The EPOS study
Barriers, difficulties, solutions in multicentre palliative care research

Pål Klepstad

D7

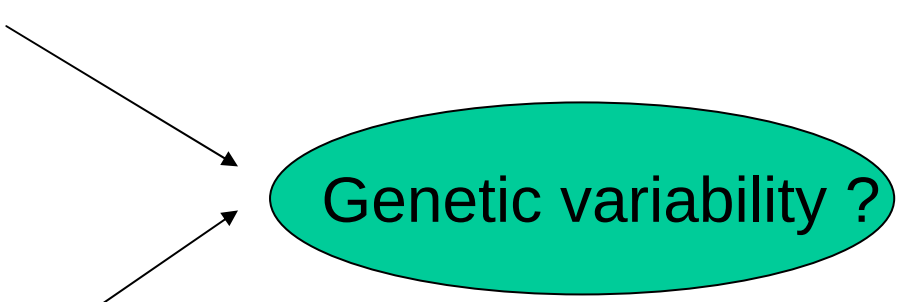
Diapositiva 1

D7 Har ikke satt inn dato... Forøvrig fjernes merknadene ved å høyreklikke på dem...
DMF; 25/01/2006

D4

Interindividual variability of opioid dose

Interindividual variability in response to specific opioids



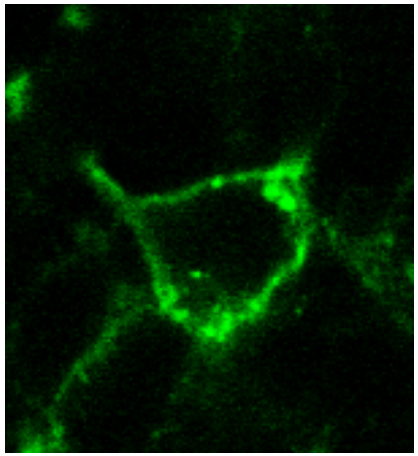
Research strategy

1. Translational research program
2. Cancer pain

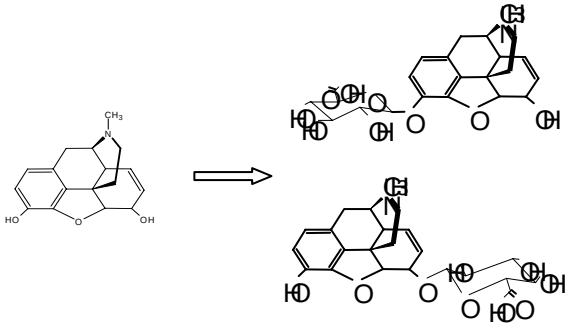
Diapositiva 2

D4 Burde det være en overskrift?

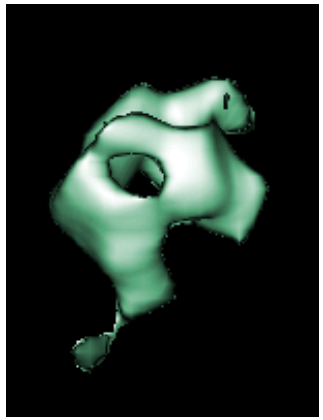
DMF; 25/01/2006



Opioid receptors



Opioid metabolism



Opioid transporters

Modifying systems

Klepstad et al. Acta Anesthesiol Scand 2005

D2

Limitations of present research on genetics and clinical effects of opoids

- Sample size
- Most studies on morphine
- Most studies from one population

Diapositiva 4

D2 Tatt vekk punktum

DMF; 25/01/2006

European Pharmacogenetic Opioid Study (EPOS)

