



Nine months that last a lifetime

The Danish National Birth Cohort

Mads Melbye
Copenhagen, Denmark



The 10-minute presentation

- Danish conditions for prospective studies
- The aim and design of the birth cohort
- Materials collected
- Ownership and access



The Danish registries are unique

- an investment worth billions of Danish kroner
- Follow the individual from birth to grave
- follow diseases through generations
- millions of individuals
- results are robust



CRS-number

- Birth characteristics
- Diseases
- Prescribed medication
- Vaccinations
- Childcare facilities
- School performance
- Family, place of living
- Education, employment
- Biological specimens



Danish Cohort of 101,000 pregnant women and offspring

The Epidemiologist's Dream: Denmark

If the planners of a U.S. study of children's health could work in an ideal world, it might be Denmark. Epidemiologists there finished enrolling a cohort of 100,000 pregnant women into a mother-child research project last September and expect to finish collecting data from the children over the next year. The entire survey—which is large for this country of 700,000 annual births—is to be completed in 2005 for about \$15 million, a tiny fraction of what the cost would be in the United States.

The Danes didn't design their Better Health for Mother and Child cohort study to answer specific questions or conduct long-term follow-up, as the Americans plan to do (see main text). Instead, they aim to create a database that generations of researchers can mine and use as a starting point for studies of how medications, infections, nutrients, and even psychological factors affect pregnancy and child health.

Physicians have recruited volunteers among women making their first pregnancy visit. Participants give two blood samples during pregnancy and one blood sample when the baby is born. The samples are saved for later use, including possibly for genetic studies. The mothers also answer a detailed questionnaire concerning nutrition. In an 18-month follow-up, they give information on their health and environmental exposures. The public health system is funding the study with support from private and public foundations.

"Because the Danish population is probably the world's best regulated, Denmark is the ideal place for such studies," says epidemiologist Mads Melbye, a steering group member from Statens Serum Institut.

In Copenhagen, each citizen has a personal identification number that can be used to track data in centralized health care records, disease registries, and a population registry. Even centralized school records may be used. "It's an epidemiologist's dream," says Mark Kishor of the U.S. National Institute of Child Health and Human Development, who says tracking subjects is one of the oddest aspects of long-term U.S. studies.

However, which has a system like Denmark's, is launching a mother-child study that will pool data with the Danish group's. Both benefit from streamlined management, it's difficult to get things done with too many decision makers, says Melbye. "Running such a large study has taught us many things, but the chief lesson is that it is essential to put a very small group of people in charge."

Results are already beginning to trickle out of the Danish study. For example, one group published an article in The Journal last November that suggested the existing consensus view that a lower parity in pregnancy increases the risk for miscarriage. That's just the beginning. Denmark's scientific ethics committee had to far given the green light to more than 70 research protocols based on the mother-child study.

—Lisa Parnes
Lisa Parnes is a science writer in Copenhagen.



Danish Cohort of 101,000 pregnant women and offspring

\$ 12 mill.

The Epidemiologist's Dream: Denmark

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Norway, which has a system like Denmark's, is launching a mother-child study that will pool data with the Danish group's. Both benefit from streamlined management, it's difficult to get things done with too many decision makers, says Madhav. Running such a large study has taught us many things, but the challenge is that it is essential to put a very small group of people in charge.

The Danish group design their Better Health for Mother and Child cohort study to answer specific questions on conduct long-term. For example, as the Americans plan to do (see main text), they aim to create a database that provides a starting point for researchers to mine and use as a resource.

Researchers are planning a major study of mothers and children after 2 years. They've narrowed the possible objectives of the study down to 70.

US cohort:

Epidemiology

Everything You Wanted to Know About Children, for \$2.7 Billion

Researchers are planning a major study of mothers and children after 2 years. They've narrowed the possible objectives of the study down to 70.

Science, 11 July 2003



Overall aim

To identify prenatal and perinatal determinants of importance for reproductive failures and diseases that manifest themselves later in life.



Practical aims

- To recruit 100,000 pregnant women and offspring
- Collect exposure information by means of 4 telephone interviews
- Set up a biobank with 2 blood samples from the mother and 1 from the child
- Get food frequency data and over-the-counter medication from questionnaire



Participants

- Target population: all pregnant women
 - living in Denmark
 - speaking Danish well enough to take part in interviews
 - intended to carry their pregnancy to term
- Recruitment as early as possible in pregnancy (first visit to general practitioner)



Recruitment

- During 1996-2002 we enrolled 101,042 pregnancies. We have prospectively monitored the outcome of these pregnancies
- Approximately 30% of all pregnant women in Denmark were recruited through collaboration with GP's and midwives
- About half of all GPs were active, about 60% of women invited finally joined



Three types of data collected

Self-reported data on exposures and outcomes.

Main exposures of interest are: lifestyle factors, diet, social conditions, infections, medications & environmental exposures

Biological data.

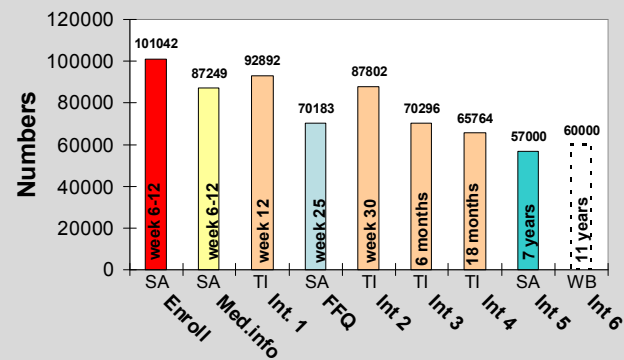
Blood from mother (pregnancy week 12 and 24), and child (cord blood and PKU card at day 3-5) stored in biobank

Data from existing registers.

F.ex. National Patient Registry & the Medical Birth Registry, medical prescriptions, disabilities, and death



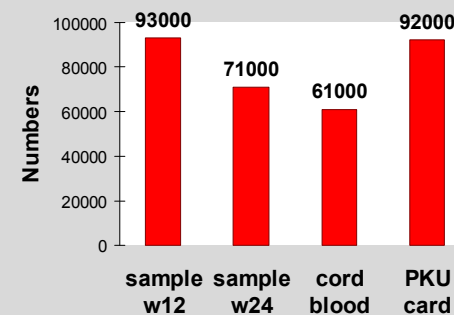
Number of respondents



SA: self-administered quest.; TI: telephone interview; WB: web-based



Blood samples





Access to Data

- The DNBC is a national registry, owned by the Danish National Board of Health.
- DNBC data are available for all researchers (see DNBC@ssi.dk)
 - As long as projects
 - do not harm the DNBC's reputation
 - are compatible with the overall aim
- Access to biological specimens is restricted
- All applications must be approved by the Management Group and Steering Committee



11-year follow-up



- Internet-based questionnaire to mothers and children.
- www.club11.dk

The screenshot shows the Danish National Birth Cohort website. At the top, there is a navigation menu with links for 'News', 'Public Health', 'R & D', 'SSI Diagnostica', 'Vaccines', and 'Contract Services'. Below this, there are sections for '7-year follow up' and '11-year follow-up'. The '7-year follow up' section includes a photo of a family and text about internet-based questionnaires. The '11-year follow-up' section has a blue header and text about the study for 11-year olds. On the right side, there are sections for 'For researchers...', 'DNBC Publications', 'Contact the DNBC', and 'DNBC News'. The footer contains contact information for Statens Serum Institut, including the address, phone, fax, and email.