International Registries:
The Government-Driven Model

Pål Surén

Norwegian Institute of Public Health

Norwegian Institute of Public Health

Presentation outline

- Overview of Norwegian health registries
- The Norwegian Mother and Child Cohort Study (114,500 children and their parents)
    - Sub-studies of autism, epilepsy, ADHD, cerebral palsy
- Choosing a registry model
    - National laws and regulations
    - Resources available
    - What do you want to achieve with the registry?
    - Examples: MoBa sub-studies, Cerebral Palsy Registry of Norway


YAHOO! Travel
Norway
N
Jan Mayer (Norway)
Arctic Ocean
Norwegian Sea
Faroe Islands (Denmark)
North Sea
Baltic Sea
Tromsø
Harstad
Narvik
Bodø
Mo i Rana
Namsos
Trondheim
Ålesund
Molde
NORWAY
Gjøvik
Hamar
Bergen
Hønefoss
Oslo
Drammen
Haugesund
Skien
Stavanger
Grimstad
Kristiansand
SWEDEN
Stockholm
FINLAND
Helsinki (Helsingfors)
Tallinn (Reval)
ESTONIA
LATVIA
Riga
LITH.
Vilnius
BELA.
RUS.
RUSSIA
UNITED KINGDOM
DEN.
0 100 200 mi
0 100 200 km
70°
65°
60°
0°
5°
5°
10°
15°
20°
25°
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Norway

- 5.1 million inhabitants (Ireland 4.6 million)
- 385,000 km^2 (Ireland 70,000 km^2)

- Most healthcare services government-funded

- Most healthcare institutions government-run
  - Private providers rely on government funding
  - Reporting to nationwide registries mandatory for all providers (public and private)

Norway: Registry framework

- PIN: Personal identification number
  - 11 digits (DOB + 5 digits)
  - Unique to each individual
  - Used in all public registries and databases

- Norwegian Population Registry
  - Births, deaths, residence, immigration, emigration

- Statistics Norway
  - Demographic and socio-economic data

The central registries

- Mandated by law; no consent or opt-out
- 17 in total

- General registries
  - Medical Birth Registry of Norway
  - Genetic Screening of Newborns (Biobank)
  - Norwegian Patient Registry
  - Norwegian Prescription Database
  - Norwegian Immunisation Registry
  - Norwegian Cause of Death Registry

- Disease-specific registries:
  - Norwegian Cancer Registry
  - Norwegian Cardiovascular Disease Registry
  - Norwegian Surveillance System for Communicable Diseases

Nationwide quality registries

- Regulated by the Norwegian Directorate of Health
- 47 in total

- Most are subdivisions of central registries → no consent or opt-out

- One registry for neurodevelopmental disorders: The Cerebral Palsy Registry of Norway (CPRN)
  - Consent-based, opt-in
  - Recruitment and data collection by clinicians
  - Linked to the nationwide CP follow-up program (CPOP)
  - Children born 1996 and later

