projects on infectious (tuberculosis and viral hepatitis) and non-infectious (cardiovascular disease, diabetes, renal

disease) co-morbidities seen in HIV-infected persons, on bacterial infections in the intensive care setting (the PASS and CASS studies), on pandemic influenza, on post-transplant infections (the MATCH initiative). I have the distinct impression that CHIP's research profile will continue to diversify in the years to come.

So why diversify? Firstly, the innovation potential for HIV research is now reduced compared to what was the case 10 years ago. Critical research questions of strategic relevance for the clinical management of the HIV infection itself have been resolved. The only pending question that is realistic to solve is: When in the course of the HIV infection should antiretroviral therapy be initiated? We are currently addressing this question in the START study. Secondly, challenges in infectious disease are wider reaching than merely HIV. Hence, it is actually an ideal situation to apply to other areas the research capabilities and infrastructure that have been built to get HIV research where it is now.

One of the other critical components currently under strategic discussion is to ensure maintenance of a strong leadership profile of CHIP. Perhaps some have the impression that CHIP is "a one-man-shop". Although CHIP was formed initially by a few of us, the present organization is far from this. The management team, led by Jesper Grarup, holds critical governance roles and responsibilities for all components of the work within CHIP, exemplified in part by the formal takeover of the EuroSIDA project leadership role by Ole Kirk during 2010. So we are heading for exciting times and important decisions will be made in 2011 that will influence how CHIP will continue to develop. I will ensure that all relevant parties are informed in a timely way once these decisions have been made.

From the Director of Administration

Jesper Grarup

The past year was one of the more challenging – the broader scope of CHIP beyond the clinical trials led to an increased activity level in areas we are less familiar with. Successfully driving a Master of HIV education through the process from idea, through accreditation to final Faculty approval is a good example.

Related to randomized clinical trials, the monitoring group has been very busy establishing and initiating the START and NEAT001 clinical sites within the many countries of our region – manoeuvring in the different regulatory requirements of the many countries is a huge and time consuming task. Nevertheless, we have been able to ensure top enrolment from our region! In the beginning of the year these heavy trial initiation activities were conducted on top of the activities to maintain the performance of the many sites in the FLU002 and FLU003 studies. This would not have been possible without our valued and close collaboration with Klaus Tillmann and Dejan Adzic from the Site Coordinating Centre in Frankfurt and Paco Lopez and Begoña Portas from the Spanish SCC.

The initiation of the PARTNER study, with identification and initiation of the more than 60 sites and establishment of electronic data capture, is a huge achievement. Likewise, the Indicator Disease survey has gained broad interest and is running according to schedule with results expected in the beginning of next year.

The cohort flagships D:A:D and EuroSIDA are sailing steadily. In D:A:D the challenge of capturing the new cancer, kidney and liver endpoints and even retrieving retrospective events has been successful and the more frequent face-to-face-meetings with our collaborators at UCL have been fruitful. A more integrated data entry and query process for D:A:D and CoDe has been developed to get rid of double entry of data and ensure as close to real time evaluation of events as possible when data are merged once annually. EuroSIDA has finalized its last year of independent EU Commission funding and has been able to fulfil more than the promised deliverables within the timeframe. More than 130 publications have been produced as a result of EuroSIDA activities so far – a fantastic achievement and evidence of a good collegial collaboration across the more than 90 EuroSIDA sites.

In the beginning of the year the IT, data management and bioinformatics group finalized and delivered a structures database project to WHO for local, national and regional

capture of HIV resistance data and participated in training of regional representatives – the group received a lot of very positive feedback from users and will likely enter into a contract for development of an extended version. The database is a good example of the transparency we value in all CHIP projects, as the software can run independently on local computers, being easily merged at central levels and maintaining an open source code.

CHIP's location at Panum and our vision our vision of bridging activities to the Rigshospitalet have been clearly proven by the establishment of the MATCH project in collaboration with the microbiological and clinical departments at Rigshospitalet. CHIP has invested considerable effort in developing a database to match transplant donor and recipient virological profiles and establishing efficient monitoring plans for identification of viral infections in transplant patients ensuring optimal patient management.

The EuroCoord application process has been a challenge. The four founding networks behind the Network of Excellence established a non-profit society, the EuroCoord Society, to manage the network on their behalf in order to avoid the sensitive process of having to select one of the four as coordinator. Unfortunately, the current responsible administrative and financial officers at the Commission would not allow the EuroCoord Society as coordinator. As representatives of the EuroCoord Society, CHIP staff members were the leading force behind the successful compilation of the EuroCoord application, negotiation and development of the Description of Work document. We are glad to have been able to clear the road for MRC, which took over the role of coordinator after the fall of the EuroCoord Society and we wish them the best of luck in their efforts.

A very positive experience for CHIP was being granted the five-year title of Centre of Global Excellence by the hospitals of the Capital Region of Copenhagen. From our daily work in our broad and international network we experience international acknowledgement – however, the national acknowledgement is highly appreciated and emphasizes the potential and importance of further development of national collaborations and initiatives.

We are lucky that we have managed to maintain our many skilled staff members and even attract new members in the past year. A young doctor, Lene Ryom Nielsen, has joined CHIP to do her PhD within the framework of D:A:D and Signe is doing a great job of introduction. Ravi Shastry is an MD with origin in India and a Russian education – Ravi is focusing on the randomized trials and safety issues. As monitoring activities have increased due to the expansion of START we are very pleased to have Søren Reilev back and having Christiane Pahl join us to strengthen the monitoring group. The IT group has engaged Frederik Marcher as IT-supporter – a highly appreciated initiative. Finally we are pleased that we have a more stable solution to data entry by having our temporary keyers, Ane and Troels on longer-term contracts. Daniela Gey is on maternity leave and gave birth to a lovely daughter this July - Congratulations!

CHIP's annual strategy process has been intensified this year to try to have a fresh helicopter view of our environment, our vision and the direction to follow to achieve it. We are convinced that the analysis of stakeholders and evaluation of approaches and organization of other successful research groups will benefit CHIP staff and our many collaborators, sponsors and partners.

Administration

Mette Brandt-Madsen, Jens D. Lundgren, Helle Bo Duus, Jesper Grarup.
Not pictured: Peer Aagaard, Ruth Kjærgaard

Global Excellence

CHIP has been recognized as a Centre of Global Excellence by the hospitals of the Capital Region of Copenhagen and on 28 September 2010 was presented with an award of 1.5 million Danish kroners. As one of 10 centres in Denmark to receive the award, CHIP was acknowledged as a hub for international world-class research in the area of HIV. CHIP, active for many years in the dissemination of results, training and patient care, appreciates the recognition on a national level and hopes this award will lead to further development of national collaborations. The direct collaboration with both the University of Copenhagen and clinical departments at Rigshospitalet, namely the Finsen Centre, is one of CHIP's strengths and reinforces the high quality results produced by the various projects and studies conducted and coordinated by CHIP. In addition, CHIP's innovative work and large international network prove useful in other areas of infection and viruses, such as influenza preparedness for H1N1.

Randomized Clinical Trials

START

Description and study objective

Strategic Timing of AntiRetroviral Therapy (START) is an international randomized trial comparing early antiretroviral therapy (ART) vs. deferred ART. The purpose of START is to determine whether the immediate initiation of ART in HIV-1 infected persons, who are antiretroviral naïve with a CD4+ lymphocyte count above 500 cells/mm3, is superior in terms of reducing the occurrence of serious morbidity and mortality, compared to deferral of ART until CD4+ lymphocyte count declines below 350 cells/mm3, as most of the current guidelines recommend.

The pilot phase of the START study was successfully completed in September 2010 and based on the pilot phase performance, funding for the definitive phase of the START study has been granted by the Division of AIDS (DAIDS, NIH).

CHIP is one of four international coordinating centers (ICC) within the INSIGHT network. For the pilot phase of the START study, CHIP was responsible for coordinating 28 sites in Belgium, Denmark, Finland, Germany, Poland and Spain. In the definitive phase of the study CHIP will be expanding to 59 sites in 13 countries, enlarging the study group to include Austria, Czech Republic, Estonia, Luxembourg, Norway, Portugal and Sweden. We welcome all of our new investigators to the study group and aim for a sustainable high-performance level in our region.

The total number of study participants recruited as of December 2010 is approximately 25% of the total enrolment goal of 4000 study participants from all participating sites, and more than 300 study participants were enrolled from sites in the Copenhagen region.

The aim is to recruit a total of 4000 participants worldwide by the end of 2012:

START

Sub-studies

There are 5 sub-studies in START to which the sites are committed to engage and contribute: Informed Consent, Neurology, Genomics, Arterial Elasticity Pulmonary and Bone Mineral Density. Sub-study participation is based on recruitment potential and geographical diversity.

START has major scientific merits and all the sub-studies raise appealing supplementary research questions focusing on various organ dysfunctions, which HIV and antiretroviral therapy may either improve or further deteriorate.

FLU 002 and 003

Observational studies to characterize adults with influenza A pandemic (H1N1v)

Description and study objective
FLU 002 and FLU 003 are two international observational studies on the pandemic Influenza virus (H1N1v) with the objective of describing the outcome of patients who seek medical care for an influenza-like illness (FLU 002) and those who are hospitalised with severe or complicated influenza A (FLU 003). Both studies are funded by the U.S. National Institutes of Health.

As one of four International Coordinating Centres (ICCs) within the International Network for Strategic Initiatives in Global HIV trials (INSIGHT), CHIP is responsible for the implementation and conduct of the FLU studies at 28 sites in 10 European countries: Austria, Belgium, Denmark, Estonia, Germany, Lithuania, Norway, Poland, Portugal and Spain. Depending on how the H1N1v pandemic unfolds, the goal is to enrol 5000 patients in FLU 002 and 1000 patients in FLU 003. As of November 2010, the total numbers of enrolled patients are 1047 in FLU 002 and 315 in FLU 003.

