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NEW ZEALAND ASSOCIATION *of* Plastic Surgeons
Te Kāhui Whakamōhou Kiri

Health New Zealand
Te Whatu Ora

New Zealand | Aotearoa

The Consensus Guidelines for National Cleft Care

February 2024

CONTENTS

1. Introduction

Cleft Services New Zealand are largely performed by four regional Multidisciplinary Team (MDT) units in Christchurch, Wellington, Waikato and Auckland. Cleft care is also provided in Dunedin. Whilst there has been inter-unit collaboration and sharing of resources no formal national service guidelines have existed. Globally, there have been reviews of cleft care with standardisation of protocols and nationalisation of services in places like Scandinavia and the United Kingdom [Bearn[1] et al, 2001].

At the end of 2022, MDT clinicians working in cleft units across the country met to discuss the current and future states of cleft care in Aotearoa, New Zealand. One of the outcomes of this meeting was for a national working group to establish a document detailing minimum national standards and guidelines for the care of our cleft community.

New Zealand Māori have the highest incidence of cleft palate in the world. The incidence of cleft palate in Māori is over twice that of Europeans (1.54 vs 0.73 per 1,000 live births) [Smit& Fowler[2] , 2010, Thompson[3] et al, 2016]. Māori experience disparities in outcomes compared to the rest of the population across nearly all areas of health, due to inequity in determinants of health, including access to quality health care[11]. Māori have on average the poorest health status of any ethnic group in Aotearoa [MoH[4,] 2015] [MoJ[5] 2019].

The Ministry of Health has highlighted health equity and cultural safety as two strategic areas for review [MoH[6] 2015]. These guidelines expect to incorporate Te Tiriti o Waitangi principles and to continue to work closely with tangata whenua to help ensure equitable access and outcomes.

The purpose of this document is to capture three main elements of the New Zealand Regional Cleft Service. Firstly, the scope of the service is defined, as well as how it functions at a tertiary level and collaborates with the broader community network.

Secondly, the role and function of the Multidisciplinary team (MDT) a. And lastly how we measure our service goals and outcomes as clinicians, regional units and a national service.

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2. Scope of the Cleft Service

Objective

Mission statement

The cleft service provides specialist care and surgery for tamariki and rangatahi (children and young people) with cleft lip and/or palate (CLP) and non-cleft velopharyngeal insufficiency (VPI) to ensure that they have equitable access to timely specialist intervention in order to achieve the best possible outcome in aesthetic facial appearance, feeding, hearing, speech and psycho-social well-being.

Treatment aims

To accomplish the following in accordance with the care pathways:

1. Repair the birth defect
2. For cleft lip, achieves good lip and nose aesthetic and functions
3. For cleft palate, achieve good palate function for acceptable speech, normalised hearing, optimal dental health, and optimal dentofacial development (including jaw growth and dental occlusion)
4. For non-cleft VPI, achieve improved speech
5. Optimise psychosocial well-being and developmental outcomes

Service aims

The cleft service aims to enhance the quality of life for people with long-term conditions in CLP and VPI by ensuring:

1. The treatment goals are achieved
2. The services necessary for the entire care pathway described in this specification are in place or available for patients at each regional centre
3. Providing patients with timely surgery, treatment and regular follow-up in line with the clinical pathway
4. Offering a safe, clinically effective and accessible service to patients with CLP or VPI and their whānau (families/carers)
5. Providing a high-quality and evidence-based service offering effective clinical interventions that ensure optimal clinical outcomes
6. Supporting patients and their whānau with high-quality and appropriate information in a format that meets their individual needs
7. Supporting patients and families to make informed choices regarding their options using shared decision-making principles and tools to manage their condition to achieve their goals and the best possible quality of life
8. The CLP services are sensitive to individual patients and their whānau's physical, psychological, cultural and emotional needs
9. Treatment and service data collection and analysis for service improvement (under national cleft data framework)
10. Provide up-to-date and ongoing cleft education to support the learning of health and allied health professionals

Principles of care

To provide a safe, cost-conscious, high-quality, specialised service for people with CLP and VPI to improve their quality of life by:

1. Facilitating the service aims and achieving the treatment goals
2. Promote partnership with whānau throughout the cleft care pathway in alignment with the New Zealand Health Strategy 2023 (The Whānau Ora Outcomes Framework)
3. The service has a formal appointment policy and follow-up process in case of non-attendance, reflecting that no child will be disadvantaged or discharged due to disengagement with the cleft service
4. When it comes to service delivery, particularly in fields like speech and language therapy and dental care, different service providers and funding structures may be involved in the same district. Regardless of whether the service is funded locally, regionally, or centrally through Ministry of Education (MoE) or Ministry of Health (MoH), the leading provider or cleft centre must have the necessary resources to ensure that the service delivery adheres to the standards and timeline established by the cleft MDT
5. The lead provider and end service providers should maintain timely communication on the treatment prescribed by the MDT for cleft patients, whether in a hospital or the community
6. Ensuring an appropriate transition to adult care if required
7. None of the services listed in this specification will be subject to prior approval, whether for children or adults

Service description

The overall Cleft Lip and Palate care pathway should comprise the following elements:

1. Coordination of cleft care
2. Prenatal and postnatal diagnosis
3. Hospital and community paediatric care
4. Prenatal and perinatal specialist cleft nursing
5. Support of new-born feeding and ongoing assessment and management
6. Access to genetic assessment and chromosomal studies
7. Access to Māori and other cultural support services and interpreters
8. Multi-disciplinary pre-surgery assessment
9. Initial lip and/or palate surgery and postoperative assessment
10. Paediatric dentistry, including dental health education and oral health promotion
11. Alveolar cleft bone grafting and associated orthodontics
12. Cleft-related dentoalveolar surgery
13. VPI investigations, therapy, surgery and/or prosthetics with follow-up
14. Specialist cleft speech and language assessment and therapy
15. Access to audiology and otology assessment and treatment for hearing problems
16. Orthodontics
17. Restorative dentistry, including implants and prosthetics
18. Orthognathic surgery/distraction osteogenesis techniques to correct cleft-related jaw deformities and associated orthodontics

19. Septorhinoplasty
20. Cleft lip and palate revisions and fistula repair
21. Psychological care for children, adults and their families
22. Revision treatment, which may include surgery, orthodontics and restorative dentistry in adulthood
23. Other Locally-provided and community-based services guided or supported by the specialist cleft centre team

Pre-existing community, local or greater regional services will be required to support these service elements where necessary.