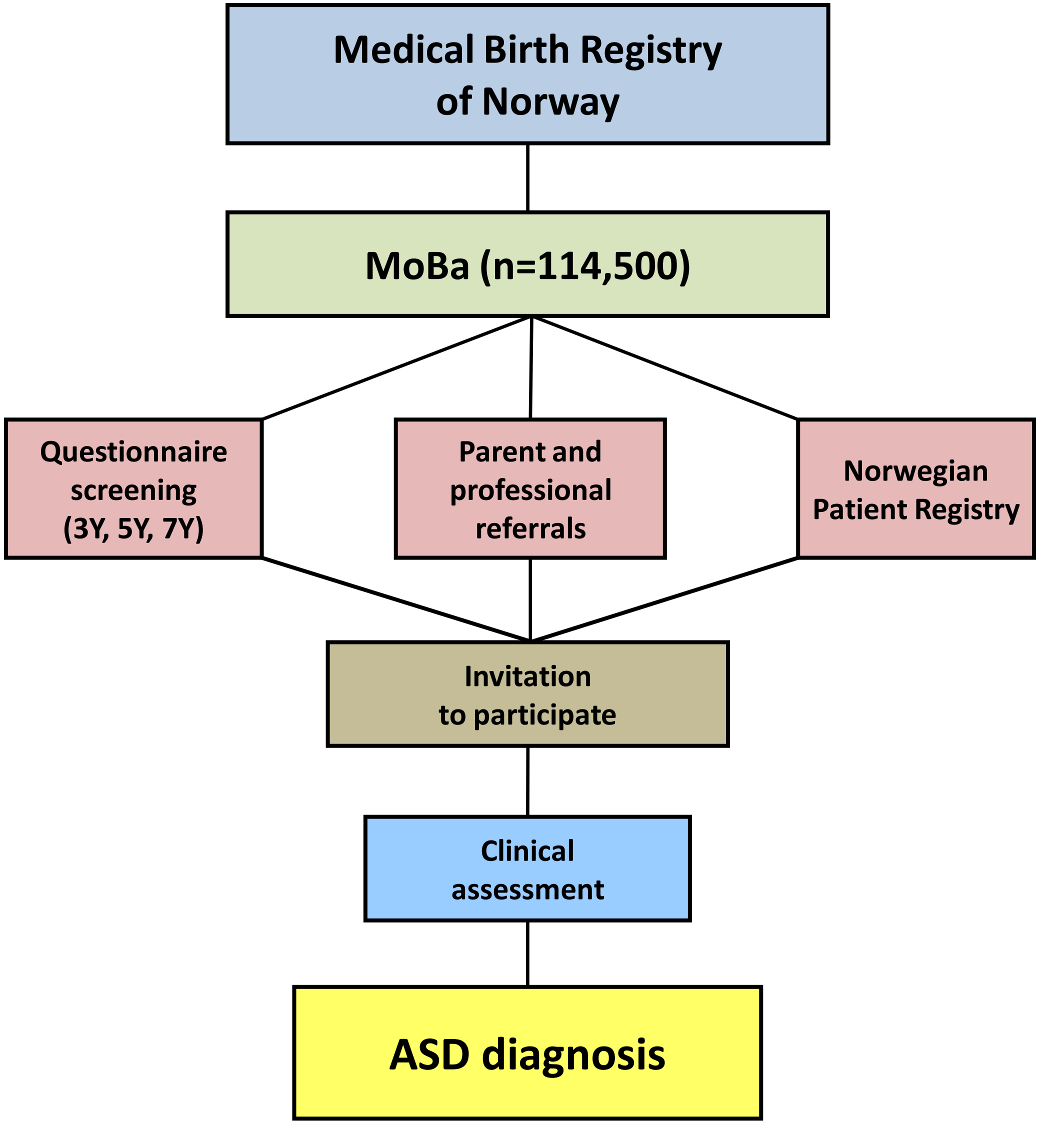
The Norwegian Mother and Child Cohort (MoBa)

- 114,500 children
  - Born 1999–2009
  - Age 5–15 years, mean 8.5 years
  - 93,500 mothers and 75,200 fathers

- Questionnaires through pregnancy and childhood
- Blood samples (DNA, RNA, plasma)
- Registry linkages
- Large number of ongoing sub-studies

MoBa sub-studies of neurodevelopmental disorders

- Autism spectrum disorders: The Autism Birth Cohort (ABC) Study
- Epilepsy: The Epilepsy in Young Children (EPYC) Study
- ADHD: The MoBa ADHD Study
- Cerebral palsy: Mothers and Babies in Norway and Denmark (MOBAND)
- Language and learning: The MoBa Language and Learning Study


Medical Birth Registry of Norway
MoBa (n=114,500)
Questionnaire screening (3Y, 5Y, 7Y)
Parent and professional referrals
Norwegian Patient Registry
Invitation to participate
Clinical assessment
ASD diagnosis

How to choose a registry model

- Case identification
  - Healthcare databases
  - Patient organizations
  - Population screening

- Recruitment
  - Mandatory vs. consent-based
  - If consent-based: Through clinicians or parents

- Data collection
  - Record reviews (by registry staff)
  - Parental questionnaires
  - Clinicians

The Autism Birth Cohort (ABC) Study: Relevant experiences

- Recruitment to MoBa associated with socio-economic characteristics
  - Education, marital status, number of children, country of origin
  - Lifestyle (BMI, smoking)

- Early screening not successful
  - Low sensitivity
  - Captured only severely affected cases

- Referrals from clinicians not very successful
  - No incentives
  - High probability of autism among referred children

- Clinical assessment: Participation affected by child characteristics
  - Overburdened families
  - Older children, low-functioning → hard to travel

ABC Study: Linkages to the Norwegian Patient Registry (NPR)