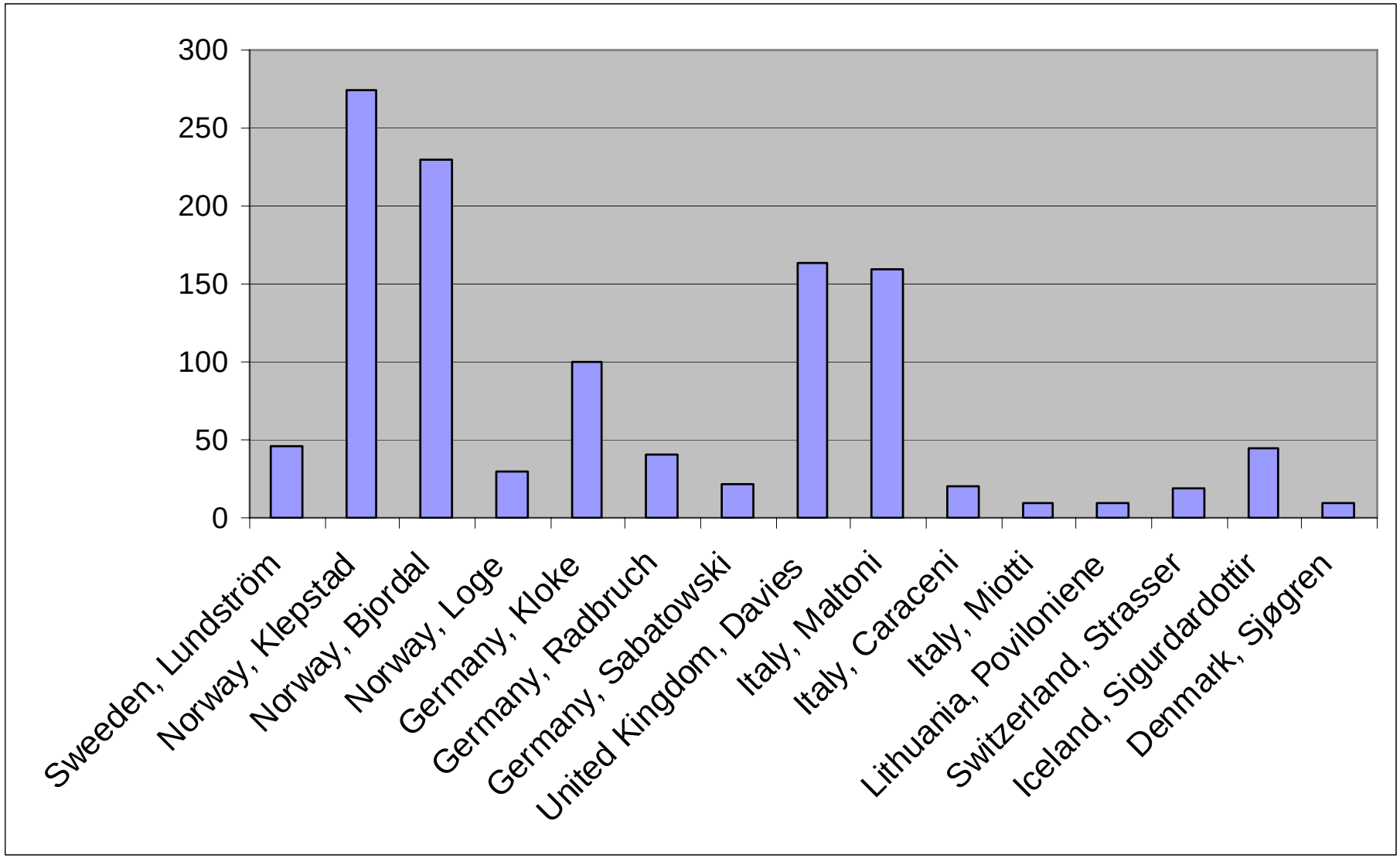
- 3000 patients
- 15 centres, 10 countries (May 2006)
- Primary aim:
  - To study the influence from genetic variability on cancer pain and the efficacy of opioids

EPOS biobank

- Data bank of clinical information
- Data bank of serum concentrations of opioids and opioid metabolites
- Blood for genetic analyses

- EPOS Ambition:
  - To perform studies on current and future candidate genes
  - To use databank also for non-genetic studies
  - To have studies performed by researchers from all participating centers

EPOS Number of patients, May 2006



EPOS General Research Issues (1)

– Collaboration and involvement of centers

EPOS General Research Issues (1)

Collaboration and involvement of centers

Solutions:

