

# International Registries: The Government-Driven Model

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# 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



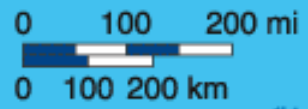
**N** Norway

Jan Mayer  
(Norway)

Arctic Ocean

Norwegian  
Sea

Faroe  
Islands  
(Denmark)



UNITED  
KINGDOM

North  
Sea

Baltic  
Sea



# Norway

- 5.1 million inhabitants (Ireland 4.6 million)
- 385,000 km<sup>2</sup> (Ireland 70,000 km<sup>2</sup>)
- 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

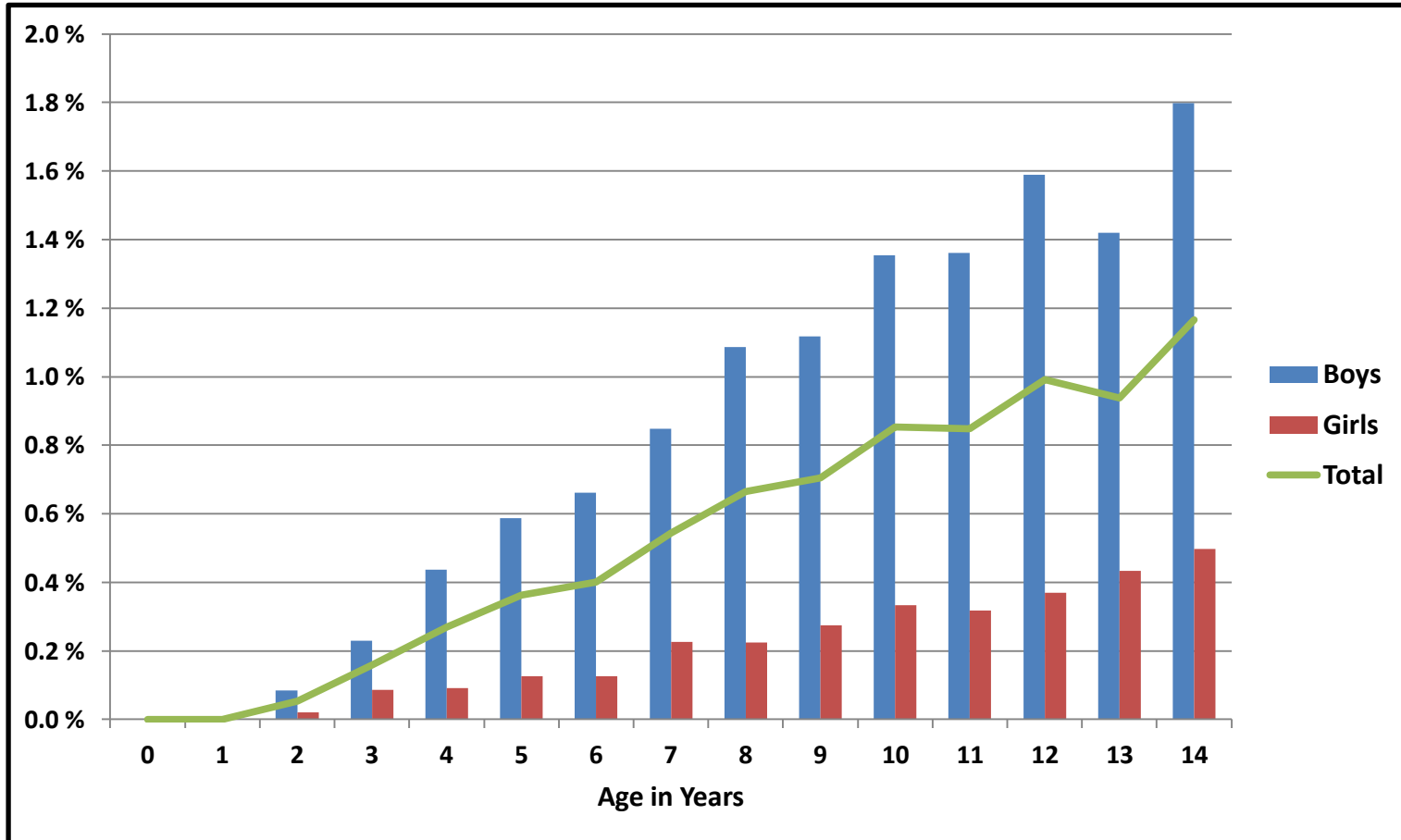