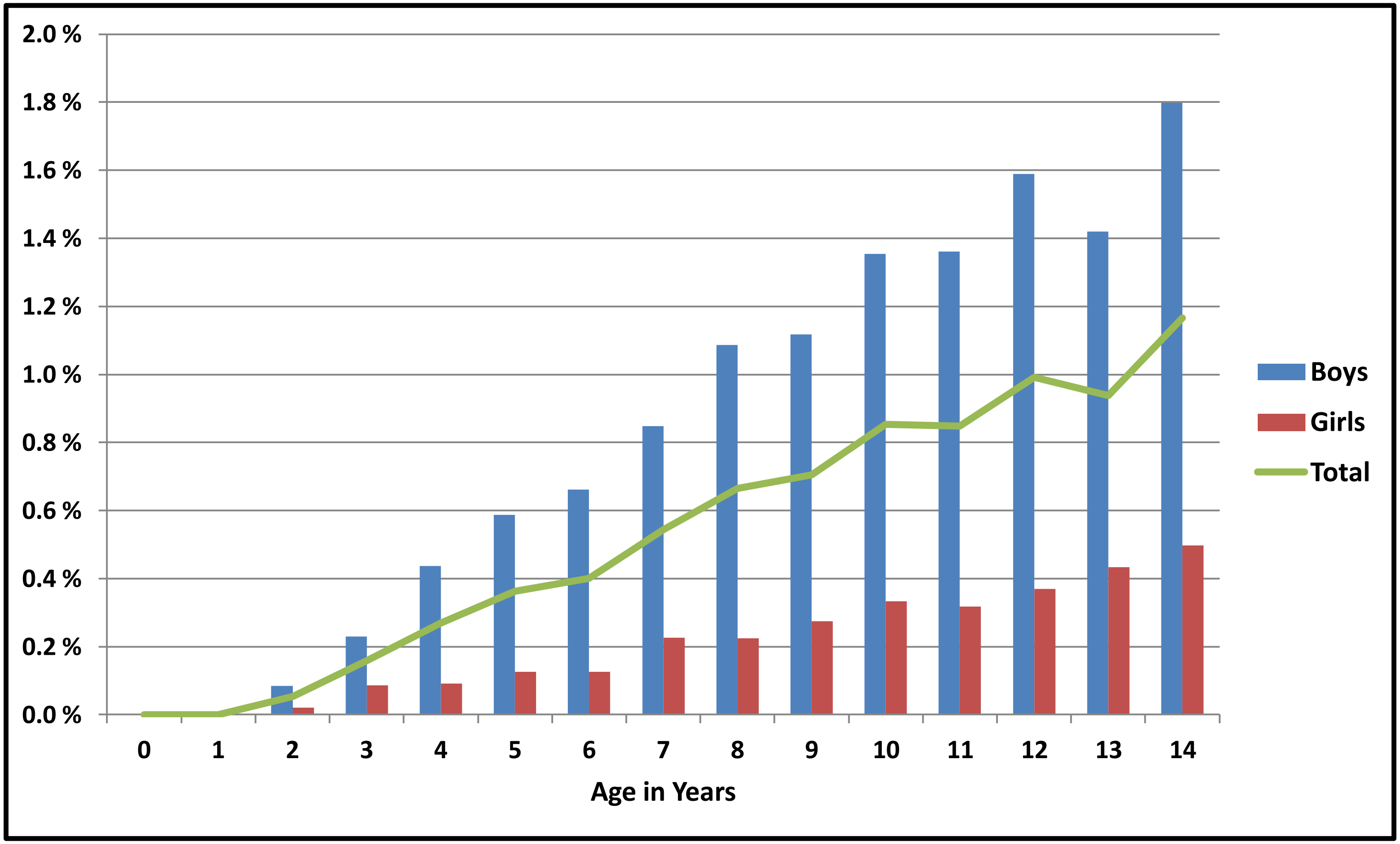
- Major source of ASD cases in the study

- Validation study (clinical assessment)
  - 58/60 ASD diagnoses confirmed → PPV 97%
  - Low participation rate (28%), selection bias
  - PPV high for autistic disorder, low for PDD-NOS and Asperger