Service structures and care pathways

1. All clinicians and clinical services providing care to cleft-affected patients will work with colleagues in the core cleft team to provide integrated services across the care pathway
2. All major cleft surgery will be performed at the regional specialist centres, (Regional Cleft Service), and all core disciplines centred at and directed from there. The same team should deliver the service if children's and adult's services are based in separate hospitals
3. Services may be delivered by regional service clinicians in the centre or by outreach and local specialist clinicians working as prescribed and coordinated by the regional lead clinicians (e.g. SLT, dentistry, orthodontics, ENT/audiology). The end service provider should deliver those prescribed services coordinated by the MDT, using pathways based on national guidelines and best practices. Such therapy should be delivered according to the prescription by the MDT for as long as is considered clinically necessary and within a timely fashion. In the absence of specific clinical reasons, there should be no more than 16 weeks in delay in implementing the prescribed treatment
4. Service provision will align with the principles of Te Tiriti o Waitangi and acknowledge the Tangata Whenua status of Māori under Te Tiriti o Waitangi
5. The service will strive to contribute to research in the field of CL/P
6. The service will also strive to develop innovation in care delivery whenever possible and share its findings with the wider cleft care community
7. The care pathway diagrams are shown in Section 5. The precise pathway will vary with the extent of cleft diagnosis, co-morbidities, geography and how local and centre services are delivered
8. Some services need not be based locally or regionally but must be readily available. These include genetics and restorative dentistry

Interdependencies with other services/providers

Patients with CL/P may have other medical conditions and care managed by other services. (e.g. airway, congenital cardiac anomalies, other craniofacial anomalies etc.) It is essential that strong clinical communication and collaboration are made with these services.

Co-located services

Related services that need to be provided on the same site as CL/P surgery are:

- Paediatric airway support with appropriate protocols for paediatric airway support
- Paediatric high dependency/observation support with access to or written protocols for retrieval to a paediatric intensive care unit
- Specialised paediatric anaesthesia

Referral to service

The service will accept inward referrals from primary, secondary, tertiary and community care clinicians.

The service will accept referrals for patients who meet one of the following criteria or needs to be assessed and is within the catchment area of the accepting service:

- Patients with CL/P
- Patients with non-cleft VPI
- Expectant mothers with a prenatal diagnosis of a baby with CL/P

Referrals from outside of the patient's own regional catchment will be discussed by the MDT, and their rationale for acceptance will be considered.

Where transfer of care is desired, a formal request from the regional team is required.

There are no specific exclusion criteria that apply to this service.

Clinical governance

1. The service will ensure that all staff adhere to Health New Zealand | Te Whatu Ora's policies, procedures, and clinical guidelines
2. Every patient must have a named primary consultant responsible for their care

National cleft service

1. Each regional service will engage in (and report on) annual audits
2. Representatives from regional teams will meet every two years at our national conference, to present unit audit data, review the service utilisation and improve on any aspects of the services as required
3. Reporting back to MoH as required

Cleft team composition

MDT is required to deliver the cleft services outlined earlier (in section 2B). Most, if not all, members should be based at the cleft regional centre and include the following personnel:

1. Service Manager
2. Cleft Coordinator*
3. Lead Clinical Nurse Specialist (CNS)* (may share the role of coordination)
4. Lead Cleft Surgeons*, ideally 2 or more surgeons per unit
5. Lead ENT surgeon*
6. Audiologist
7. Lead Orthognathic Surgeon* (Maxillofacial or Craniofacial)
8. Lead Specialist in Paediatric Dentistry*
9. Lead Consultant Orthodontist*
10. Lead Specialist Cleft Speech Pathologist/Speech and Language Therapist*
11. Lead Health Psychologist or Clinical Psychologist*
12. Lead Paediatric Anaesthetist
13. Lead Consultant Paediatrician*
14. Lead Consultant Restorative Dentist
15. Lead Consultant Clinical Geneticist

*(*Recommended Core MDT members)*

Each lead clinician will have additional staff in their discipline/specialty as needed to provide the service.

The regional units will require the support of clinical photography, database management and dedicated Information Technology (IT) support, especially for archiving of records and to support usual team activity. Access to radiologists and radiographers, maxillofacial and orthodontic technicians, secretarial and clerical staff, and audit support staff will be required. The extended team will include local/community-based speech and language therapists, audiologists, orthodontists, lactation consultants, local and community paediatricians, geneticists and ENT surgeons. There will also be close liaison with ultrasound diagnosticians and fetal medicine experts.

Team Work

The MDT roles are defined in the previous section. Expectations of how the team functions, are detailed as follows;

1. Core team meets face to face, on a minimum monthly basis
2. Team has central and shared files on each patient at the regional unit level
3. Each regional unit performs an annual audit of their cleft care across each sub-speciality
4. Peer review meetings at least annually (this is meeting in which clinicians seek to improve their treatment of patients, and to maintain the currency of their practice by focusing on recent events and outcomes (individual or collected) of the patients under the care of the group forming the meeting)
5. All clinicians in the team must have access to regular, formal clinical support (and supervision, if indicated) by a member of the same profession

Team member role descriptions & FTE requirement

1. Coordinator/clerical support

- Required member of team
- Provision made for succession planning and training

Duties include;

1. Arranges clinic appointments/supports structure of clinics
2. Maintains database of patients
3. Supports running of clinics -clinic nurse role
4. Arranges and takes minutes of team meetings

2. Clinical Nurse Specialist (CNS)

- Required member of the team
- Minimum FTE :1.0 FTE per 40- 45 pts
- Provision made for succession planning and training
- Previous paediatric experience required

Duties include;

1. Support family and provide information around cleft diagnosis from antenatal through the cleft journey

2. Partnering with SLT, LMC, and well-child providers to support feeding
3. Antenatal counseling
4. Pre and post-operative information and support
5. Ensures assessment by relevant clinicians according to care pathway schedule
6. Monitor psychosocial issues for parents and child
7. Education
8. Refers to community providers to support engagement with whānau
9. To be involved in audits and research

3. Cleft Surgeons

- Required member of the team
- Provision made for succession planning and training
- Fellowship training in cleft surgery (2023 onwards)
- Each surgeon undertaking primary lip and palate repair should be treating at least 15 newborn patients per year (on average) in addition to VPI patients
- Fellowship training and a commitment to maintaining competence through continuing medical education
- Affiliation with a cleft team, attendance at meetings for planning and outcomes and audit
- The Unit needs adequate FTE to enable above the duties & responsibilities to be fulfilled

Duties include:

1. Cleft lip and palate repair
2. Velopharyngeal surgery for VPI
3. Septorhinoplasty – primary & secondary
4. Alveolar bone graft (ABG)
5. Lip revisions
6. Facilitate MDT care through involvement in a CL/P team
7. Attend meetings for planning & outcome audits
8. Succession planning
9. Referrals to multidisciplinary services as required

4. Speech Language Therapist

- Required member of the team
- Minimum 0.6 FTE per 15 new babies/year (cleft care does not include feeding)
- Provision made for succession planning and training
- Required to have a current practicing certificate with at least six years of post graduate clinical experience
- Needs to have completed cleft palate care competencies and be affiliated with a cleft team