- Organize the study through the EAPC network
- Democratic organization
  - Use off data and biological samples decided by an EPOS steering committee
- Use of data available for all participants
- Personal contacts

EPOS General Research Issues (2)

The EPOS could be in conflict with other studies at a center

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The EPOS could be in conflict with other studies at a center

Solutions:

– Allow other studies to be performed.
– Integrate such studies with the EPOS studies
– Data management and printing of CRF by EPOS organization

– Result is motivation not conflict

Some studies not performed at all centers

- Patients barriers
- Sleep
- Hope
- Cachexia

EPOS General Research Issues (3)

Chose the right assessments

EPOS General Research Issues (3)

Chose the right assessments

Solutions:

Chose validated and in general translated assessments tools

Chose tools that are accepted by the study group

Chose simple assessments tools

Chose not to many assessments

- Clinical symptoms (14 item checklist). Used in the EAPC cross-sectional study
- HRQOL - EORTC QLQ-C30
- Pain - Brief Pain Inventory
- Cognitive function - MMS

EPOS General Research Issues (4)

Make a good protocol which is clear and easy to understand

EPOS experience:

We chose to write a short and direct protocol (15 pages) in order to ease the readers immediate comprehension of the study

Result:

+ All centers did understand the project

- To short for some advisory boards (especially those used to company studies)

Solution next time:

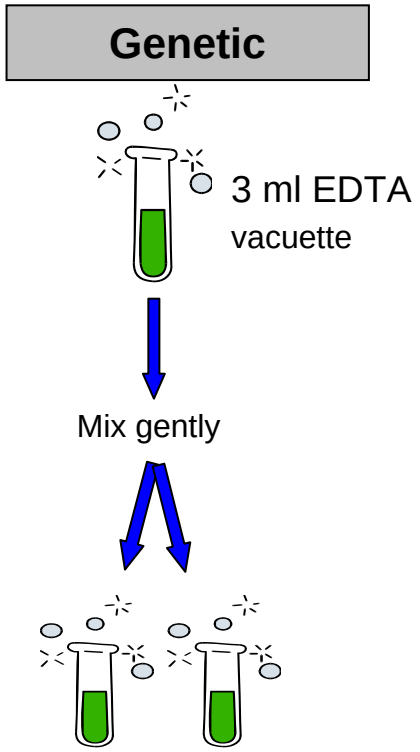
One short version for practical researchers and one extended version to the bureaucrats

EPOS General Research Issues (5)

Think a lot of handling of samples

Number of tubes
Fabric of tubes / containers
Storage
Shipment
Identification
Analytical work

EPOS	OPI 03-006	ÒSiteÓ
ID/No	J.D. _____	NO1-001
Date	_____/_____/_____	Set A
Time	_____/_____	
Matrix	EDTA blood	
Analysis	Genetics	



2 Cryotubes. min 1.5 ml in each. Labelled due to Appendix 1: Laboratory procedures.

Stored at minus 80ºC until shipment. The study team in Trondheim will decide date of shipments.

EPOS General Research Issues (6)

Organization !!

Solutions:
Dedicated personnel for coordinating the study

E-mail and phone that is operational

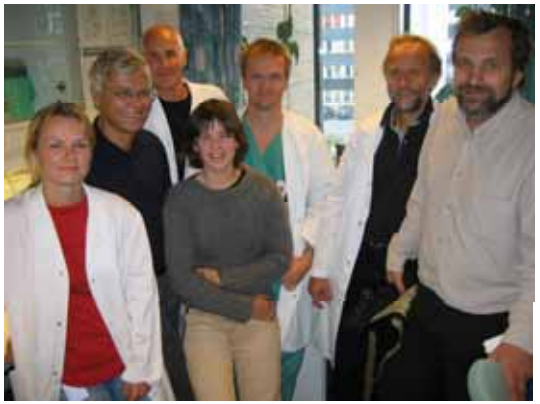
Short distance between basic researchers and health care personnel

The final EPOS challenge

To utilize this body of information

Data should end

Not here

But here

And finally thanks from Trondheim