When there is no influenza activity, the participating sites are paused until there is evidence of ongoing influenza; sites are then re-opened for enrolment. Decisions about when to pause/open sites are based on the weekly updated surveillance numbers and national surveillance numbers from the European Centre for Disease Prevention and Control (ECDC). This is to ensure that sites are opened at the right time in order to capture the influenza waves.

Recent data in the northern hemisphere indicate that H1N1v is still circulating but other strains of influenza A may be more prevalent. Thus, the protocol team has decided to open enrolment at clinical sites even when H1N1v is not the dominant strain circulating in their community.

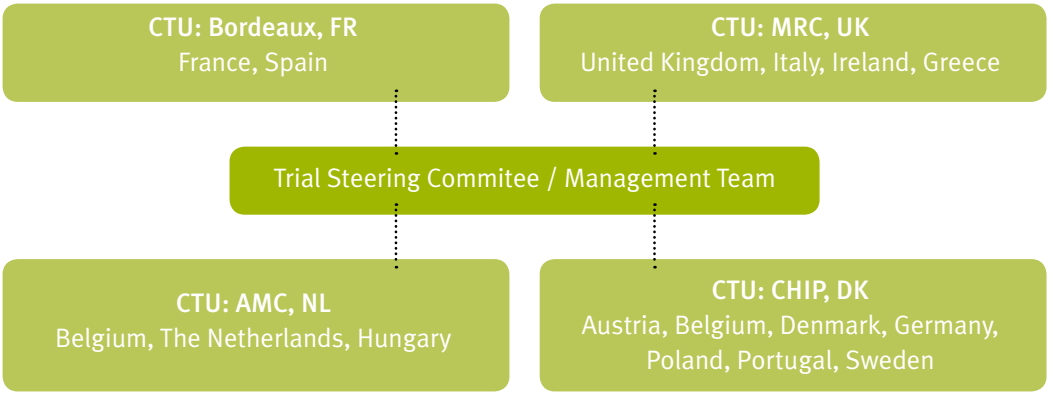
The FLU studies are expected to continue at least until August 2011.

FLU002 FLU003

NEAT

Description and study objective
NEAT 001/ANRS 143 is a phase III, multicentre open-label randomized trial comparing the efficacy and safety of two first-line regimens in HIV-1-infected antiretroviral naïve subjects: darunavir (DRV)/ritonavir(r) + tenofovir (TDF)/emtricitabine (FTC) vs. DRV/r + raltegravir (RAL). Throughout 2010 extensive preparations have been ongoing, including the set-up of trial logistics and obtaining approvals from Ethics Committees and Competent authorities. The first patient was enrolled in France in September 2010, followed closely by the enrolment of study participants in Denmark, Germany and Sweden, which are among the countries coordinated by CHIP. CHIP is one of four Clinical Trials Units (CTU) within the NEAT network and is responsible for the implementation and conduct of the trial at 22 sites in 7 countries:

NEAT 001 Organization



Important parts of the trial logistics have been delegated to the CTUs such as drug repository settlements (Theradis in France), investigator training, biobank agreements, endpoint review, etc.
In addition to some of these tasks, CHIP is responsible for establishing an Endpoint Review Committee.
The data collection for the NEAT study also includes

Ancillary studies in all study participants:
- Pharmacogenetics and population pharmacokinetic
- Viral sub-type study
- Renal function study
- Quality of life study (patient questionnaires)
- Adherence study (patient questionnaires)
- Pharmaco-economics sub-study (Italy only)

Substudies at selected sites:
- Viral and immunologic dynamics and inflammation sub-study
- Bone sub-study
- Neurocognitive function sub-study

PASS

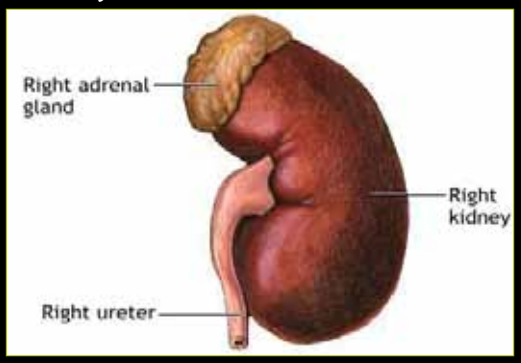
The Procalcitonin And Survival Studies
The PASS study was completed on 30 June 2009 and the primary results were presented at the Infectious Diseases Society of America Meeting, Philadelphia, October 2009. Since then, several studies exploring organ failure, life quality and mortality in critically ill patients have begun to use the PASS database and biobank.

Status
Follow up is now complete for:

- All data from the ICU
- Microbiology from baseline to day 28
- Vital status until 180 days after discharge
- All admissions in Denmark until day 180
- Use of dialysis until day 28
- Use of medical ventilation until day 28
- Antibiotic prescriptions until day 28
- Creatinine, carbamide, platelets and bilirubin until day 28

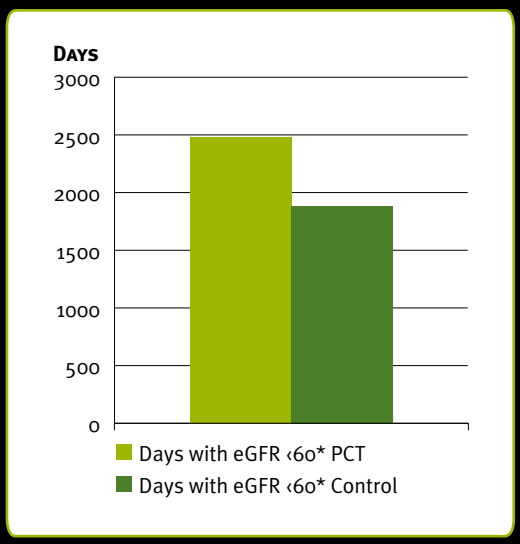
Studies currently conducted focus on renal organ failure, lung failure, fungal infections and quality-of-life after admission to the intensive care unit.

Kidney studies – side effects and prediction of kidney failure

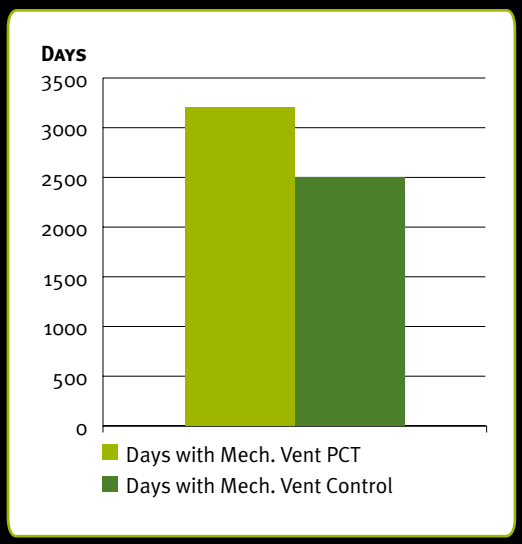


Lung studies

Renal failure (biochemically defined)



Respiratory failure



ICU-division at CHIP: Jens-Ulrik Jensen, MD, PhD, Kristian Reinholdt, med.stud., Maria E. Johansen, med. stud., Marie Louise Jakobsen, RN, Clin. Monitor, Zoe Fox, MSc, PhD, Jesper Kjær, MSc, Jesper Grarup, DVM, Jens D. Lundgren, MD, DMSc

CASS

The Cooling And Surviving Septic Shock study is a randomized trial to determine whether mild induced hypothermia via apoptosis-inhibition, metabolism-lowering, anti-coagulation and inhibition of bacterial growth can improve survival among patients with septic shock.

Status

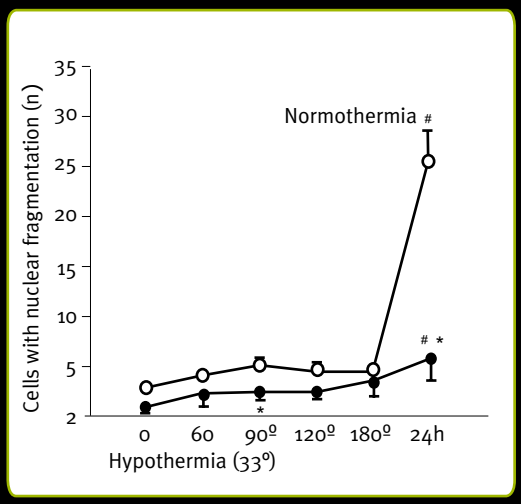
- Ethics approval achieved
- Steering Committee constituted from 10 ICUs, 1 clinical research group and several clinical microbiology departments
- Target recruitment: 560 patients with septic shock or severe sepsis
- 1 mio kr. grant from Lundbeck Foundation
- First patient expected to be recruited by fall, 2011

Facts about severe sepsis and septic shock

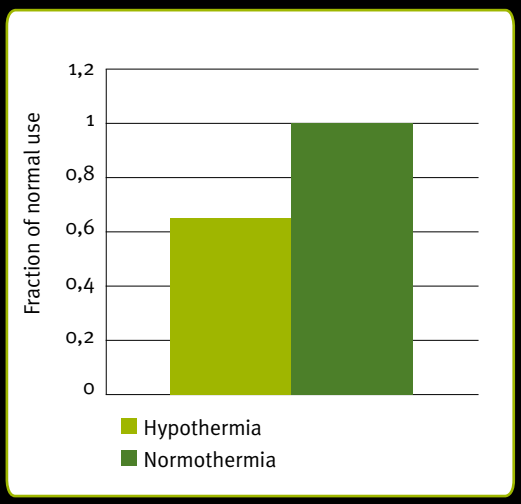
- In Denmark, about 1/5 of all ICU patients develop severe sepsis or septic shock
- In the US, about 750,000 sepsis cases per year
- Mortality of 35-60%

Despite numerous randomized trials, only few evidence-based effective therapies have been developed and mild induced-hypothermia has so far only been used sporadically.