- A commitment to attend CL/P team meetings and to maintain competence through continuing medical education

Duties include:

1. Monitor speech and language development
2. Assessment of VPI
3. Leads Video fluoroscopy (VFS), contributes to nasendoscopy
4. Provides speech therapy intervention
5. Maintains records of hospital and community therapy progress
6. Provides training, communication, and support with community SLTs in prescribed therapy
7. attends meetings for audit and research

5. Orthodontist

- Required member, minimum 0.4 FTE per unit (15 babies/year)
- Provision made for succession planning and training
- Has a caseload that ensures regular experience in CL/P care and is affiliated with a cleft team
- Demonstrates commitment to attend CL/P team meetings and discuss surgical planning and outcomes
- Required to have Fellowship training and a commitment to maintaining competence through continuing medical education

Duties include;

1. Pre-surgical orthopaedics as needed (in accordance with evidence based practice (EBP)
2. Monitor dental eruption
3. Provide hygiene advice
4. Monitor facial and jaw growth
5. Move dental arches/teeth
6. Liaise with dental and jaw surgery clinicians
7. Obtain and maintain dental records relevant to orthodontic and orthognathic care

6. Health/Clinical Psychologist

- Required member, a minimum of 0.3FTE per 15 new babies per year
- Provision made for succession planning and training
- Ideally paediatric and cleft care experience, or with appropriate clinical supervision
- Appropriate clinical supervision and affliliated with other regional cleft team psychcologists

Duties include:

1. Monitor and treat psychosocial challenges associated with cleft lip/palate
2. Patient and whānau support in preparing for cleft-related interventions

7. Paediatric Dentist

- Required a minimum of 0.3FTE per 15 new babies/year
- Provision made for succession planning and training
- Paediatric trained, defined for cleft as at least 3 years of relevant post graduate training and experience

Duties include:

1. Optimisation of dental health and oral hygiene and timely preperation for cleft related surgeries
2. Support and liason to community oral health provider

8. Maxillofacial/Craniofacial Surgeon

- Provision made for succession planning and training
- Required to have Fellowship training and a commitment to maintaining competence through continuing medical education

Duties include:

1. Liaise closely with the orthodontic team for timing of ABG
2. Coordinate the timing of orthognathic surgery with the wider cleft team
3. Demonstrates commitment to attend CL/P team meetings and discuss surgical planning and outcomes

9. Ear, Nose & Throat (ENT) Surgeon

- Provision made for succession planning and training
- Fellowship training in cleft care with paediatric otology experience and/or audiological physician with an interest in children's hearing

Duties include:

- Provide direction on complex airway patients, timing of surgery in conjunction with paediatric team

10. Paediatrician

- Works collaboratively with the cleft team
- Provision made for succession planning and training

Duties include;

1. Ensure general well-being of babies/children born with CL/P and coordination of care for complex needs patients
2. Monitor development and growth
3. Provide recommendations to cleft service regarding timing of procedures
4. Referral to genetic services
5. To ensure neonatal/paediatric outreach is in place if required

11. Audiologist/Audiology Team

- Works collaboratively with the cleft team
- Provision made for succession planning and training
- See appendix for national pathway of audiological management of babies with cleft palate

Duties include:

1. Timely audiology reviews for cleft patients
2. Communications to assist coordination of care

3. CLEFT SERVICE OUTCOME MEASURES

National framework for data collection

New Zealand national cleft data framework

- Primarily provides data on treatment and outcomes of cleft patients. The data is kept regionally for regional audits and de-identified for national audits for outcome analysis and quality assurance
- Secondarily provides data on cleft service volume and diagnosis, useful for resource distribution and future service planning
- Data collected in accordance with the national framework is on an opt-out basis
- The agreed methodology for collecting standardised data is a minimum dataset on the International Consortium for Health Outcomes Measurements (iCHOM) for CLP, with modifications to suit New Zealand[7]

Treatment outcome measures

Use the following measures to report at regular intervals. These will be used to measure and improve the quality of care.

1. Cleft lip outcomes
    - Revision procedures rate
    - 5 year appearance outcome audit
    - Final outcome at age 18 years or discharge
2. Cleft palate repair outcomes
    - Complications recorded: bleeding or airway compromise (requiring airway adjuncts, high flow, ICU or intubation)
    - Mid-palatal fistula rate (Pittsburgh 2-5, Appendix A)
    - Speech outcomes (in the parameters of acceptability, intelligibility, velopharyngeal function, and speech characteristics at 5 years, 12 years and post orthognathic surgery)
    - Secondary speech surgery rate
3. Secondary speech surgery outcomes
    - Outcomes of secondary speech surgery – VPI rate.
4. Alveolar bone graft outcomes
    - Bone graft fill rate (Kindelan score) at 6 months post-op[8]
    - Revision alveolar bone graft rate.
5. Orthognathic outcome measure (5-year index and Goslon yardstick)

6. Dental outcome measures Average Decayed Missing Filled Teeth (DMFT) and treatment index scores of 5-year-old and 12 year old children with any cleft are as good or better as children without CL/P in their region
7. Psychological outcome measures
8. Patient reported outcome measures (PROM and PREM measures)

Service delivery performance measures

The following measurable service parameters are for the cleft service as a whole.

1. Goal: 100% of families are supported by the CLP CNS at an early stage following diagnosis

   Measures:

   - % of parents contacted by the cleft team CNS 48 hours after receiving referral of notification of an antenatal diagnosis of CLP
   - % of families that receive a hospital visit from a cleft team CNS/Spoke team representative for advice within 48 hours of first referral at birth or first diagnosis after birth

2. Goal: 100% of the patient and family meet MDT within 8 weeks of birth

   Measure:

   - % of patients attended the MDT clinic within 8 weeks of birth.

3. Goal: 100% of babies with CLP receive initial lip and palate surgery at the optimal time to achieve the best results

   Measures:

   - Number of babies receiving first lip repair by 6 months of age, in the absence of specific clinical reasons for delay (e.g. syndromes, co-morbidity and approved research)
   - Number of babies receiving first palate repair by 12 months in the absence of specific clinical reasons for delay (e.g. syndromes, co-morbidity and approved research)

4. Goal: 100% of all 5-year-old children with CLP will have had hearing issues addressed

   Measure:

   - % of all 5-year-old children (i.e. over 5 years and under 6 years) with a cleft palate (including cleft lip and palate) who have had their hearing assessed and a plan made to address any hearing issues that have been found.

