



Norwegian Registry of
CLEFT · LIP · PALATE



**NEWSLETTER TO PARENTS AND GUARDIANS
OF CHILDREN WITH CLEFT LIP AND PALATE**

NORWEGIAN REGISTRY OF CLEFT LIP AND PALATE

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DEAR PARENTS/GUARDIANS

We would like to invite you to participate in the newly-launched Norwegian Registry of Cleft Lip and Palate, a quality registry aimed at facilitating the collection and analysis of data needed for quality improvement. Such registries contain data on the course of treatment in patients and are routinely used by health professionals to document the overall quality of treatment.



Before you decide whether your child is to be included in this registry, we would first like to explain why this registry was established and what participation would entail for you. Please read through the information provided in this brochure. If you need more information or clarification, you are welcome to contact us directly. You can find our contact details online at www.helse-bergen.no/LKG.

Registration in the Norwegian Registry of Cleft Lip and Palate is entirely voluntary and requires written informed consent. If you would like your child to participate, we ask you to sign the attached declaration of consent. Please note that you can withdraw your consent at any time without the need to provide a reason. Importantly, withdrawal from the registry does not have any consequences for your child's further treatment. The declaration of consent must be renewed by your child when he/she turns sixteen.



PURPOSE OF THE REGISTRY

The registry will collect data from the treatment teams in Oslo and Bergen. Our hope is that data from the registry will be valuable in deciding the best possible treatment for children born with clefts.

- Ensure that a child born with clefting of the lip and/or the palate receives the best possible treatment and follow-up.
- Ensure that data collection and registration of treatment given to cleft patients in Norway is unambiguous.
- Register whether the patient group and parents/guardians feel they are well taken care of.
- Facilitate the comparison of treatment and outcomes with other cleft-repair teams.
- Help foster research.
- Provide data for preparing annual reports.

BACKGROUND

Every year approximately 130 children are born with various types of clefts in Norway. Clefting of the lip and/or palate is the most common birth defect in the head and throat region, occurring in approx. 2 out of 1000 live births. Although many factors can cause a cleft, genes and environmental factors are thought to play major roles. The frequency of clefting in Norway has remained unchanged for the last forty years.

The outcomes of treatment are first noticeable when the patient has reached adulthood. This applies to appearance (scars and the development of facial structures), speech (palatal function and the amount of space in the throat), hearing (the recurrence of middle ear problems can lead to impaired hearing in adulthood), occlusion of teeth, and psychosocial adaptation.

Given the relatively small number of children born with clefts in

Norway, it would be advantageous to include as many of them as possible in the registry. Our aim is to register a large enough number of patients to be able to make more reliable comparisons. The results will be valuable to our own Norwegian teams, as well as other cleft-repair teams around the world, when faced with decisions on how to best treat children born with clefts in the future. Your participation is therefore very important in helping us build this registry.

DECLARATION OF CONSENT

As parents/guardians of new-borns or adopted children born with clefts, you will be asked to attend an information meeting arranged by the cleft-repair treatment team you have been referred to. Here we will provide you with more information about the registry and you will have ample opportunities to ask questions.

At the meeting, you will be asked to give written informed consent to include information about your child in the registry. If you need more time to decide, you can also do this when your child is admitted to the hospital for his/her first operation. The declaration of consent provides detailed information on the type of data to be registered and how the data will be used.

The registry has been approved by the Norwegian Data Protection Authority, which ensures that data are being collected, stored and used in full compliance with established rules and regulations. This is important in safeguarding the privacy rights of each patient. The registry is based on parental/guardian consent during the first hospital check-up, which is generally given when the child is a new-born infant. When the patient turns sixteen, consent must again be given in connection with routine check-ups provided by the treatment teams (refer to the Norwegian Personal Data Act, section 9 a).

THE RIGHT TO INSPECT, CHANGE AND DELETE INFORMATION

Data processing and management have been approved by the Norwegian Data Protection Authority. The data are stored electronically and will be treated as strictly confidential. Thus, anyone working with the information in the registry is under a confidentiality agreement not to disclose information that comes to their knowledge.

- You are fully entitled to inspect the information registered on your child.
- You may, at any time, demand that the information be deleted from the registry without specifying why.
- Your decision not to include your child in the registry will not affect your child's treatment with the team.



HANDING OUT INFORMATION

- A control group has already been established with the primary responsibility of preparing separate guidelines for accessing data registered in the Norwegian Registry of Cleft Lip and Palate for quality assurance and/or research purposes.
- Data that are accessible to researchers and those taken from the registry will be anonymized by removing all identifiable information. The Norwegian Registry of Cleft Lip and Palate is the only authority that will store (and have access to) names and other characteristics.
- It may be necessary in some research projects to link data across different national registries, such as the Medical Birth Registry of Norway, Cancer Registry of Norway and Norwegian Patient Registry. This is clearly specified in the declaration of consent.

TWO CENTRALISED TREATMENT TEAMS IN NORWAY

Oslo team

- Oslo University Hospital at the Department of Plastic and Reconstructive Surgery at Rikshospitalet
- Statped, Bredtvet kompetansesenter (The National Support System for Special Needs in Education, competence centre)

Bergen team

- Haukeland University Hospital at the Department of Plastic Surgery and Burns
- Fylkestannlegen i Hordaland ved Senter for Leppe- Kjeve- Ganespalte (Hordaland County Dentist at the cleft lip and palate centre)
- Statped Vest (The National Support System for Special Needs in Education Western Norway)

NORWAY

The treatment is centralized to hospitals in Bergen and Oslo. The teams work closely together and consist of Plastic Surgeons, Speech Therapists, Orthodontists, Nurses, Otolaryngologists and Psychologists.



ORGANISATION AND MANAGEMENT OF THE REGISTRY

- Helse Vest RHF (The Western Norway Regional Health Authority) and Helse Sør-Øst RHF (South and Eastern Norway Regional Health Authority) have delegated financial responsibility and administration of the registry to Helse Bergen HF (Bergen Hospital Trust).
- Helse Bergen HF is responsible for processing data gathered in the registry.
- Helse-Vest IKT (The Western Norway Regional Health Authority - IT Department) is responsible for technical operations.
- The Clinic of Surgery at Helse Bergen HF is responsible for the administration of the registry. The secretariat and general management of the registry has been placed under Helse Bergen HF.
- The two treatment teams for cleft lip and palate in Norway (at the Department of Plastic and Reconstructive Surgery at Oslo University Hospital Trust, and the Department of Plastic Surgery and Burns at Haukeland University Hospital Trust) are professionally responsible for the registry.



PUBLIC INTEREST GROUP

The Norwegian Cleft Lip and Palate Association (NCLPA; www.lgs.no) is a public interest group for children, youth and adults born with a facial cleft, as well as their parents and guardians. NCLPA is actively involved in the work of the Norwegian Registry of Cleft Lip and Palate where it is duly represented by a Board Member. We in NCLPA consider it extremely valuable that such a Quality Registry is being established, as this ensures a uniform registration of the treatment of patients with facial clefts in Norway. In the long term, the registry aims to play a key role in research and development related to cleft treatment in Norway. We therefore encourage everyone to consent to participation in this registry.

The Norwegian Cleft Lip and Palate Association:



**Leppe - Ganespalte
Foreningen**

PERSONAL NOTES

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