Anti-Apoptosis (2)



Metabolism lowering (o2-consumption) (1)



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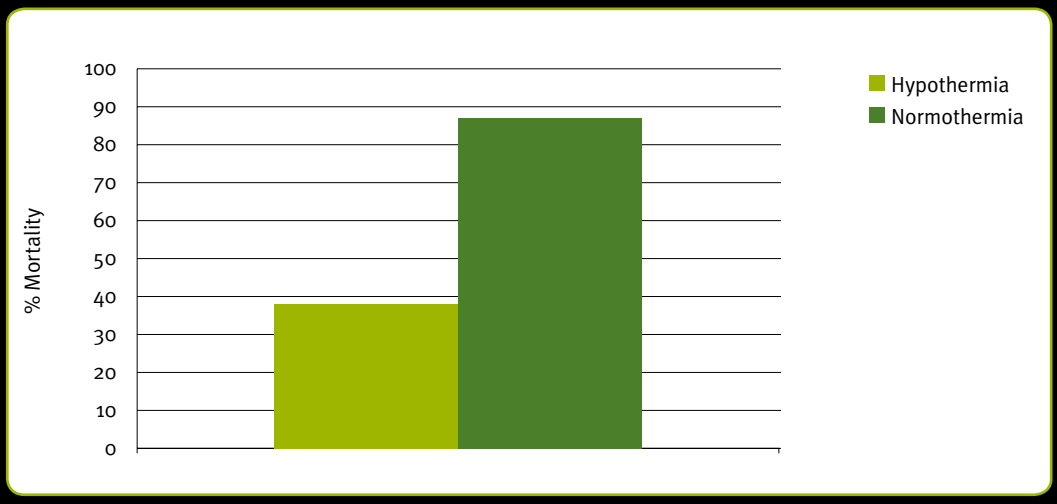
Mortality - animal experiments



CASS – Steering Committee & Principal Investigators

- Else Tønnesen (Chair, Århus)
- Niels-Erik Drenck (Roskilde)
- Hamid Tousi (Herlev)
- Morten Steensen (Hvidovre)
- Peter Søe-Jensen (Herlev)
- Jesper Løken (Hvidovre)
- Morten Bestle (Hillerød)
- Hans Christian Boesen (Glostrup)
- Lars Hein (Hillerød)
- Jens-Ulrik Jensen (Hvidovre/Panum)
- Thomas Mohr (Gentofte)
- Christian Østergaard (Hvidovre)
- Kim Michael Larsen (Århus)
- Bettina Lundgren (RH)
- Mads Holmen Andersen (Århus)
- Jens D. Lundgren (Panum)
- Maria Johansen (Panum)
- Palle Toft (Odense)

CASS

Monitor Group

Heidi M. Juncher-Benzon, Mary Pearson, Karoline B. Jensen, Marie Louise Jakobsen, Birgitte Gram Jensen, Per-Olof Jansson, Marianne Jeppesen, Bitten Aagaard.
Not pictured: Ellen Moseholm Larsen, Søren Stentoft Reilev, Christiane Pahl

Observational Studies

D:A:D

Study Objectives

The D:A:D (the Data Collection on Adverse events of Anti-HIV Drugs) is a prospective multi-cohort study of HIV-infected persons under active follow-up. The main objective of the study is to assess the incidence of myocardial infarction (MI) and other cardiovascular disease endpoints in HIV-infected persons, and to investigate whether treatment with antiretroviral drugs is associated with development of cardiovascular disease as a late-onset adverse effect. The relation between these antiretroviral drugs and other long-term adverse effects, such as non- AIDS malignancies, end-stage renal disease and chronic liver disease are also investigated

At a glance

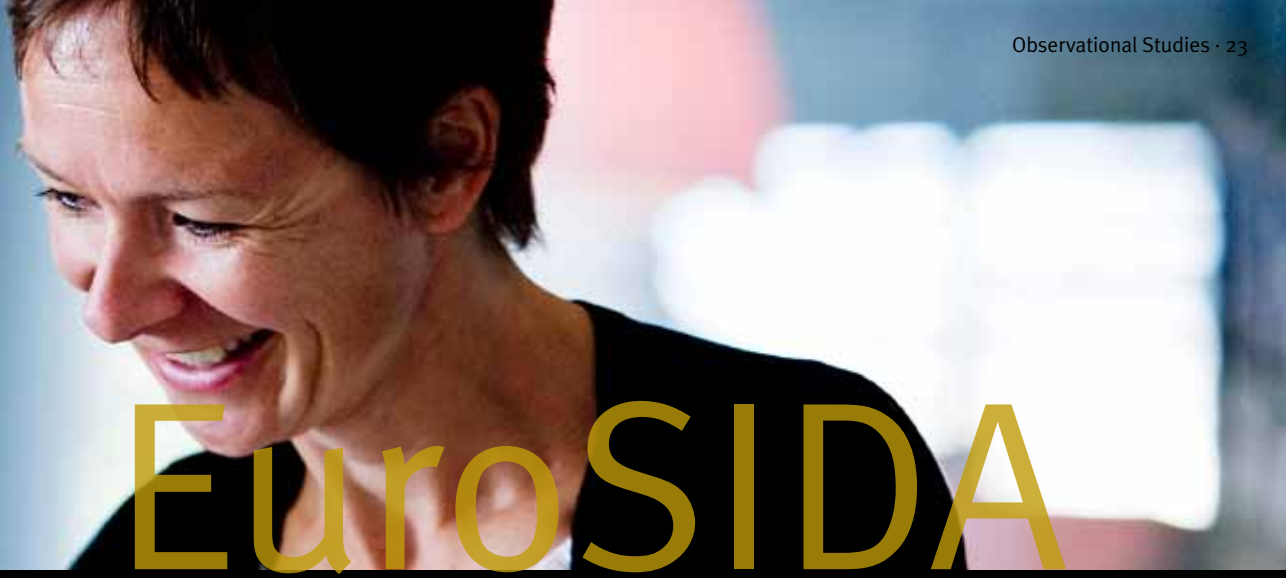
Study Overview (status as of November 2010)	
Patients enrolled	›49,000
Number of clinics	212
CD4 count measurements	1013478
Total Person-years of follow-up	300,004
Triglycerides measurements	516,224
Centrally validated endpoints, MIs	718
Non-AIDS defining malignancies	971

2010 in review

The D:A:D study expanded with the inclusion of more than 16,000 patients in cohort III and initiated the collection of 3 new end-points (non-AIDS defining cancers, chronic liver disease and end-stage renal disease) for central validation at the D:A:D coordinating centre at CHIP. Three articles were published in peer-reviewed journals, another article has been accepted for publication and 2 others have been submitted. The articles cover topics such as the risk of MI assessed in 13 individual anti-HIV drugs, a coronary heart disease (CHD) prediction model tailored to HIV+ patients, hepatitis co-infection and risk of MI and the impact of smoking cessation in HIV+ patients and the risk of MI.
Additionally the study group had 3 oral presentations and 2 posters at international conferences in 2010. Please visit www.cphiv.dk/dad/ to view presentation and publication details.

What's next?

Due to the large size of the D:A:D study the study will have the potential for exploring possible relationships with drug exposure and rare outcomes such as end-stage renal disease and chronic liver disease in the years to come. From 2010 onwards the study will focus on the associations with long-term drug exposure and long-term complications, in particular non-AIDS defining cancers and risk factors for the development of chronic kidney disease. Additionally, the D:A:D study will assess the relationship between immunodeficiency and non-fatal cancer outcomes.



EuroSIDA

Study objectives

For the 16th year, CHIP is actively coordinating EuroSIDA, an observational study designed to follow patients throughout Europe in order to study regional differences in the long-term virological, immunological and clinical outcomes.

At a glance

Study Overview (status as of November 2010)	
Patients enrolled	16 500
Number of countries	35
Number of clinics	103
Total Person-years of follow-up	108 908
Viral load measurements	318 816
Plasma samples collected	59480

2010 in review

EuroSIDA received renewed funding for a 5-year period from the European Commission under their 7th Framework Programme. This will allow the study to continue follow-up on the enrolled participants and also to include additional centres and patients so that the study remains robust.

One of the unique contributions of the EuroSIDA study is the ongoing follow-up in patients from Eastern Europe. Today EuroSIDA is following 4000 patients from Eastern Europe.

This follow-up provides unique information about clinical care and disease progression in the region as well as allowing for comparisons to other regions in Europe.

The study has produced a total of 137 articles in peer–reviewed journals, of which 13 were published in 2010. The articles cover topics like hepatitis C, HIV virology, pharmacokinetics and issues addressed in the cohort collaborations D:A:D, ART-CC, HIV/TB and COHERE. Additionally, the study group had 5 oral presentations and 12 posters at international conferences in 2010.

Next steps in EuroSIDA

EuroSIDA is planning to include more centres in Eastern Europe. EuroSIDA also needs to develop a scientific agenda collaboratively with the other partners in EuroCoord. A first step in this process is to ask all EuroSIDA Investigators to consider the areas of research they think EuroSIDA should focus on in the period 2010-2015.

a multicentre study
EuroSIDA

Cohort group

Dorthe Raben, Michelle Ellefson, Annette Hauberg Fischer, Jorunn Tverland, Jette Elfving Nielsen, Maria Paulsen, Charlotte Matthews, Maiken Mansfeld. Not pictured: Tina Bruun, Annemette Borch

Projects

The CoDe Project
("Coding of Death in HIV")

Scientific purpose

The CoDe project was initiated in 2004 out of the need to harmonize and standardize the approach taken when collecting data and reviewing the causes of death in HIV-1 infected patients. This has become increasingly necessary as a significant proportion of deaths in HIV-1 infected persons are now caused by non-AIDS events. Many illnesses that are related to HIV-infection are poorly identified in the ICD system, and some diseases (e.g. CNS diseases, renal disease) have a different aetiology in HIV patients and are therefore not covered by the ICD system, or are at great risk of mis-classification.