5. Goal: 100% of children with CLP at 5 years of age will have dental health, which is at least as good as children without CLP in their region

   Measure:

   - Average DMFT and treatment index scores of 5 year old children with any cleft[9]

6. Goal: All Children with CLP are assess by specialist cleft speech therapist at the ages of 18 months, 3-year, 5-year and 12-year

   Measures:

   - % of children between 18 months to 24 months are assessed by a specialist cleft speech therapist
   - % of children between 3 and 4 years are assessed by a specialist cleft speech therapist
   - % of children between 5 to 6 years are assessed by specialist cleft speech therapist
   - % of children between 12 to 13 years are assessed by specialist cleft speech therapist

7. Goal: Children with UCLP have good maxillary growth and achieve good facial appearance

   Measure:

   - The 5 year Olds' Index as an indicator of maxillary growth in patients with complete UCLP (either no Simonart's band or a band <5mm in height).

8. Goal: All children with CLP/VPI have the opportunity to access cleft team psychologist input for psychosocial stress related to cleft/VPI

   Measure:

   - % of cleft MDT team clinics attended by clinical psychologist
   - % routine psychosocial screening at MDT clinic appointments for primary school aged children and older
   - % of children screened by psychologist for psychosocial issues and management implemented

9. Goal: All children requiring ABG will receive that treatment at optimum times and with good results

   Measures:

   - % of children in a single year who have an alveolar defect and who are assessed by a cleft team orthodontist and the surgeon responsible for ABG between 7 years and before 9 years of age
   - The Kindelan score (Appendix C) is obtained at 6 months post-operative based on an oblique occlusal radiograph of each initial ABG carried out in a designated year as part of their routine protocol of care in children having their first bone graft at less than 16 years of age

4. SERVICE STANDARDS BY LIFE STAGE AND SPECIALTIES

	ANTENATAL CARE STANDARDS	POST-NATAL AND INFANT CARE STANDARDS	CARE AND FACILITIES STANDARDS	AUDIT OF RECORDS AND PROMS	ADULTS RETURNING TO THE SERVICE
Core Standards	• Parents will be contacted by a cleft team CNS 48 hours after time of receiving the referral. MEASURABLE SERVICE OUTCOME DELIVERY • Parents will be offered a visit/appointment with a CNS at an appropriate and negotiated time and place. • A record will be kept by the regional cleft team of the outcome of the pregnancy (including, as appropriate, cleft type) for all antenatal referrals.	• All babies born with CL/P should be diagnosed within 24 hours of birth. • All babies are to be referred by relevant professionals to the cleft team • at the time of diagnosis. • A cleft feeding specialist (or the community lead maternity carer and lactation specialist directed by the regional team) should consult the mother and baby within 72 hours (ideally within 24 hours) of receiving the referral (face-to-face/virtual/phone consultation) MEASURABLE SERVICE DELIVERY OUTCOME • A feeding plan should be devised and documented by a paediatric feeding specialist which supports the mother's preference for feeding. • All babies should have a nationally-recognised feeding assessment prior to the introduction of assisted feeding. All parents to be offered: • Counselling and support • Verbal and written information re cleft treatment and management • Written information about Cleft NZ • Details of the baby and his/her parents, cleft diagnosis, treatment and outcome data (based on the national cleft data framework) will be held securely on regional hospital cleft databases in accordance with the regional hospital policy. De-identified data will be used for regular national audits.	• All babies with clefts will be fully assessed clinically by a paediatrician for the presence of other congenital malformations and investigated further if required by the age of 6 weeks. • All children and young people receiving cleft care will be treated in an appropriate paediatric environment. • All whānau of children with a cleft will be offered an assessment by and will have access to support from a member of the cleft clinical/health psychologist before the first operation is carried out. • Babies with CL/P will have regular, local, paediatric follow up to ensure appropriate growth and development, especially in the first 24 months of life.	• Regular auditing of outcomes in units will include patient reported outcome measures (PROMS)	• ADULTS RETURNING TO THE SERVICE
Recommended Standards	The regional cleft team will agree protocols with, and provide information to, each antenatal care unit in its region that carries out 20 week scans to maximise the diagnosis of cleft lip, and to ensure that on the day of initial diagnosis: (a) parents are referred by relevant professionals to the cleft team; and (b) parents are given printed information provided by the cleft team/fetal medicine team. The CNS will make contact with the primary health care team during the antenatal period In the antenatal period following a diagnosis, all parents will be offered: • An appointment with the regional cleft team (such as the CNS, or local colleagues/providers) • Counselling and support • Appropriate feeding preparation and plan for the immediate postnatal period • Verbal and written patient information pamphlet regarding cleft treatment and management (e.g. The Blue Book) • Written information about Cleft NZ	• An electric breast pump should be offered to all mothers who need one via Cleft NZ, for as long as they need it. • A CNS will make contact with the families within one week of discharge. • Satisfaction questionnaires are in place for the early care of the child and the effectiveness of the initial interventions.		• The standard record set should be available, or else the reason for non-collection recorded, for 100% of all cleft individuals at each nominated age collection point and at the end of care. This is outlined in iCHOM. • Patient and whānau satisfaction questionnaires will be used to assess the service's performance in adolescence and at the end of routine care	
Measurable Service Delivery Goal/Outcome					