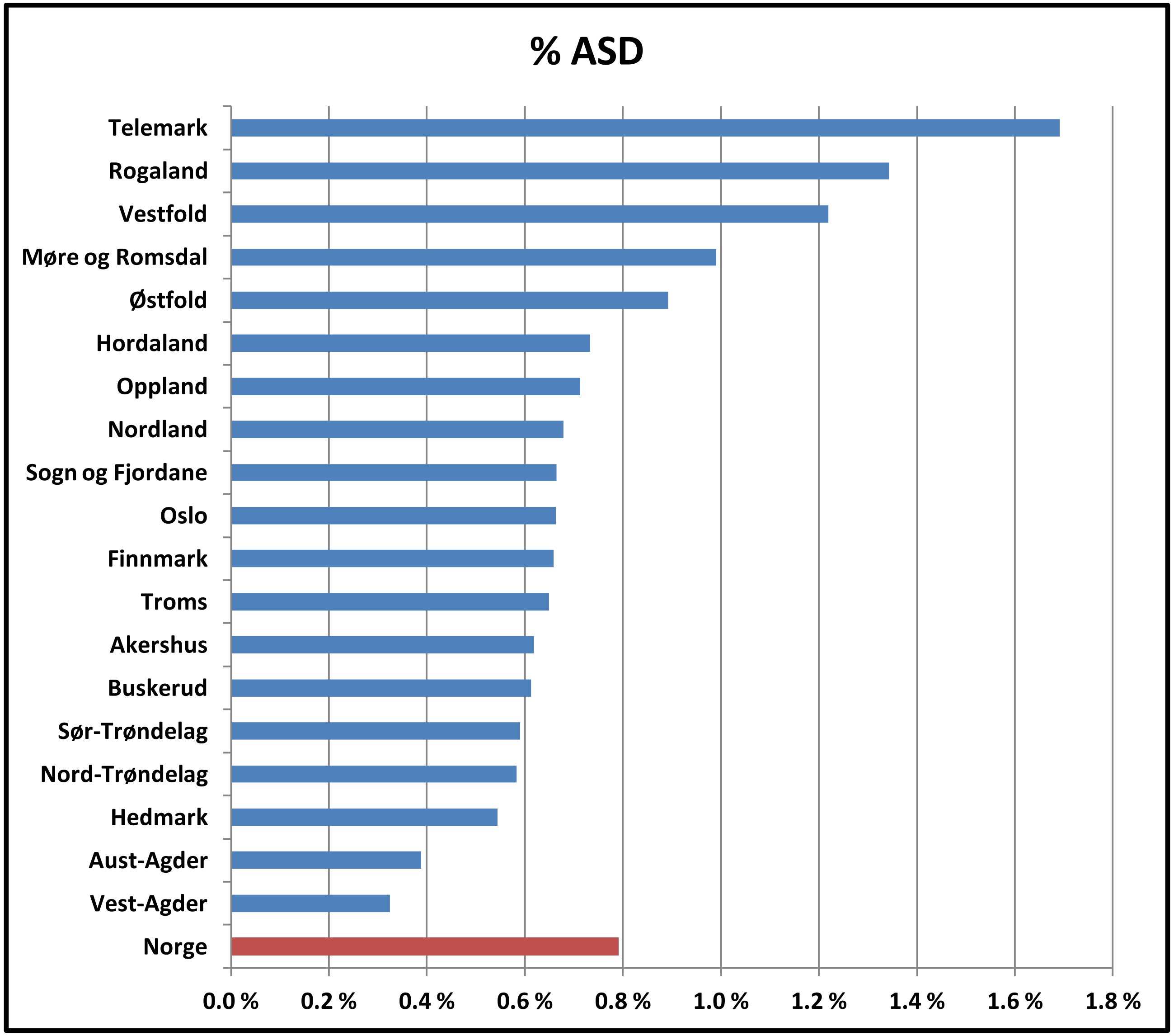
- Registry data alone:
  - No information about IQ, language level, etc.
  - ASD subtype diagnoses problematic

- ABC Study: Record-based validation and characterization ongoing

Norway: ASD prevalence



Prevalence by county (age 6–12 years)



Cerebral Palsy Registry of Norway (CPRN)

- Recruitment:
  - By clinicians, consent-based
  - Nationwide network, all hospitals included
  - Pediatric neurologists, physioterapists, occupational therapists

- Data collection
  - At time of diagnosis: Medical data
  - Age 5 years: Medical data
  - Age 15–17 years: Medical data, test results (cognitive, language, motor)

CP follow-up program (CPOP)

- Nationwide follow-up program
  - Standardized protocol; best-practice
  - Goal: Prevent complications, optimize outcomes
  - Funded by ordinary health services
  - 1–2 check-ups annually: Physician, physiotherapist (gross motor), occupational therapist (fine motor)
- Collaboration with CPRN
  - One network, one advisory board
  - Coordination of recruitment
  - CPOP data feed into CPRN

CPRN: Coverage

- Calculated by comparing to the NPR
  - CPRN included 63% of recorded CP diagnoses

- Validation study (record review):
  - 40% of non-captured diagnoses were not CP
  - True coverage 84%
  - 2006 and later: True coverage > 90%
  - Variations by county: 64–96%

CPRN: Advantages

- CP: Relatively rare, life-long follow-up
  - Limited number of clinicians involved, people know each other
  - Long-lasting relations between families and hospitals

- CPRN + CPOP
  - Incentives for parents: Best-practice follow-up
  - Incentives for clinicians
    - Academic support and guidelines
    - Networking

CPRN: Surveillance and research

- Prevalence:
  - In conjuction with the NPR
- Causes and risk factors
  - Linkages to birth registry, MoBa
  - Biobank of the Genetic screening of newborns program?
- Interventions and outcomes
  - Data collected by the CPRN
  - Difficult to obtain relevant data elsewhere

Conclusions

- Case identification
  - Important to identify the source population
  - Determine true prevalence and coverage
  - Identify selection bias

- Recruitment
  - Mandatory or opt-out easier than consent-based
  - If consent-based: Include incentives to participate
  - Networking and trust

- Data collection
  - Through clinicians/parents: High-quality, labor-intensive
  - Record reviews by registry staff: Cost-effective, no selection bias