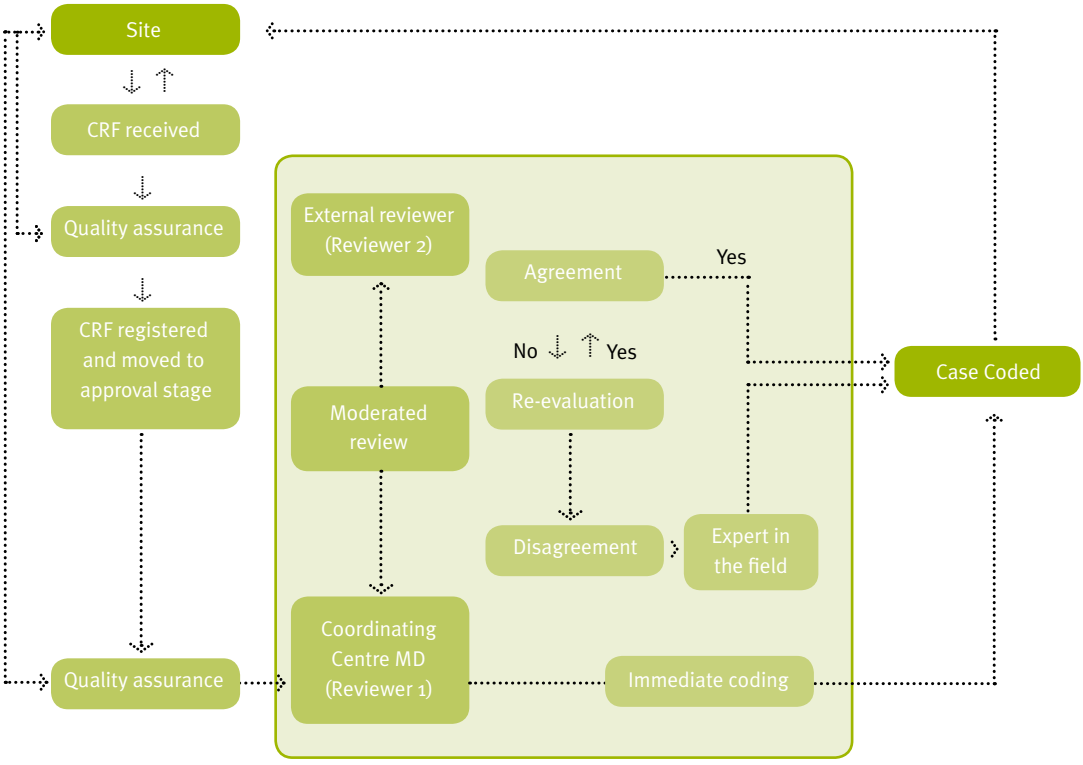
Methods

CoDe is a uniform coding system that can be applied to studies of individuals with HIV infection, including:

– A detailed data collection on the causes of death and contributing factors, and

– A centralized review process of the data collected.

All study documents, CRFs, and other materials are free to use and accessible online at www.cphiv.dk/CoDe.



Status

During the pivotal stage of the project a number of modifications were made which could help in further strengthening the data evaluation process and its efficiency. These observations suggest a better use of existing resources by expanding the role of the central physician to also acts as a reviewer and by allowing the review by the physician to be sufficient in 'obvious' cases, thus initiating the adjudication process earlier in the project, making it more efficient and decreasing the workload for external reviewers. The revised procedures are presented in the figure to the left and have been verified prior to implementation by a 10% random sample sent out for external quality control review.

Implementation

As the coordinating office CHIP implements the CoDe project within the D:A:D study and is responsible for the review process as well as coordinating and testing the overall methodology.

As of November 2010 a total of 2354 CRFs have been registered in the central CoDe database. Of these, 1790 cases have gone through the review process and have received a final classification of death as well as a classification of whether the death was related to immuno-deficiency.

The CoDe project is also used by the HIV/TB Project, the INSIGHT group collaborative work for SMART, ESPRIT and SILCAAT and The Antiretroviral Therapy Cohort Collaboration (ART-CC). See below for references.

Currently, the CoDe project's reviewers group consists of 31 senior physicians actively involved in HIV patient care and representing all regions of Europe (http://www.cphiv.dk/CoDe.aspx).

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6 Cause of death in patients treated with ART, 1996 to 2006; Collaborative Analysis of 13 Cohort Studies. J Gill, M May, C Lewden, M Saag, M Mugavero, M Egger, et al.
16th Conference on Retroviruses and Opportunistic Infections, Abstr 708, 9 Feb 2009.

HIV/TB project

In 2010 the retrospective phase of the "Co-infection with Mycobacterium tuberculosis among HIV-infected patients in Europe" or HIV/TB project was completed. The last round of data collection was performed during spring 2010 in order to ensure at least 2 years of post-TB diagnosis follow-up time and collect information on TB relapses.

In 2009 the HIV/TB project has documented pronounced differences in survival of HIV/TB patients in Eastern compared to the other regions Europe: HIV/TB patients in EE, compared to those in the other regions, were at 3-5-fold increased risk of death within the first year after TB diagnosis.

In 2010 we further investigated the underlying reasons of such significant differences in clinical prognosis of HIV/TB patients. Detailed analysis of causes of deaths revealed that patients in Eastern Europe were more likely to die of TB whereas patients from other regions were more often dying of causes other than TB (figure 1). We hypothesized that the reasons for differences in survival may include access to and use of health care across Europe. A clear association between the clinical prognosis and a weighted score based on access to and use of health care indices (HCI) such as use of TB diagnostics, type of initial TB treatment, and usage of cART was found. The chances of successful treatment outcome were thus significantly higher in patients with a higher HCI score (figure 2), and the average HCI score for patients in Eastern Europe was significantly lower than elsewhere.

Funding from EuroCoord provided the opportunity to extend the HIV/TB project into the prospective phase starting from 2011. During this phase we plan to enroll at least 1200 HIV-infected patients with active TB disease from existing and new collaborative centers. The two main objectives to address will be various clinical aspects and management of HIV/TB patients and temporal trends in the epidemiology of the co-infection.

Figure 1. Causes of death among HIV/TB patients who have died within 12 months of TB diagnosis according to the time of death

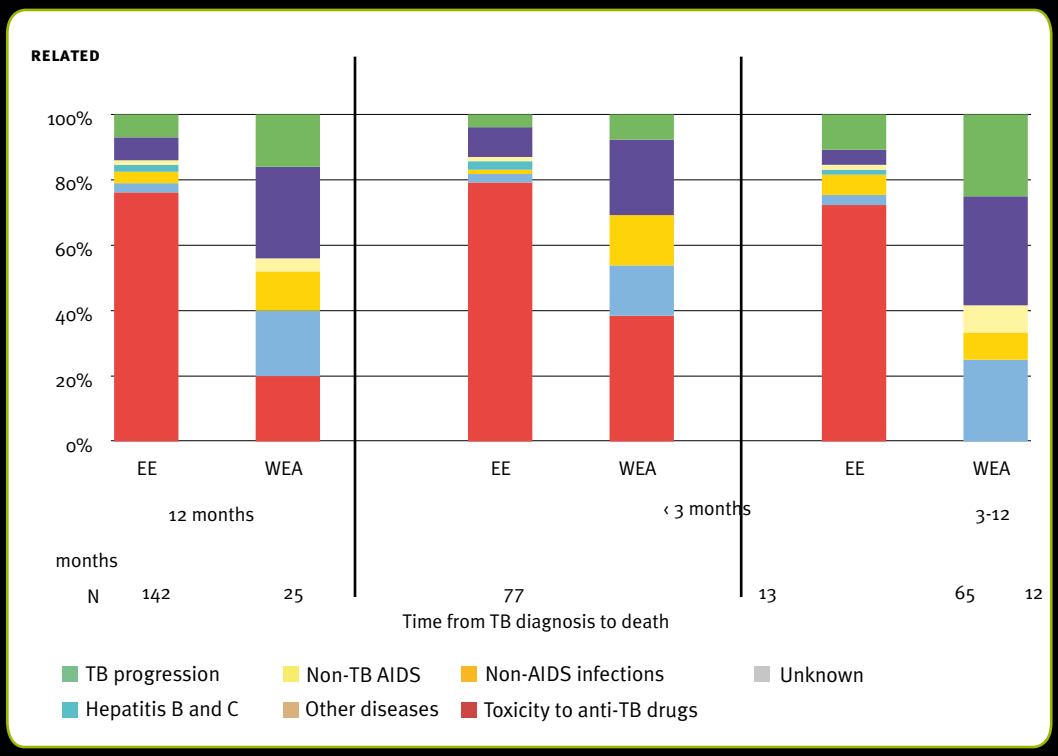
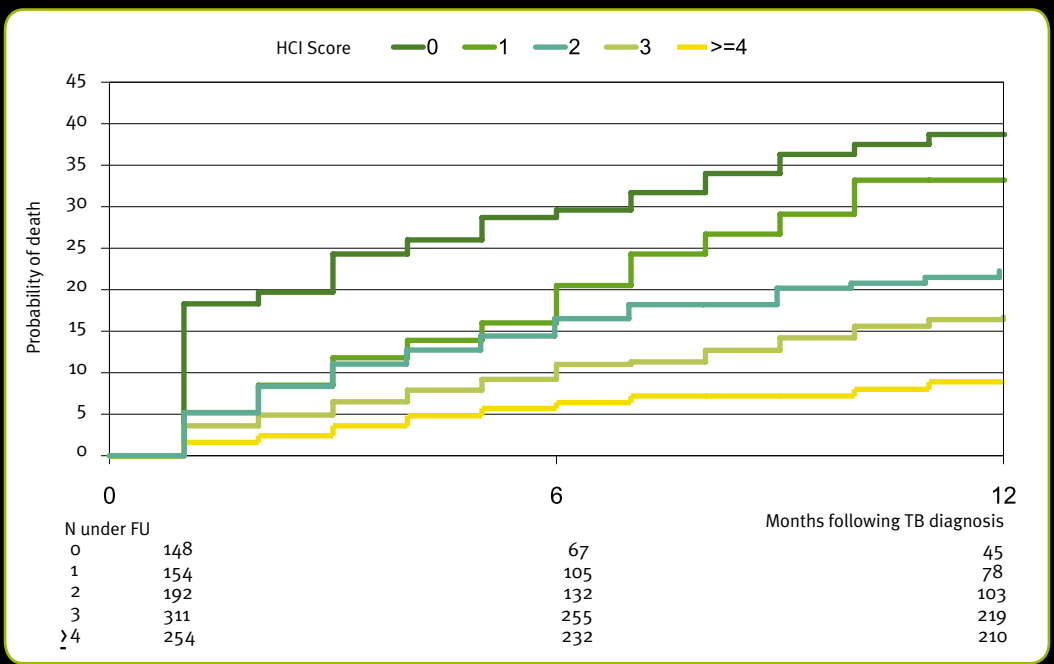