* Measurable service delivery goal

	CLEFT SURGERY STANDARDS	ENT & AUDIOLOGY SERVICES STANDARDS	SPEECH & LANGUAGE THERAPY STANDARDS
Core Standards	• Cleft surgeons must have appropriate experience and training and a proven commitment to cleft care. They will devote a significant of their clinical time to cleft care and will work within the multi-disciplinary team, bearing in mind the team's need to manage succession planning. • Surgeon(s) undertaking primary lip and palate repair should be treating not less than 15 new patients per year per surgeon in addition to VPI patients. The number of new patients treated over a period (e.g. 3 years) will be considered. New surgeons shall have met the requirements of a minimum one-year of acceptable fellowship training in cleft surgery (2023 onwards). • With regard to cleft surgery in general and the need to devote a significant amount of their clinical time to cleft care, the surgeon's experience, historical numbers treated, past audited performance/ outcomes, other cleft surgery performed e.g. secondary/revision surgery, surgery for VPI, ABGs and orthognathic surgery, will be considered. • All cleft surgeons will participate in audits and will aim to achieve good outcomes in terms of the appearance of lip repair, as well as lip function, and palatal function as demonstrated by speech and good growth outcomes as well as quality of outcome in all aspects of cleft surgery including ABG, orthognathic, implants, speech and revisional surgery. • The cleft surgeon(s) must adhere to a strict protocol as part of an integrated care pathway of surgical care as previously agreed by the centre, notwithstanding the need from time to time to vary that protocol to deal with unusual clinical situations. No variation from the general protocol will be acceptable unless agreed by the team as a result of evidence-based audit / research. • All clefts involving the alveolus (including isolated cleft lip which may involve the alveolus) will be assessed before the age of 9 years by a cleft team orthodontist in conjunction with a cleft surgeon responsible for ABG. The assessment will be carried out in a multidisciplinary clinic, involving a paediatric dentist where appropriate, and will determine the need for, preparation for and timing of the ABG procedure. MEASURABLE SERVICE DELIVERY OUTCOME • All clefts involving the alveolus will be grafted by the age of 12 years provided that it is done before the eruption of the permanent maxillary canine tooth on the cleft side unless there is a specific reason. (e.g. medical considerations, very delayed dental development or hypodontia, patient refusal or non-compliance). MEASURABLE SERVICE DELIVERY GOAL • All babies requiring a cleft lip repair will have had their surgery before 6 months of age in the absence of specific clinical reasons for the delay (e.g. syndromes, co-morbidity and approved research) MEASURABLE SERVICE DELIVERY GOAL • All babies requiring a cleft palate repair will have had their surgery before 12 months of age in the absence of specific clinical reasons for the delay (e.g. syndromes, co-morbidity and approved research) MEASURABLE SERVICE DELIVERY GOAL	• All children with a cleft palate should have their hearing assessed by a clinician trained in paediatric audiology before the age of 10 months (in addition to the national new-born hearing screen within the first few days of life). They should receive follow-up audiological care and appropriate audiometric assessments, not less frequently than once a year for the first 3 years, then again at 5 years and 10-12 years of age. NB: In some cases, domicile ENT and audiology services may provide follow-up care. • 5-year-old children (i.e. over 5 years and under 6 years) will have had their hearing checked and a plan made to address any hearing issues that have been found MEASURABLE SERVICE DELIVERY GOAL • All families of children with cleft palate should receive information about the risks of hearing loss and how to look out for it before the child is 10 months old.	**Documentation** • All patient notes must be written in accordance with local hospital documentation policy and be audited on an annual basis • Assessment forms and relevant clinic reports must be filed in patient notes • Videofluoroscopy or nasendoscopy images must be stored in a secure patient management system. A report must be written for each instrumental investigation. • Reports are to be finalised in an acceptable timeframe in accordance with the local hospital policy. **Intervention** • All patients with cleft palate will be seen post palate repair for early speech advice and information. • All patients with cleft palate will receive an appointment with the cleft specialist SLT at 18 months of age to monitor language and speech development. This appointment will also include coaching for parents on encouraging anterior oral pressure sounds. MEASURABLE SERVICE DELIVERY GOAL • All patients with cleft palate will be known to early intervention services (SLT) in the community (e.g. Child Development Service) to provide support around feeding and to monitor speech and language development. • All patients with cleft palate will be seen at 3 years by the specialist cleft SLT for speech assessment. MEASURABLE SERVICE DELIVERY GOAL • Audit Assessment will be carried out at the age of 5 years by the cleft specialist SLT. MEASURABLE SERVICE DELIVERY GOAL • Audit Assessment will be carried out at the age of 12 years by the cleft specialist SLT. MEASURABLE SERVICE DELIVERY GOAL • All audit assessments will be video recorded. • Pre-surgical (VPI surgery) speech recordings will be taken no more than 6 months prior to surgery. • Post-surgical (VPI surgery) speech recordings will be taken between 6 – 12 months post-operatively. • Diagnostic and therapeutic intervention will be carried out as appropriate. This will be done by the SLT in partnership with parents. Therapist provision may occur at the cleft regional unit and/or in the community services under the guidance of the cleft specialist SLT. **Assessments tools** • Language Screener: Rossetti Infant Toddler Language Scale • Phonetic Inventory • Rhinocleft speech assessment or GOS.SP.ASS. • VFS Assessment Form **Competency** • Speech Language Therapists working as part of the cleft palate MDT should have education, training and experience in the assessment and treatment of cleft CL/P and non-cleft VPI. • SLTs should attend team meetings • SLTs should evaluate a minimum of 25 patients per year with cleft CL/P • SLTs should complete the Competency Framework for SLTs working in cleft CL/P • SLTs should engage in peer review meetings at least 4 times per year • SLTs should partake in a minimum of 10 cases for consensus listening each year • Annual peer review will be undertaken for all SLTs working with CL/P **Training and support to others** • Recognise the importance of whānau in goal setting, decision making and success of therapy/ interventions. Work in partnership. • SLTs provide support, and continuing education to community SLTs working with children with CL/P and non-cleft VPI • SLTs provide case management (follow-up, referrals, coordination of care) and advocacy as needed.
Recommended Standards			
Measurable Service Delivery Goal/Outcome			

* Measurable service delivery goal

	DENTAL & ORTHODONTIC STANDARDS	PSYCHOLOGY SERVICE STANDARDS	GENETIC SERVICES STANDARDS
Core Standards	• All children born with CL/P will receive preventive dental advice and support by the time the child is 6 months of age and, if needed, will have treatment arranged or provided to ensure that their level of dental disease is the same as or better than the average in their local community. MEASURBLE SERVICE DELIVERY GOAL • All children born with CL/P will receive treatment as needed to maintain optimum dental health. Where possible treatment will be provided locally but all patients should have access to advice and treatment by the lead specialist in paediatric dentistry dependent on the level of care needed. • All children with missing or abnormally formed teeth will be assessed by a specialist in paediatric dentistry before the age of 10 years. The aim is to determine the degree of dental abnormality and provide protection of defects to prevent further deterioration and for aesthetic improvement if indicated prior to a change to high school. • Planning and provision of longer-term restorative solutions be undertaken in conjunction with the team orthodontist by either a paediatric dental or restorative dental consultant (implants to be provided if clinically indicated by the restorative dental team after completion of growth) by age 15 years, although it is recognised that later assessments for adults and treatment will be required in some cases.	• Children with clefts will be regularly assessed and offered psychological support if needed. • Psychology input should be offered to whānau at the time of cleft diagnosis. • Psychology input should be available to whānau for cleft-related challenges while their child is under the care of the cleft service. • Cleft team psychologists should attend all MDT clinics. • Psychology input should be available in the form of brief intervention at the time of MDT clinics, or through short-term therapy in outpatient psychology clinics. • Psychologist input should be available in-person or via telehealth if appropriate. • Psychologists working in cleft MDTs should meet quarterly for peer supervision/review. • Psychologists working in cleft MDTs should also have regular supervision in accordance with the New Zealand Psychologists Board requirements. • The lead clinical/health psychologist will ensure that all children with CL/P have audit records collected in line with national audit recommendations to allow for national and international comparisons. • All children with CL/P or VPI will have completed psychosocial screening questionnaire by the age of 13 MEASURABLE SERVICE DELIVERY GOAL	• All patients (and their whānau) will be offered a referral to the clinical genetics service at discharge from the cleft service and/or at any other time during their care.
Recommended Standards			
Measurable Service Delivery Goal/Outcome			