# ABC Study: Linkages to the Norwegian Patient Registry (NPR)

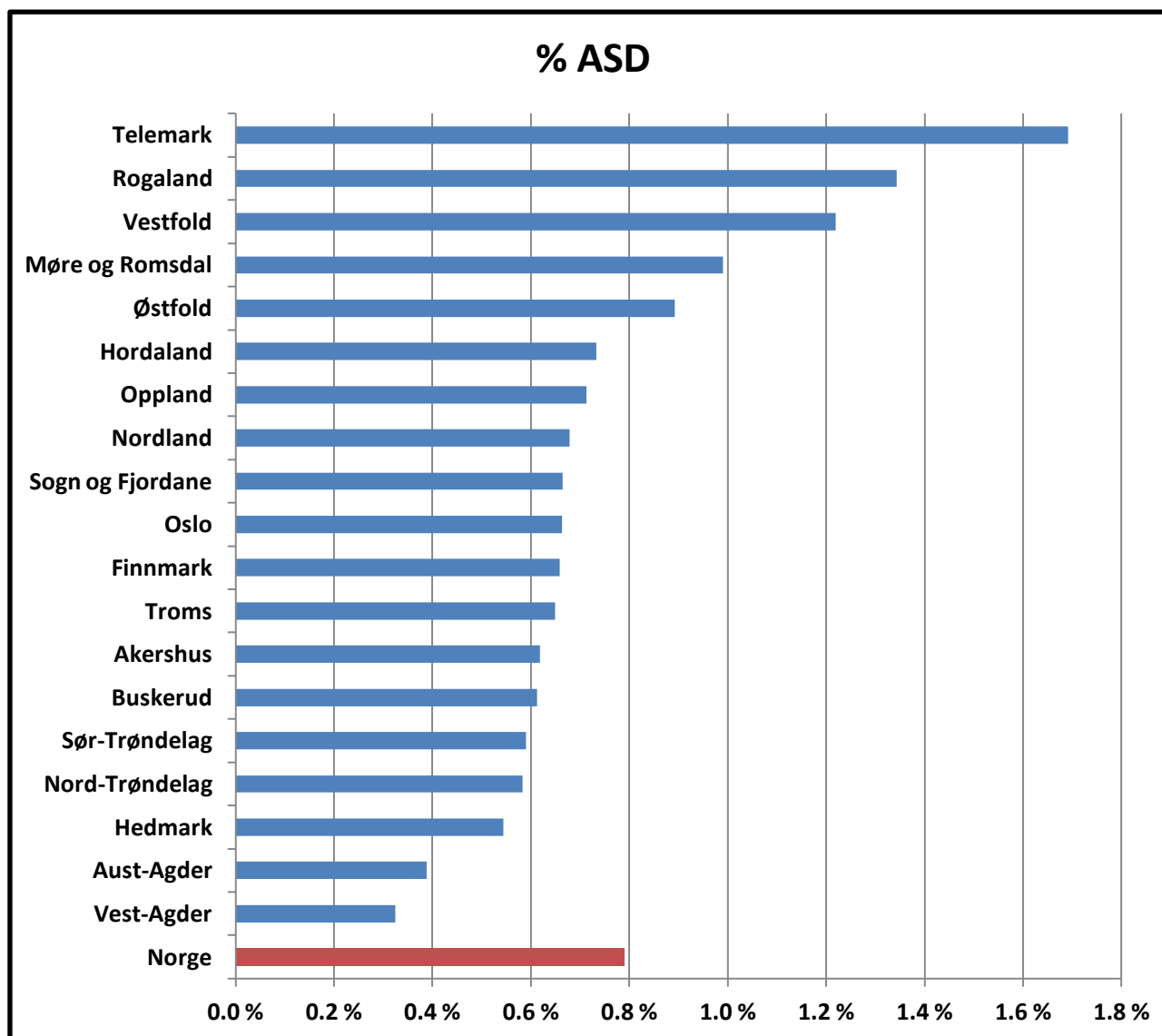
- Major source of ASD cases in the study
- Validation study (clinical assessment)
  - 58/60 ASD diagnoses confirmed → PPV 97%
  - Low participation rate (28%), selection bias
  - PPV high for autistic disorder, low for PDD-NOS and Asperger
- Registry data alone:
  - No information about IQ, language 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, physiotherapists, 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 conjunction 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