Figure 2. Kaplan Meier probability of death and HCI score



EuroCoord

The EuroSIDA, COHERE and HIV-TB activities coordinated or managed by CHIP are being conducted under the umbrella of EuroCoord for the period of the five-year funding circle which began 1st January 2011. As mentioned on page 8 the successful achievement of securing the funding has been a challenge, but we are now eager to get started to ensure that the many deliverables we are responsible for can be met in a timely manner.
Currently the partners are in the process of establishing third-party agreements with their respective third parties and the last details of the consortium agreement have been negotiated between the partners. The coordinator (MRC) has signed the Grant Agreement with the Commission and it is expected that the Commission will counter-sign before Christmas allowing for project initiation by 1st January 2011.

EuroCoord CHAIN
The EuroCoord founding networks have been responsible for a resistance project through CHAIN. This project is now under finalization and a publication is expected shortly. The merger and analysis of resistance data from a large number of individuals has allowed for presentation of results beyond what each independent cohort would have been be able to achieve individually. The project was made possible due to a valuable contribution from Gilead.

ACTIVATE
The founding networks behind EuroCoord have been collaborating on a finalization of the ACTIVATE project activities. ACTIVATE (capACity building and Training in hIV/Aids Treatment and management across Europe) was funded until 2010 by DG SANCO. The experience CHIP gained through developing and conducting training sessions for infectious disease physicians in Minsk, Belarus has contributed to the extension of CHIP's network in Eastern Europe and will form the basis for continued activities within EuroCoord. The experience has also been utilized in CHIP's collaboration with the WHO on establishing an electronic platform for training under the Monitoring Medicines project funded by the EU and focusing on benefits and risks of antiretroviral therapy.

IWHOD (Cohort Workshop)
IWHOD - International Workshop on HIV Observational Databases
In 2010 the founding networks behind EuroCoord, in partnership with the scientific committee (SC) of the IWHOD, arranged a successful 14th cohort workshop in Sitges, Spain.
The cohort workshop involves cohorts from Europe, Australia, North America and resource limited countries. The data presented at this workshop is not made public, thereby allowing for discussion of works-in-progress and exchange of ideas and creation of new interest or project groups. The 2010 workshop was a two and a half-day programme that included representation from 77 cohorts submitting 168 abstracts of which 135 were accepted.

COHERE

(Collaboration of Observational HIV Epidemiological Research Europe)

This year has been focused on securing a successful second merger of data for the Plato II projects on triple-class failure and resistance. Likewise, the EuroCoord CHAIN resistance project has followed up on the preliminary data presented at the IWHOD workshop in March and, after much discussion and some delay, third-party reimbursements to contributing cohorts can now proceed. The remaining COHERE project groups (hepatitis, OI, cancer, and mortality) are focused on preparing for the initiation of the COHERE work packages under EuroCoord. Apart from handling the data merger for the cohorts in our region, CHIP has led the work to produce a COHERE Manual of Operations, detailing all aspects of the collaboration.

A publication on discontinuation of prophylaxis for Pneumocystis jiroveci pneumonia in virologically well-suppressed patients was accepted during 2010; several other manuscripts are under final review and will be submitted shortly.

ACTIVATE

capACity building and Training in hIV/Aids Treatment and management across Europe

HIV

Pharmacovigilance Website

In partnership with the WHO and Uppsala Monitoring Centre, CHIP is currently developing an HIV pharmacovigilance website. As part of a project funded by the Seventh Framework Programme (FP-7) of the Research Directorate of the European Commission (EC), the website will provide access to the latest information on ARV side effects and toxicity, e-learning modules, and risk calculator tools to aid physicians in patient management.
Please visit the website at www.hivpv.org.

MATCH

Management of Post-Transplant Infections in Collaborationg Hospitals

Following solid organ or bone marrow transplantation, treatment with immunosuppressive drugs used to prevent rejection renders patients susceptible to several opportunistic infections. Among these is the post-transplant cytomegalovirus infection - a potentially serious complication which puts the patient at risk for progression to CMV disease associated with increased morbidity, mortality and reduced graft survival.

CHIP, in collaboration with the liver, kidney, heart and lung transplantation clinical departments at Rigshospitalet have established a prospective transplantation database to monitor and evaluate the risk of developing viral infections among transplant patients. Intended as a patient safety and monitoring tool, the data will be collected centrally for the clinical management, care, and shared expertise for the care of patients.

The platform will also be used for collaborative scientific purposes.

The major focus for 2010 has been on the development and implementation of the database so that the transplant departments can start to use the tool. The clinical departments have started to implement the standardized viral screening for the patients' individual planned monitoring.

The project initiated monitoring of the kidney and liver transplanted patients and the infrastructure is being adapted so that the lung and heart transplanted patients can be followed by the end of 2011.

Participating departments:

Epidemiklinikken, Nefrologisk Klinik, Kirurgisk Gastroenterologisk Klinik, Hjertemedicinsk Klinik, Hæmatologisk Klinik, Klinisk Mikrobiologisk Afdeling og Blodbanken

Monitoring: 350 transplant patients/year

HIV in Europe

The HIV in Europe Initiative

HIV in Europe is a pan-European initiative with the overall objectives to:

1) Determine and work towards reducing the number of people living with HIV in Europe who are unaware of their serostatus;
2) Identify political, structural, clinical and social barriers to achieving optimal counselling and testing and earlier access to care;
3) Promote evidence based practices and guidance on HIV testing in Europe;
4) Study the proportion of people living with HIV presenting late for care.

Achievements 2010

- Consensus definition of late presentation published and used in several presentations and publications (ex. European Centre for Disease Prevention and Control (ECDC) 2010 Special Report).
- Improved methods to estimate the number of infected not yet diagnosed people living with HIV.
- Indicator disease guided testing on the European (testing) agenda.
- Initiatives started to develop and implement evidence-based strategies to reduce the barriers to testing due to stigmatization, discrimination and criminalization.
- Communications policy and strategy 2010-2012.
- On December 1st 2010, World AIDS Day, the European Centre for Disease Prevention and Control (ECDC) launched its new HIV testing guidelines in the European Parliament to support countries to improve their national HIV testing strategies. HIV in Europe and Jens Lundgren have been part of the ECDC Technical Advisory Group on HIV testing and presented at the launch of the guidelines with participation of the Belgian Minister of Social Affairs and Public Health for the Belgian EU Presidency, Laurette Onkelinx, Member of the European Commission John Dalli, ECDC Director Marc Sprenger among others.

2010 Publications

Late presentation of HIV infection: A consensus definition. A Antinori, T Coenen, D Costagiola, N Dedes, M Ellefson, J Gatell, E Girardi, M Johnson, O Kirk, J Lundgren, A Mocroft, A d'Arminio, A Phillips, D Raben, JK Rockstroh, C Sabin, A Sönnerborg, F De Wolf; European Late Presenter Consensus Working Group. HIV Med. 2011 Jan;12(1):61-4. Published Online: 17 Jun 2010.

Overcoming obstacles to late presentation for HIV in Europe. JV Lazarus, R Jürgens, M

Weait, A Phillips, J Hows, J Gatell, T Coenen, A Sönnerborg, D Raben, J Lundgren.