* Measurable service delivery goal

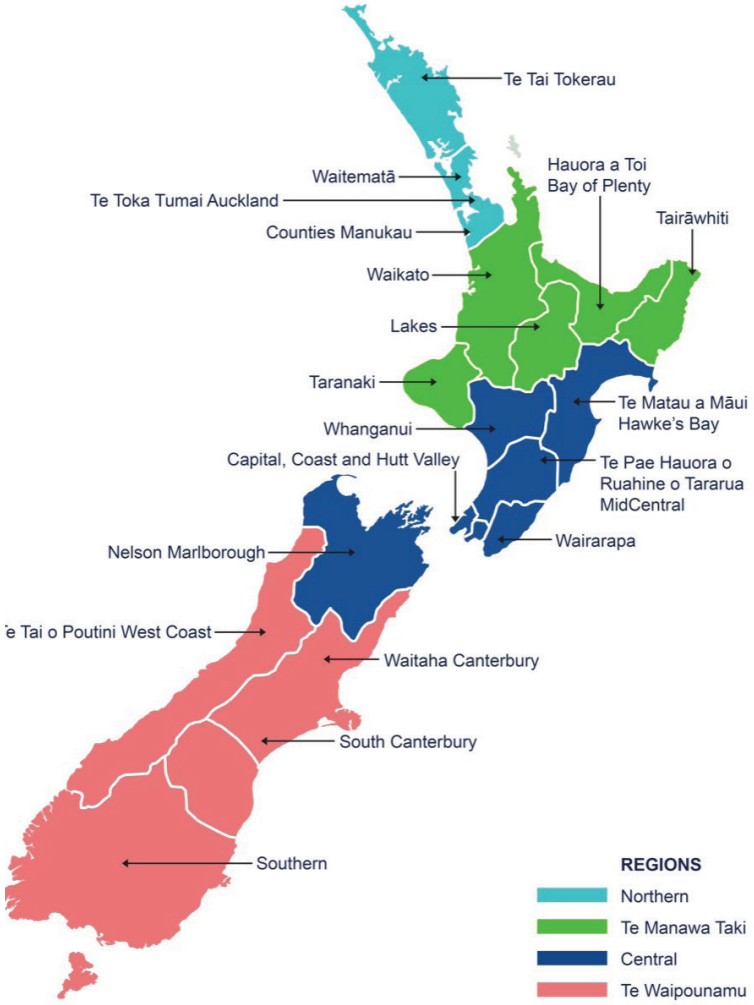
5. CLEFT CARE PATHWAYS

	Antenatal	Birth to 12 wks	3mo - 2 yrs	3 - 7 years	8 years – 14 years	15 – 21+ years	> 21 yrs returning
Local and Community Obstetric Services	• Ultrasound scan diagnosis, confirmed if necessary by fetal medicine specialist • Local obstetric service or LMC to contact the cleft team within 24 hours of diagnosis	• Local maternity unit to contact cleft team within 48 hours of birth					
Regional Cleft Unit (include MDT at regional centres and community services)	• Contact by CNS within 48 hours of referral. • Provide printed information • Negotiate face to face meeting • Offer contact with Cleft NZ	• CNS contact within 48 hrs of referral • Specialist feeding assessment and management, printed information, offer Cleft NZ referral • Meet cleft team and/or MDT baby clinic, ideally within the age of 8 weeks, before any cleft surgery • Refer for local ENT assessment and management if cleft palate. • Apply pre-surgical moulding if necessary (with orthodontist). Monitor compliance until surgery. • Ensure appropriate paediatric surveillance for co-morbidity & syndromes • Clinical psychology support offered at all team clinics and available throughout all the time points in the care pathway • Genetics referral if indicated	• Lip repair at 3-6 months • Palate repair 6-12 months • Speech and language assessment at 18 months, and management • Paediatric dentist for dental health education/ advice by 6 months of age and direction / liaison with appropriate general dental care • Later investigation (e.g. nasendoscopy and videofluoroscopy) for speech problems if necessary and this may be required at any stage in the care pathway	• Psychological support prior to school entry • Surgery to revise lip and speech (velo-pharyngeal) surgery if necessary, these to be available if needed throughout the care pathway • Full MDT and records at 5 years • Paediatric dentistry advice and/or intervention if necessary • Coordinate later speech and language therapy if needed throughout the care pathway • Implement speech therapy depending on availability of adequate community SLT, if needed throughout the care pathway.	• Assessment between 7 years of age and before 9 years by cleft team orthodontist, paediatric dentist and surgeon responsible for ABG, if an alveolar defect is present • Paediatric dentistry and orthodontic treatment • If required, pre-ABG orthodontic care followed by ABG completed before 12 years – follow-up at 6 months post-op • Full orthognatic records at 10 years • Speech and hearing checked and managed if palatal involvement • Definitive orthodontic care • Paediatric dentistry if necessary	• Definitive orthodontic care • Full MDT clinic and records at 15(-17) and 20(-22) years • Offer genetic referral • Team assessment for orthognathic surgery if indicated • Planning and pre-treatment for skeletal surgery • Orthognathic surgery and associated orthodontics if indicated • Revisional surgery if indicated (nose, lip) • Paediatric restorative dentistry as indicated • Completion of Post-Orthognathic surgery records and Speech assessment • Speech revision surgery if indicated • Routine psychology screening and intervention provided if needed	• Continuation of/or return to care from previous period • Adult patients returning for care may require speech assessment and therapy • Lip and/or nose revisional • surgery • Speech revision surgery • Palatal fistula repair • Orthodontics • ABG if not done previously • Orthognathic surgery • Psychology assessment and intervention available • Hearing assessment and treatment • Restorative dentistry
Community Services		• Paediatric surveillance for co-morbidity & syndromes • Neonatal hearing test within first few days after birth for ALL babies • Genetic counselling to parents if indicated	• 10 months hearing test if cleft palate and treatment as necessary • Annual hearing assessments up to 3 years of age if cleft palate • Speech and language therapy assessment	• Speech therapy • ENT and audiology assessment if cleft palate at 3 years of age, pre-school entry and 5 years of age (5 years of age assessment may be local or at cleft team 5 year MDT)	• Speech and hearing problems managed • Local orthodontics	• Continuing orthodontic treatment and/or paediatric and restorative dental care in close liaison with regional cleft centre	
Primary Care		• Dental health education in liaison with main centre	• Dental health education in liaison with main centre • Routine child health surveillance	• Routine preventative dental advice and treatment	• Routine preventative dental advice and treatment	• Regular dental care	• Regular dental care

6. Locations of regional cleft units

- Auckland
- Waikato
- Wellington
- Christchurch

* Cleft services are also provided in Dunedin



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New Zealand Paediatric Dental and Speech Therapy Associations for sharing their speciality guidelines

Health New Zealand I Te Whatu Ora - Canterbury Waitaha Medical Illustration

We would like to thank and acknowledge the insights from Megan Stowers (Ngā puhi) of Waikato University for her cultural expertise in helping to write this document.

