How the "Newborn cohort" was established in terms of management and governance – a personal report from Bodolf Hareide, general director of NIPH from 1984 to 2001

Notes from an interview conducted by Anita Haugan, Kristine Vejrup and Per Magnus on October 27, 2014 at the Norwegian Institute of Public Health, Oslo, Norway

Bodolf Hareide, MD, was the general director of the National Institute of Public Health (NIPH) during the crucial years when MoBa was planned and initiated. The following paragraphs are excerpts from a meeting between Hareide and the guest editors of this issue.

The National Institute of Public Health (NIPH) was established in 1929. At that time, combatting diseases caused by microorganisms was the main task. The institute was the national microbiology laboratory. It also developed expertise on blood typing, and performed research in immunology and vaccine development. For decades, infectious disease control was the primary activity. From the 1970s, changes took place. The hospitals expanded with more academic staff and took responsibility for patient-oriented diagnostic laboratory procedures. This changed the scientific landscape and the duties of the NIPH. The Institute continued to work with infections and vaccines, but also established toxicology as a major discipline, and later set up departments of health services research and epidemiology.

The use of the assumed harmless drug thalidomide among pregnant women caused birth defects in children in the 1960s. This called for surveillance of congenital malformations and was a major reason for establishing the Medical Birth Registry of Norway (MBRN) in 1967. There was much debate on the governance and localization of the registry. A committee led by Hareide concluded that the registry should be located in affiliation with the University of Bergen. Many decades later, when NIPH reorganized in 2002 and became the Norwegian Institute of Public Health, MBRN became an integrated part of NIPH, still located in Bergen, based on a recommendation by another Hareide committee. The fusion made NIPH responsible for the management of the registry.

Hareide started his career at NIPH in 1981. In 1984, when Christian Lerche left the position, Hareide was appointed the new general director. During the 1980s, a white paper on NIPH's national obligations to promote public health was discussed in Parliament. Afterwards, NIPH stopped performing routine diagnostic tests and became an institution that had general research in disease prevention as a major activity. This shift meant reallocation of resources and personnel, and gave Hareide the flexibility to establish new activities. Child health became an important area for research.

There was close collaboration between researchers in Oslo (NIPH) and Bergen (MBRN) in the early planning of what was originally called "the Newborn Cohort", later "Better Health for Mother and Child" and finally "the Norwegian Mother and Child Cohort Study". It was not always easy to agree on positions and the use of personnel and resources. To promote decision making, Hareide appointed a steering committee consisting of researchers from both cities. The committee was led by Hareide. All issues and challenging resolutions were broadly discussed and considered scientifically before decisions were made. Even though many stakeholders and research groups were skeptical to such a big research project, the good collaboration with scientists in Bergen paved the way for establishing the cohort with a main goal of finding new causes of diseases, aiming at prevention. Thus, Stein Emil Vollset and Rolv Terje Lie in the early 1990s prepared the first version of the protocol of the study based on recruitment of the women through the general practitioners.

External expert groups were set up to ensure that the study was conducted by high ethical standards, and that all stakeholders were heard in the initial phases. These expert panels did not meet often, and they were mainly important for discussion about the recruitment part. This was also the case for the external group with focus on the ethical aspects. The broad expertise at the NIPH was an important support in planning the study more generally.

Leiv Sigmund Bakketeig was the first principal investigator in the 1990s. After many meetings with the Data Inspectorate, the study obtained its approval in 1996. The pilot started in the island of Sotra on the Western coast of Norway. The pilot study was successful, but the Medical Association of General Practitioners raised concerns about the study. As a consequence, the Minister of Health announced that the study had to be put on hold until it had been discussed in Parliament in 1998 which was potentially troublesome for NIPH as the study had not been mentioned earlier in the correspondence between NIPH and the Ministry of Health. Furthermore, the study had not been included in the financial allocations to the NIPH. However, this did not become an issue in the discussions, and the Parliament voted for the approval of the study and granted one million NOK annually. This was a clear message that we should continue. During this summer, Bakketeig was offered a position as a professor of epidemiology at the

University of Southern Denmark, and Per Magnus was appointed the new PI of the study. The concern raised by the general practitioners resulted in a change in recruitment strategy. Pregnant women were to be recruited through the hospitals at the time of ultrasound examination in gestational week 18.

There were many meetings with the aim of engaging the hospitals to take part in the recruitment of pregnant women to the project. Initially, we talked directly to the hospitals and the heads of the maternity wards to invite them to recruit pregnant women for the study. In general, the obstetricians, who were not much involved in the routine ultrasound measurements, were positive to the study. Midwives were compensated economically for their work load. The Haukeland University Hospital in Bergen was the first hospital to include pregnant women into the study, due to the efforts of Lorentz M. Irgens and coworkers at the University of Bergen.

As director at that time, Hareide was strongly supportive of MoBa. He traveled the country and abroad to promote the study and raise financial support, initially a difficult task. He was often met with skepticism and lack of ability to see the benefits of the study. During his career, Hareide had worked with different health related issues, either as part of national health institutions or in the political system, and was able to point to the many areas where new research was needed. When Hareide stepped down as general director, in 2001, MoBa was still in its early phase of recruitment. Now, looking back, he sees that establishing MoBa was well worth the effort, and he enjoys witnessing its many scientific accomplishments.

A summary of early events based on an interview with Bodolf Hareide, NIPH general director 1984-2001.

Year	Event	Result
1929	The National Institute of Public Health was established in Oslo	Main task to perform laboratory diagnostics for infectious diseases and toxicants
1957-1961	Women used thalidomide against nausea in early pregnancy	Epidemic of specific birth defects
1968	The Medical Birth Registry of Norway established in Bergen	Intention: to monitor adverse pregnancy outcomes, and to perform research in perinatal health
1984	Bodolf Hareide is appointed the new director general of NIPH	The white paper gave the him the flexibility to reallocate resources and start new activities, such as child health
1980s	White paper on NIPH's obligations to promote public health discussed in Parliament	A change from laboratory diagnostics to disease prevention in general including epidemiology and environmental medicine
1991	Scientific conference in Australia	The ideas of a pregnancy cohort emerged and led to collaboration between NIPH and MBRN
1993	Leiv S. Bakketeig appointed PI of the Newborn Cohort	Bakketeig, Rannveig Nordhagen and Kari Kveim Lie allocated to work with the cohort in collaboration with scientists in Bergen
1994	Bakketeig sets up the first protocol	Pregnant women were to be recruited through their general practitioners
1996-98	Approvals were obtained	License from the Data Inspectorate of Norway, and a recommendation from the Regional Committee on Medical Ethics
1997	Pilot study at Sotra	Recruitment on a small scale
1998	The Medical Association of General Practitioners raised their concerns	The study set on hold by the Ministry of Health until Parliament voted and approved the study
1998	Change of PI and new protocol	Bakketeig was offered a position at the University of Odense in Denmark. Per Magnus was appointed new PI of MoBa
1999	Recruitment of pregnant women starts at Haukeland Hospital in Bergen	Gradual expansion to other hospitals
2001	Hareide ends his employment	Geir Stene-Larsen is appointed new general director. A Division of Epidemiology was set up with Camilla Stoltenberg as director