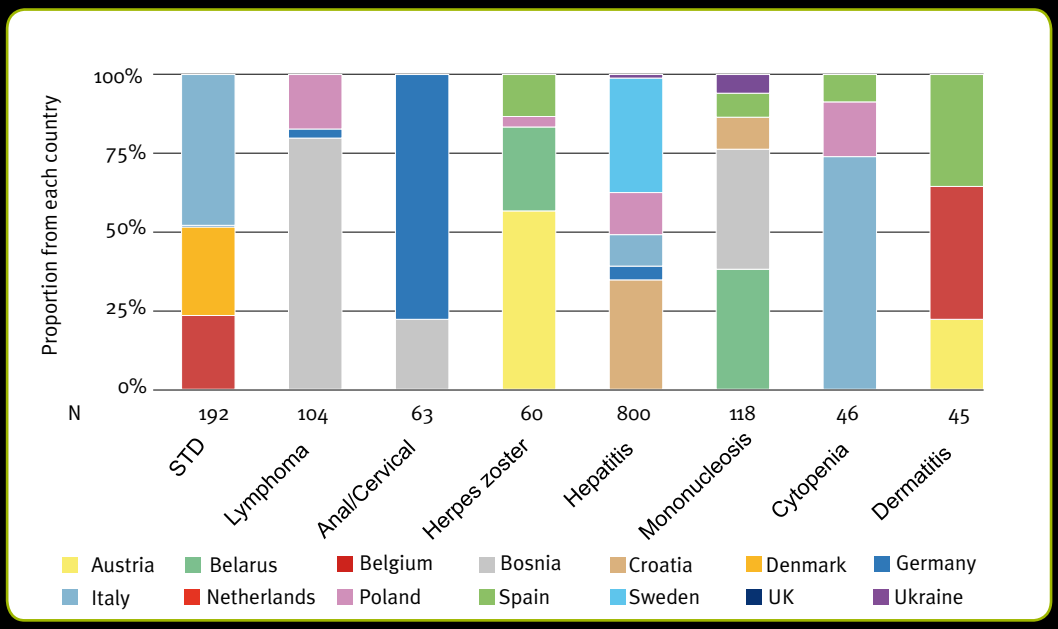
HIV Med. 2010. Published Online 29 Aug 2010.
A timely reminder. J Lundgren, T Coenen, D Raben.
Public Service Review, Health and Social Care. Issue 25, Nov 2010.

2010 Presentations
Ensuring optimal HIV treatment in Europe: Overcoming obstacles to late presentation. J Lazarus, on behalf of the HIV in Europe Initiative.
International AIDS Conference, Vienna, July 2010.
Overcoming obstacles to late presentation for HIV in Europe. J Lazarus, D Raben, T Coenen, JD Lundgren, HIV in Europe Steering Committee.
International AIDS Conference, Vienna, July 2010.
A pilot study to determine the prevalence of HIV in persons presenting for care with selected conditions: preliminary results from the HIV in Europe study. A Sönnerborg, on behalf of the HIV Indicator Diseases Across Europe Study Group.
10th International Congress on Drug Therapy in HIV Infection, Glasgow, November 2010.
Overcoming obstacles to late presentation for HIV in Europe. N Dedes.
2010 National Summit on HIV Diagnosis, Prevention, and Access to Care, Washington, November 2010.

The HIV Indicator Diseases Across Europe Study
In autumn 2009, a pilot study was initiated to develop and evaluate the best methods to estimate HIV prevalence of conditions handled by the health care system and to estimate which of 8 conditions have an HIV prevalence of ⟶0.1% in various settings in Europe.
Throughout 2009-2010, the 38 surveys were launched in 17 centres in 14 countries. As of December 2010, 2700 patients were enrolled into the different surveys. The surveys were intended to capture the number of patients who tested HIV positive when they went to the clinic or hospital department with one of the indicator diseases (listed in the graph below). We know that many HIV patients are being diagnosed late and are entering care when the disease has advanced. We also know that some have been in contact with the health system for other symptoms prior to an HIV test and diagnosis.
The preliminary results of the pilot phase were presented during the 10th International

Congress on Drug Therapy in HIV Infection, Glasgow 7-11 November 2010 and indicator disease guided testing is now being discussed on the European testing agenda. The concept has proved effective through the pilot phase with an overall HIV prevalence of 1.8%.
Physicians in some specialities however appear reluctant to adopt HIV testing as part of routine care. Final results of the pilot phase will be presented in May 2011. Thereafter Phase 2 will be implemented with additional surveys for other conditions. Another aspect of Phase 2 will be implementation of audits to see to what extent AIDS defining diseases are being routinely tested for HIV (for example, TB).

38 surveys of 8 conditions in 14 countries
% of enrollment for each condition by country as of 15 June 2010



PARTNER study

In 2010 CHIP began another collaboration with the Royal Free Hospital by launching and co-coordinating the PARTNER study. The study is funded by the NIHR (National Institute for Health Research in the UK) and sponsored by UCL (University College London).

The PARTNER study enrols couples where one partner is HIV positive and the other is HIV negative, looking at the risk of HIV transmission when someone is taking effective HIV treatment. Even though we know generally which are high and low risks, very few studies have quantified this, especially since new drugs have become available. This is still the case even after 25 years of research.

The aim of this study is to follow serodifferent partnerships that report recent unprotected sex in order to study the risk of HIV transmission to partners and study why some partnerships do not use condoms and to describe the changes in condom use.

The study includes over 60 sites in 14 European countries: Finland, Sweden, Denmark, UK, Ireland, Germany, Belgium, The Netherlands, France, Austria, Switzerland, Italy, Spain and Portugal. The study will enrol 1650 partnerships.

The study initiated enrolment 1 October 2010, with the first 19 pairs enrolled by 1 December.

MD Group

Daniela C. Gey, Ole Kirk, Signe W. Worm, Daria Podlekareva, Caspar da Cunha-Bang, Jens-Ulrik Jensen, Justyna D. Kowalska, Lene Ryom, Ravi Shastry, Lars Peters.
Not pictured: Ulrik B. Dragsted, Nina Friis-Møller

CHIP
COPENHAGEN HIV PROGRAMME

IT & Bioinformatics

WHO

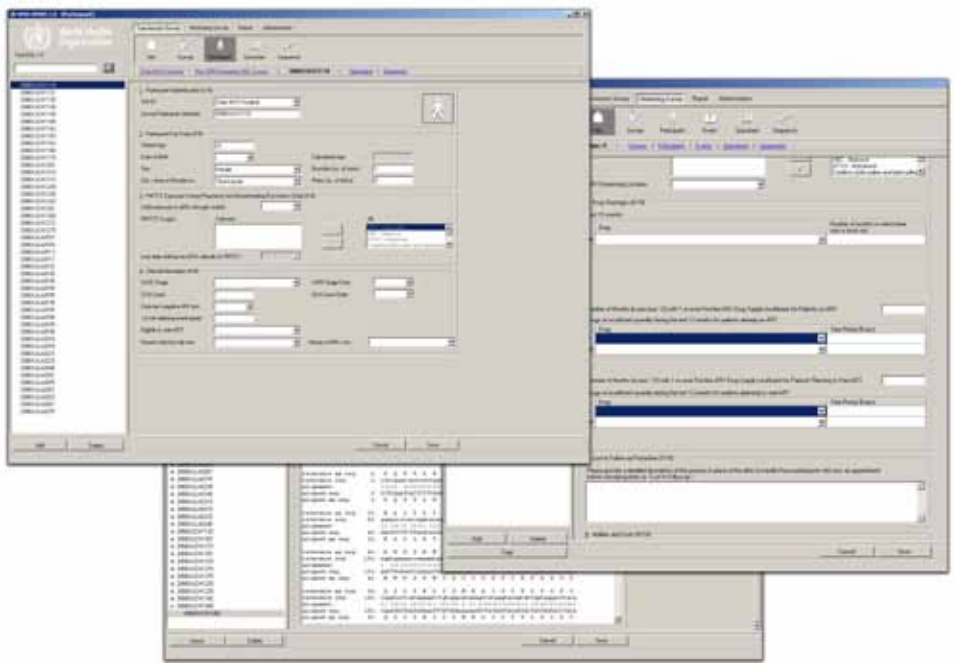
HIV Drug Resistance Database v2.0

Since early August 2009 the CHIP IT team has, together with WHO and CDC, worked on developing a stand-alone database tool to capture information on monitoring and transmission of drug resistance. The database tool covers all data elements from clinical site profile, access to treatment, drug shortage, patient characteristics, clinical events, sample handling and genotypic resistance data, thus providing empirical data to support ongoing discussions and decision-making

Features of the database tool:

- Integrated configuration of available data items
- User access control
- Multiple languages
- Quality assurance and interpretation of genotypic resistance based on the Stanford algorithm
- Integrated analysis and reporting functionality
- The ability to export the data for national, regional and eventually global analysis of resistance development

The tool runs license-free, works on all Windows platforms since Windows 2000 and has so far received positive feedback for its ease of use and user-friendly interface while still allowing for a wide range of customisation options.



PARTNER

Online CRF Data Entry

Throughout autumn 2010 the IT team at CHIP developed a new data capture system to allow for direct data entry for enrolment and follow-up of pairs enrolled in the PARTNER study. The data entry system allows for entry of clinical data and immediate verification of basic completeness of the entered data. In addition, each site has a portal page displaying all pairs enrolled at the site and notification of upcoming and overdue visits.

This allows for fast turnaround of data collection and verification of data between the sites and CHIP. The system also allows the sites to be aware of their own status and progress in respect to enrolled and planned follow-up visits.

The IT team will work further on exploring and implementing direct data entry during 2011 to support other projects such as HIV in Europe Initiative, EuroSIDA and HIV/TB.

IT & Bioinformatics Group

Rikke Salbøl Brandt, Jesper Kjær, Frederik Marcher, Casper M. Frederiksen, Nanna Lange.
Not pictured: Dennis Kristensen

CHIP
COPENHAGEN HIV PROGRAMME

Teaching and Outreach

Teaching

CHIP has continued to grow and professionalize activities related to teaching both within the University environment as well as outside. An important component to research is disseminating and applying the scientific results. Teaching is and will remain an important priority for the group.
In 2010 the activities included lectures, faciliting group work, as well as supervising OSVAL (Medical students), MIH, and other thesis work.

OSVAL students

- **Predictors of a sustained virologic response in chronic hepatitis C treatment; a comparison between HCV mono-infected and HCV/HIV coinfected.**
  Josefin Eklöf, medical student, OSVAL 2.
- **Mechanisms of CD4+T-lymphocyte depletion in Hiv-1 infected individuals.**
  Bojan Kovacevic, medical student, Bachelor of Science in Medicine.
- **Epstein-Barr virus and post-transplant Lymphoproliferative disorder.**
  Marie Bangstrup, medical student.
- **Genetic variations in the CCR5 gene associated with HIV-1 resistance.**
  Karina Juhl, humanbiology student.
- **Evolution of HIV-1 co-receptor tropism.**
  Pernille Nilsson, humanbiology student.
- **Clinical characteristics of stroke and stroke-like events in HIV-1 patients.**
  Karin Skullman, medical student.