Appendix A

Definitions, Abbreviations and Descriptions

Cleft lip is a congenital split in the upper lip. It may involve one, or both sides of the upper lip. It may or may not involve a split (cleft) of the alveolus (gum) also. If other medical factors are stable, cleft lip repair is usually done when the child is 3-6 months old. Closure involves meticulous repair of the skin, muscle and mucosa of the lip. Correction of the cleft lip and of any associated nasal deformity is usually done at the same time.

Cleft palate is an opening or split in the roof of the mouth that occurs when the tissue doesn't fuse together during development in the womb. The usual age for cleft palate repair (palatoplasty) is 6-12 months, which usually corresponds to the emergence of early infant speech. Closure of the palate is complex and involves reorientation of the muscles and closure of the layers of the soft palate, as well as tissues of the hard palate. Failure of part or all of the repair to heal can result in a fistula, which permits air or fluid to move between the oral and nasal cavities. Inadequate function of the soft palate can result in nasal air leakage and a speech disorder known as velopharyngeal insufficiency (VPI).

Submucous cleft palate is more difficult to diagnose. In a submucous cleft of the soft palate, there is continuity of the mucosa, but not of the underlying muscle. The muscle is inserted anatomically in the wrong way. A submucous cleft palate is classically diagnosed by the presence of a bifid (split) uvula, a tented central area in the soft palate, parasagittal bunching of the levator muscle, and a palpable notch at the back of the hard palate. Since most individuals with submucous cleft palate are asymptomatic, this type of palatal cleft is repaired only when there are significant symptoms (feeding problems, speech difficulties, and ear infections). It usually diagnosed later, often preschool age.

VPI (Velopharyngeal Insufficiency) occurs when the soft palate is not long enough or strong enough to close against the back of the throat during speech, resulting in air escape into the nose and hypernasal speech. Non cleft VPI is usually diagnosed in children who have whānau/ teacher/therapist detected hypernasal speech. They don't have a cleft diagnosis to account for this and may present later in life. Usually formal assessment with speech language therapists is required and additional investigations. Surgery is often required to correct the VPI.

Treatments for VPI include surgical intervention which may offer the possibility for long-term improvement in speech. Surgical options include palatal lengthening (e.g. Furlow technique), a sphincter pharyngoplasty, pharyngeal flap or pharyngeal augmentation maybe considered. Disadvantages include: a risk for over-correction of the air leak leading to post-operative obstructive sleep apnea (OSA) and hyponasality. When these occur, additional surgical modifications may be needed.

ABG (Alveolar Bone Graft) repairs the residual bony cleft in the maxilla (upper jaw) and is usually performed between 8-11 years of age. A small amount of bone is taken from a donor site (usually the hip) and grafted into the alveolar cleft.

Orthognathic Surgery (Jaw Surgery) is performed by oral-maxillofacial surgeons or craniofacial plastic surgeons. It is an operation that corrects irregulaties of the jaw bones and realigns the jaws and teeth to improve they way they work.

Septorhinoplasty is commonly primarily performed at the time of lip repair. The operation is performed to correct the functional and aesthetics of the nose created by the cleft. Some children may have residual deformities and/or difficulty breathing through the nasal passages. This usually requires a secondary or definitive septorhinoplasty that can address both form and function, it is typically performed at skeletal maturity (>16- 18yrs of age).

ENT (Ear, Nose and Throat) /ORL H&N Otolaryngologist (ORL) Head & Neck Specialist.

MDT (Multidisciplinary Team) is the group of sub-speciality clinicians involved in cleft care. Compromising of, but not limited to, cleft surgeons, oralmaxillofacial surgeons, orthodontist, paediatric dentist, oral maxillofacial surgeon, psychologist, speech language therapist, ENT surgeon/audiologist, nurse specialist.

PROMS (Patient Reported Outcomes)

SLT (Speech Language Therapist)

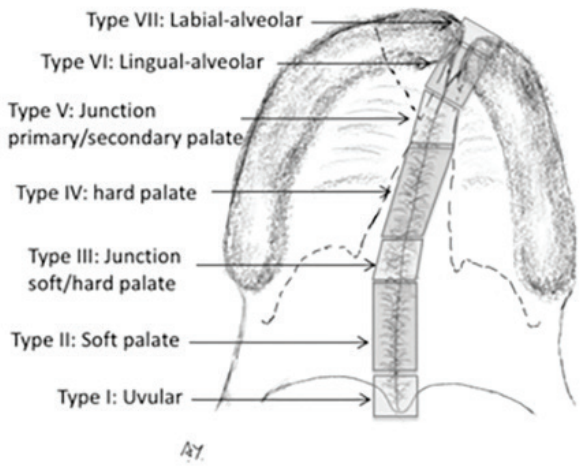
CNS (Clinical Nurse Specialist)

DMFT Decayed, Missing, Filled Teeth

MoH (Ministry of Health)

MoE (Ministry of Education)

Appendix B



Pittsburg classification of oronasal fistulas

Figure 1. Pittsburg classifictation of oronasal fistulas in unilater' cleft lip and palate (UCLP)

Yang, A. S. et al. Closer to the Truth on National Fistula Prevalence After Unilateral Complete Cleft Lip and Palate Repair? The Cleft Care UK Study. Cleft Palate-Craniofacial J. 7, 105566561985887–9 (2019)[10].

Appendix C

Kinderlan scale for radiographic assessment of alveolar bone grafts

Kindelan, J. D., Nashed, R. R. & Bromige, M. R. Radiographic Assessment of Secondary Autogenous Alveolar Bone Grafting in Cleft Lip and Palate Patients. Cleft Palate-Craniofacial J. 34, 195–198 (1997).

Grade of result of bone graft	Degree of bone fill to alveolar cleft area (up to cementodental junction)
1	>75%
2	50–75%
3	<50%
4	No complete bony bridge

Appendix D

Audiological management of babies with cleft palate

Babies identified as having a cleft palate require close audiological management to ensure appropriate access to sound and to optimise opportunities for speech and language development.

The key features of the audiological management pathway are as follows.