CHIP's PhD Programme

CHIP has an extensive history of PhD and Post Doc teaching and supervising. The environment allows for a good exchange and shared experience as well as providing teaching and supervising experience internally within CHIP. The organisational structure allows for the facilitation of the administrative and operational work so that the PhDs and Post Docs can focus on the

Master of HIV

An important activity for CHIP in 2010 has been establishing a Master program for HIV, and in April 2010 the Faculty of Health Sciences approved the Master of HIV curriculum.
The interest and need for the Master of HIV is evident. More than 400 people across the world have expressed sincere interest, however most of them are looking for scholarships. We admitted 20 students within only 3 months in the beginning of 2010. All applicants fulfilled the admission criteria and had a definite need for the education (many of them from low-income countries with a severe HIV burden). Unfortunately the majority could not afford the tuition fees.
In June 2010 it was thus decided to postpone the launch of the Master of HIV programme until September 2011. A Master of HIV scholarship fund has now been established and we have intensified marketing and fundraising for future annual Master of HIV programmes. We will launch one of the modules: "HIV-related Diseases, Treatment and Care" (5 weeks) under the Master of International Health Programme in April 2011.
In addition CHIP has established a one-week course in collaboration with Copenhagen University's summer programme. The course entitled "Effective Response to Major Infectious Diseases - where Medicine meets Public Health Policy" will be lead by Professor Jens Lundgren and Dr. Jeffrey Lazarus from The Global Fund.

research components as well as maintaining an operational overview of the research conducted.

CHIP has a long-standing collaboration with the University College London, Royal Free Hospital's HIV Epidemiology and Biostatistics Research Group. The group under the leadership of Professor Andrew Phillips as well as Caroline Sabin and Amanda Mocroft also supervises PhD and Post Doc work on the studies coordinated by CHIP. The group of statisticians at Royal Free and the clinicians at CHIP are able to learn and share experience and expertise to the benefit of both groups. This is a dynamic exchange, strengthened even more by international collaboration.

Currently active within the PhD program
Justyna Kowalska, MD, PhD student, CHIP
Caspar da Cunha-Bang; MD, PhD student, CHIP
Lene Ryom, MD, PhD student, CHIP
Joanne Reekie; PhD Student, Royal Free Hospital, London
Alim Kamara; PhD Student, Royal Free Hospital, London
Daria Podlekareva, MD, PhD; Active Post Doc, CHIP
Signe Worm, MD, PhD; Active Post Doc, CHIP
Lars Peters, MD, Research Fellow, CHIP

Internal education sessions
CHIP continues to prioritize employee training and has for the last 5 years provided a weekly internal education and update ses-

Outreach

As the activities at CHIP all involve collaborative projects, an important component is outreach and communication. This involves communication internally within the studies as well as externally to all stakeholders. We realise that research does not end with publication in peer-reviewed journals and that coordinating the experience from patient care and research results into teaching, policy making and action is also an important priority.

Activities in 2010 included:

- International consultancy
- Annual international conference coordination
- International Scientific and Operational Steering Committee and Advisory Board participation
- National networking activities related to HIV
- Developing and implementing a communication strategy

sion. The topics, identified by staff, are presented by CHIP staff as well as other guest lecturers, both national and international.

Danish Institute for Study Abroad (DIS)
Drs. Lars Peters and Signe Worm and others from CHIP have been active in teaching at DIS (affiliated with Copenhagen University). Lars and Signe coordinate the course entitled 'A biomedical exploration of HIV and AIDS', offered in the spring and autumn. This course includes an overview of the complexity of HIV/ AIDS from a biological and medical perspective. The course also includes biological characterisation of HIV (virology, immunology and epidemiology), and medical and clinical aspects of HIV/AIDS (development of HIV infection, opportunistic infections, treatments, complications and co-infections).

Acknowledge-ments

Acknowl-edgements

The CHIP management is very pleased that this has been a stable year – no one left CHIP, on the contrary Søren, one of our monitors, returned to CHIP.
Due to the general crisis in Spain and a reduction in work, our Spanish SCC was not able to keep Patricia Herrero on staff Patricia has done a great job monitoring on behalf of CHIP. She is a fast learner and an engaged collaborator and we hope the expansion of the START trial will allow the Spanish SCC to hire Patricia again.

We would also like to acknowledge the thousands of patients who take part in the trials and studies coordinated at CHIP. It is for and because of them that we continually strive to produce high quality research.

Funding
CHIP is entirely dependent on external project-specific funding; the University funds only Jens' university position and a one-time contribution to the marketing of the master education.

EU
The last year of the FP6 funding circle for EuroSIDA ended in February 2010. The continued 5-year funding will be under the umbrella of EuroCoord and will likely be initiated by January 1st 2011. In addition,

Awards

Caspar da Cunha-Bang
Panum Institute, PhD Day 2010, Best Poster

Jens-Ulrik Jensen
Lundbeck Foundation grant for the CASS study.

Daria Podlekareva
Danish Research Council Post-doctorate grant and travel grant for the AIDS 2010 Conference, Vienna.

Signe Westring Worm
Young Investigator Award, CROI 2010, San Francisco, CA

CHIP is involved as a partner in four EU projects: ACTIVATE (also finalised this year), CHAIN, NEAT and the WHO project, Monitoring Medicines.

NIH
CHIP receives limited network funding as International Coordinating Centre in the INSIGHT Network. The START study in September was granted permission to initiate the extension to include 4000 patients – the exact budget is still under negotiation but is likely to exceed 110 million USD plus an additional 100 million USD worth of study drugs delivered by pharmaceutical sponsors.

The Danish Council for Independent Research, Medical Sciences
CHIP post docs have been successful in attracting public Danish funding through the Council for Independent Research. Currently Signe Westring Worm, Jens-Ulrik Jensen and Daria Podlekareva are funded through this source.

Pharmaceutical Industry
It is important for us that the activities of CHIP are driven by an academic research agenda supported by public funding and that CHIP is a strictly non-profit research organization working solely for the benefit of patients by conducting high quality science. We emphasize that the private co-funding we raise is encouraged by and in line with the policies of our public sponsors. CHIP's engagement with industry is always based on scientific evaluation by the relevant scientific steering committee and always based on unrestricted grants.

The EuroSIDA EU-grant does not cover all proposed activities and therefore industry funding for the analytical work related to resistance mutations, toxicities and co-infections is a valuable contribution to the activities. Sponsorship agreements are only entered into if the scientific question to be investigated under the agreement is found scientifically sound. The resulting reports are often used for regulatory submission as response to requests from the regulatory authorities.

The D:A:D study was funded by the HAART Oversight Committee for an additional period including merger 13 in 2012. The prolonged funding also includes a major increase in the type of events collected by adding chronic liver disease, end-stage kidney disease and non-AIDS defining cancers. Likewise, an additional cohort of 16,000 patients was included. The Oversight Committee originally was formed based on requests from EMEA that closely follow the D:A:D results and continued funding.

Together with the University of Bordeaux, CHIP is administering the activities of the legal entity established to take care of the International Workshop on HIV Observational Databases (IWHOD).

The 'HIV in Europe' initiative is coordinated by CHIP and is a cross-European and multidisciplinary initiative working for optimal testing and earlier care for HIV in Europe.

Financial contributors current year

Study/activity	Public	Private
EuroSIDA (EuroCoord)	EU Commission Danish Council for Independent Research	Gilead Sciences Merck & Co Inc Pfizer Inc
D:A:D	The Oversight Committee for The Evaluation of Metabolic Disorders of HAART Danish Council for Independent Research EMeA FDA	The Oversight Committee sponsors: Abbott Laboratorie Boehringer-Ingelheim Pharmaceuticals Inc Bristol-Myers Squibb Gilead Sciences GlaxoSmithKline Merck & Co Inc Pfizer Inc Roche Pharmaceuticals Tibotec/ Janssen-Cilag International NV
INSIGHT network	National Institutes of Health, USA (NIH)	
INSIGHT START	Agence Nationale de Recherches sur le SIDA et les Hépatites Virales (ANRS), Australian National Health and Medical Research Council (NHMRC); Bundesministerium fur Bildung und Forschung (BMBF), Division of Clinical Research, NIAID, NIH; National Institute for Mental Health (NIMH), NIH; National Institute of Neurological Disorders and Stroke (NINDS), NIH; National Cancer Institute (NCI), NIH; European AIDS Treatment Network (NEAT); Department of Bioethics, NHI, Clinical Center	Study drug sponsors: Gilead Sciences Bristol-Myers Squibb Merck & Co Inc Abbott Laboratorie GlaxoSmithKline Tibotec/Janssen-Cilag International NV
INSIGHT FLU	NIAID, NIH	
NEAT	EU Commission	Study drug sponsors: Gilead Sciences Janssen-Cilag International NV Abbott Laboratories Ltd Merck Inc.
Monitoring Medicines, WHO	EU Commission	Bill & Melinda Gates Foundation
ACTIVATE	EU Commission	
EuroCoord-CHAIN	EU Commission	Gilead Sciences
COHERE	ANRS	
PARTNER	National Institute for Health Research, UK (NIHR)	
IWHOD	NIH Office of AIDS Research NEAT ANRS, Agence nationale de recherches sur le sida	Boehringer-Ingelheim Pharmaceuticals Inc Gilead Sciences GlaxoSmithKline Pfizer Inc Roche Pharmaceuticals Tibotec/ Janssen-Cilag International NV
HIV in Europe	Endorsed by AIDS Action Europe WHO Europe European AIDS Treatment Group (EATG) University of Copenhagen	Abbott Laboratorie Boehringer-Ingelheim Pharmaceuticals Inc Bristol-Myers Squibb Gilead Sciences GlaxoSmithKline Merck & Co Inc Schering-Plough Tibotec/ Janssen-Cilag International NV
CASS	Danish Council for Independent Research	

Publications 2010

Publications 2010

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AIDS. 2010 March 13;24(5):697-706.