- Babies born with a cleft palate are likely to develop otitis media with effusion that may have a significant impact on their hearing and so even if they have passed hearing screening as a newborn should be seen for follow-up at 7–9 months old. An assessment at this age also allows the audiologist and ORL to understand the extent of any conductive hearing loss and this information will aid in the decision as to whether or not the infant will need ventilation tubes in conjunction with their palate repair

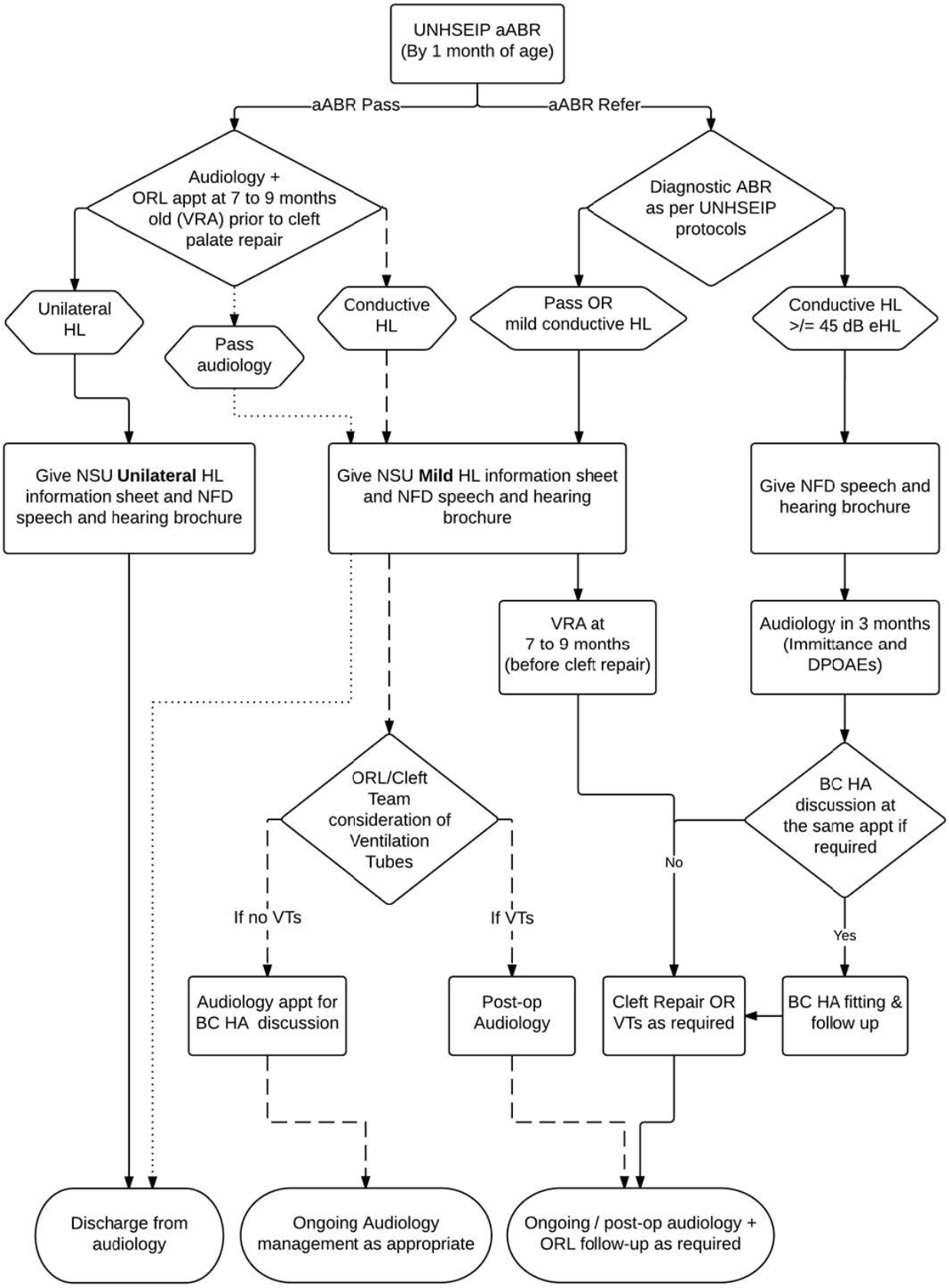
- The timing of the cleft palate repair surgery may vary for different babies and across cleft palate programmes, and this may vary the timing of the discussion regarding a bone conduction hearing aid for those babies that have passed their initial hearing screening. In principle it is important to consider the degree of any conductive hearing loss and the length of time the baby may have the conductive hearing loss to provide timely management options

- For babies that have been identified as having a conductive hearing loss warranting intervention on diagnostic ABR assessment, a discussion regarding a bone conduction hearing aid is completed early on in the audiological management pathway. In these cases it is important that amplification options are discussed with the family. Conventional BTE hearing aids are not appropriate in these children at a young age due to the possible fluctuating nature of the conductive hearing loss component

- At all appointments with the family, regardless of the test outcome, discussion should cover good communication strategies, ways to enhance the listening development, how to recognise signs that the hearing may have changed and what to do if the family are concerned about their baby/child's hearing. Give the NSU mild hearing loss information sheet and NFD speech and hearing milestones brochure

- Note that there will be local variation throughout the country dependent on the configuration of the cleft palate teams and ORL service. It is important that the audiologist liaise closely with both their local ORL service and regional cleft palate teams to provide the most appropriate audiological management for these babies.
  See Figure Audiological management of babie with cleft palate

Figure 2: Audiological management of babies with cleft palate



References

1. Bearn D, Mildinhall S, Murphy T, Murray JJ, Sell D, Shaw WC, et al. Cleft lip and palate care in the United Kingdom–the Clinical Standards Advisory Group (CSAG) Study. Part 4: outcome comparisons, training, and conclusions. ***Cleft Palate Craniofac J.*** 2001;38:38–43

2. Smit, R. and P. Fowler, Non-syndromal orofacial clefts in the Canterbury/West Coast region during the 2000-2009 period. ***The New Zealand Dental Journal,*** 2010. 106(4): p. 129-131.

3. Thompson, J., Stone, P., Sanders, M., Van der Zee, H., Borman, B., Fowler, P. ***The incidence of Orofacial Cleft in live births in New Zealand.*** NZMJ 19 August 2016, Vol 129 No 1440

4. ***Ministry of Health, Tatau Kahukura: Māori Health Chart Book*** 2015 (3rd edition). 2015, Ministry of Health: Wellington.

5. Ministry of Justice: Hauora, ***Report on Stage 1 of the Health Services and Outcomes Kaupapa Inquiry*** https://forms.justice.govt.nz/search/WT/ reports.html

6. Ministry of Health: ***Pae Ora –Health Futures.*** 2015. https://www.health.govt.nz/our-work/populations/maori- health/he-korowai-oranga/pae-ora-healthy-futures

7. Allori, A. C et al. ***A Standard Set of Outcome Measures for the Comprehensive Appraisal of Cleft Care.*** Cleft Palate-Craniofacial J. 2016

8. Kindelan, J. D., Nashed, R. R. & Bromige, M. R. ***Radiographic Assessment of Secondary Autogenous Alveolar Bone Grafting in Cleft Lip and Palate Patients.*** Cleft Palate- Craniofacial J. 34, 195–198 (1997)

9. Natarajan A, Mahoney E, Brosnan M, Thoroughgood R, Fowler P.(2023). A proposed oral health pathway for children with orofacial cleft in New Zealand. New Zealand Dental Journal, 119(3) (pp 114-120)

10. Yang, A. S. et al. ***Closer to the Truth on National Fistula Prevalence After Unilateral Complete Cleft Lip and Palate Repair?*** The Cleft Care UK Study. Cleft Palate-Craniofacial J. 7, 105566561985887–9 (2019).