4 Predictors of hepatitis B virus genotype and viraemia in HIV-infected patients with chronic hepatitis B in Europe. V Soriano, A Mocroft, L Peters, J Rockstroh, F Antunes, N Kirkby, S de Wit, A d'Arminio Monforte, Robert Flisiak and J Lundgren on behalf of EuroSIDA.
J Antimocrob Chemother. 2010 Mar;65(3):548-55.

5 Causes of death in HIV-1-infected patients treated with antiretroviral therapy, 1996-2006: Collaborative analysis of 13 HIV cohort studies. The Antiretroviral Therapy Cohort Collaboration Study Group (ART-CC).
Clin Infect Dis. 2010 May 15;50(10):1387-96.

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30 Smoking-related risk of all-cause mortality and serious clinical events among HIV-infected patients receiving highly active antiretroviral therapy in the Strategies for Management of Antiretroviral Therapy clinical trial. AR Lifson, J Neuhaus, JR Arribas, M van den Bergwolf, MN Labriola, TRH Read for the INSIGHT SMART study group.
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CHIP
COPENHAGEN HIV PROGRAMME

Presentations 2010

Presentations 2010

17th Conference on Retroviruses and Opportunistic Infections, San Francisco, February 2010

Orals

1 Rates of cardiovascular disease following smoking cessation in patients with HIV infection: Results from the DAD study. K Petoumenos, S Worm, P Reiss, S De Wit, A d'Arminio Monforte, N Friis-Moller, R Weber, P Mercie, C Pradier, J Lundgren on behalf of the DAD study group.

2 Triglycerides and the risk of myocardial infarction in the DAD study. S Worm, A Kamara, W El-Sadr, O Kirk, E Fontas, P Reiss, A Phillips, M Bruyand, A d'Arminio Monforte, M Law, R Weber, J Lundgren, C Sabin on behalf of the DAD study group.

3 Chronic kidney disease (CKD) and exposure to antiretroviral drugs (ARVs) in a large cohort with long-term follow-up: the EuroSIDA Study. O Kirk, A Mocroft, P Reiss, S De Wit, D Sedlacek, M Beniowski, J Gatell, A Phillips, B Ledergerber, J Lundgren, for the EuroSIDA study group.

Posters

1 Biomarkers of inflammation and coagulation and risk of non-AIDS death in HIV/Hepatitis co-infected patients in the SMART study. L Peters, J Neuhaus, D Duprez, JD Neaton, R Tracy, MB Klein, A Mocroft, J Rockstroh, G Dore, JD Lundgren; for the INSIGHT SMART study group.

2 Predicted effect on transmission of HIV-1 resistance of timing of implementation of viral load monitoring to determine switches from first to second line antiretroviral regimens in resource-limited settings. A Phillips, D Pillay, G Garnett, D Bennett, M Vitoria, V Cambiano, J Lundgren.

International Symposium of Intensive Care and Emergency Medicine, Brussels, March 2010

Orals

1 Trials on diagnostic tools. JU Jensen.

2 Procalcitonin-guided therapy. JU Jensen.

XVIII International AIDS Conference, Vienna, July 2010

Posters

1 Causes of death in HIV/TB coinfected patients: Results from the HIV/TB collaborative study. A Panteleev, D Podlekareva, W Bannister, V Riekstina, A Rakhmanova, F Post, JM Miro, H Furrer, M Bruyand, RF Miller, E Girardi, M Losso, J Toibaro, J Caylá, N Obel, A Skrahin, N Chentsova, JD Lundgren, A Mocroft, O Kirk, and the HIV/TB study group.

2 Disclosure and preceived HIV-related discrimination in Danish dental clinics. M Mansfeld, P Björkman.

3 Overcoming obstacles to late presentation for HIV in Europe. JV Lazarus, D Raben, T Coenen, JD Lundgren, HIV in Europe Steering Committee.

Laboratory Medicine in Health Care, Lisbon, October 2010

Oral

1 Does procalcitonin-guided antmicrobial therapy in the ICU improve survival? JU Jensen.

Scandinavian Society for Anaesthesia and Intensive Care: Interactive Symposium at Nordic ICU Course, October 2010

Oral

1 Procalcitonin Use in the ICU. JU Jensen.

The 12th International workshop on adverse drug reaction and comorbidities in HIV, London, November 2010

Orals

1 Evaluation of sudden death and non-haemorrhagic stroke and their association with HIV protease inhibitor (PI) usage. Signe W. Worm, A Kamara, P Reiss, E Fontas, S De Wit, W El Sadr, A d'Arminio Monforte, M Law, A Phillips, L Ryom, F Dabis, R Weber, C Sabin, JD Lundgren on behalf of the D:AD study group.

2 **Vitamin D and clinical disease progression in HIV infection: results from the EuroSIDA study.** JP Viard, JC Souberbielle, O Kirk, B Knysz, M Losso, J Gatell, C Pedersen, JR Bogner, A Mocroft, JD Lundgren.

Poster

1 Chronic kidney disease in patients with normal eGFR at baseline: Results from EuroSIDA. L Ryom, A Mocroft, P Reiss, B Ledergerber, S De Wit, D Duiculescu, AD Monforte, M Murphy, JD Lundgren, O Kirk for the EuroSIDA study group.

The 10th International Congress on Drug Therapy in HIV Infection, Glasgow, November 2010

Orals

1 Fatal and non-fatal AIDS and non-AIDS events in HIV-1 infected patients with high CD4 counts. J Reekie, J Gatell, I Yust, E Bakowska, A Rachmanova, M Losso, M Krasnov, P Francioli, J Kowalska, A Mocroft for the EuroSIDA study group.

2 Vitamin D and clinical disease progression n HIV infection: results from the EuroSIDA study. JP Viard, JC Souberbielle, O Kirk, B Knysz, M Losso, J Gatell, C Pedersen, JR Bogner, A Mocroft, JD Lundgren.

3 A pilot study to determine the prevalence of HIV in individuals presenting for care with selected conditions: Preliminary results: the HIV in Europe Indicator Diseases Across Europe Study. A Sönnerborg on behalf of the Indicator Diseases Across Europe study group.

Posters

1 Changing antiretrovirals whilst viral load ⁘50 copies/ml and relationship with CD4 count changes. A Mocroft, J Reekie, C Katlama, A Lazzarin, M Ristola, H Sambatakou, J Gasiorowski, D Jevtovic, O Kirk and JD Lundgren for the EuroSIDA study group.

2 Haemoglobin and anaemia in the SMART study. A Mocroft, AR Lifson, G Touloumi, J Neuhaus, Z Fox, A Palfreeman, M Vjecha, S Hodder, S De Wit, JD Lundgren, AN Phillips for the INSIGHT SMART study group.

3 A pilot study to determine the prevalence of HIV in individuals presenting for care with selected conditions: Preliminary results: The HIV in Europe Indicator Diseases Across Europe Study. A Sönnerborg, A Mocroft, JD Lundgren, D Raben, J Gatell, A Vassilenko, V Hadziosmanovic, J Begovac, H Sørensen, M Cusini, N Clumeck, B Gazzard,

J Rockstroh, M Zuin, A d'Arminio Monforte on behalf of the HIV Indicator Diseases Across Europe study group.

4 Fatal and non-fatal AIDS and non-AIDS events in HIV-1 infected patients with high CD4 counts according to viral load strata. J Reekie, J Gatell, I Yust, E Bakowska, A Rachmanova, M Losso, M Krasnov, P Francioli, J Kowalska, A Mocroft for the EuroSIDA study group.

5 Chronic kidney disease in patients with normal eGFR at baseline: Results from EuroSIDA. L Ryom, A Mocroft, P Reiss, B Ledergerber, S De Wit, D Duiculescu, AD Monforte, M Murphy, JD Lundgren, O Kirk for the EuroSIDA study group.

6 Relating protease inhibitor resistance at time of virological failure with drug exposure. M Van Luin, WP Bannister, R Paredes, AN Phillip, J Bruun, J Van Lunzen, O Kirk, A d'Arminio Monforte, A Cozzi-Lepri, DM Burger, and the EuroSIDA study group.

7 Vitamin D and clinical disease progression in HIV infection: Results from the EuroSIDA study. JP Viard, JC Souberbielle, O Kirk, B Knysz, M Losso, J Gatell, C Pedersen, JR Bogner, A Mocroft, JD Lundgren for the EuroSIDA study group.

2010 National Summit on HIV Diagnosis, Prevention, and Access to Care, Washington DC, November 2010

Poster

1 Overcoming Obstacles to Late Presentation for HIV in Europe. N Dedes, JV Lazarus, T Coenen, A Phillips, M Weait, J Hows, D Raben, JD Lundgren, HIV in Europe Steering Committee.

A day at the office

Nikolai and Caspar at Rigshospitalet working on the MATCH database.

Maria, Annette and Jorunn getting ready for the DHL race. CHIP had 2 teams competing this year, one of which placed 3rd in their division for Copenhagen University.

Bitten and Annette enjoying an after-lunch power walk around Panum.

Tina and Jens celebrating Jens' 50th birthday

Maiken, Dorthe and Helle surprised the rest of the office with a performance of Santa Lucia, a traditional Scandinavian song usually performed by children around Christmas time.

CHIP's Christmas party this year had a costume theme and everyone showed their creativity and enthusiam.