Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)
Welsh Health Specialised Services Committee (WHSSC)

Specialised Services
Service Specification: CP186

Cleft Lip and/or Palate including Non-Cleft Velopharyngeal Dysfunction: All Ages

July 2023

Version 2.0

Document information	
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Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this document
Document No	CP186
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Proposal

Contents

Statement

Welsh Health Specialised Services Committee (WHSSC) commission the service of Cleft Lip and/or Palate including Non-Cleft Velopharyngeal Dysfunction for all ages in accordance with the criteria outlined in this specification.

In creating this document WHSSC has reviewed the requirements and standards of care that are expected to deliver this service.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this document.

This document may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this document.

1. Introduction

This document has been developed as the Service Specification for the planning and delivery of cleft lip and/or palate (CLP) including non-cleft velopharyngeal dysfunction services for people resident in Wales.

This cleft lip and/or palate (CLP) service is operated through a Managed Clinical Network (MCN), which delivers the service following the NHS standard contract for Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) all ages, NHS England service specification, D07/S/a, 2013[1], and this service specification has been developed based on this contract.

This service is commissioned by Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

Cleft Lip and/or Palate (CLP) is a congenital anomaly resulting from failure of fusion of embryological parts forming the lip, nose and palate. Its treatment requires the multidisciplinary involvement of many specialties throughout the growth and development of a person to at least 20 years, as well as treatment of adults of any age.

Routine care often does not cease at 20 years of age and can continue for a number of years. Children are followed up routinely until at least 20 years of age and adults can access the service and receive treatment at any age.

CLP services are delivered through a network of care managed and often delivered from a specialist centre hub. The network of care includes outreach and spoke delivery of services and relies on strong links with and coordination of local community services. The specialist centre provides advice, education and support for both spoke and community services.

1.2 Plain language

Cleft lip and/or cleft palate are birth defects that occur when a baby's lip or mouth do not form properly during pregnancy, which can be caused by genetic or environmental factors[2]. Together, these birth defects commonly are called orofacial clefts. This may affect the lips, the roof of the mouth (hard palate) or the soft tissue at the back of the mouth (soft palate).

A Cleft Lip is when the tissues of the lip do not join properly before birth, resulting in a gap or split in the upper lip. This can be on one (unilateral) or both sides (bilateral) of the lip or the middle of the lip, and is present at

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[1] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf

[2] Cleft Lip & Palate Association

birth. Cleft lips can be incomplete or complete and this term is used to describe whether the cleft goes all the way up into the upper gum (alveolus) and nose or not.

A cleft palate is when the tissue in the roof of the mouth does not join together properly before birth. For some babies this could mean that both the front and back parts of their palate is open. Occasionally some children may have a split (bifid) uvula, this is a condition where the muscles beneath the lining of the mouth and nose (mucosa) are not joined (sub mucous cleft palate)[3].

A cleft lip and palate involves one (unilateral) or both (bilateral) sides of the lip, base of the nose, gum and palate. Occasionally the lip and palate are clefted but the nose and alveolar ridge are intact[2].

Velopharyngeal Dysfunction (VPD) is where the soft palate fails to close against the back of the wall of the throat to close off the nose during speech production[4].

1.3 Epidemiology

A cleft lip and/or palate (CLP) is the most common facial birth defect in the UK, affecting around one in every 700 babies. It is the most common congenital abnormality in the cranio-facial region. Incidence rates are approximately 1.6 per 1,000 but this can vary year to year.

Many patients suffer from impaired facial growth, dental anomalies, speech disorders, poor hearing and difficulties in psychological well-being and social relationships.

The incidence of CLP in the UK can be summarised as:

• Cleft Palate only	45%
• Cleft Lip (+/- alveolus) only	23%
• Unilateral Cleft Lip and Palate	22%
• Bilateral Cleft Lip and Palate	10%

The patient pathway extends from pre-birth to adult life and a typical cleft team will treat and monitor several thousand patients at any moment in time, with a number of patients returning for treatment in adulthood.

Techniques in cleft care have advanced over recent years and adult patients who have received surgery in the past sometimes require further specific intervention from the CLP teams to optimise previous procedures[5].

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[3] https://www.clapa.com/wp-content/uploads/2015/10/RCS.pdf

[4] Velopharyngeal Dysfunction

[5] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf

1.4 Aims and Objectives

The aim of the service is to provide surgery and specialist care for people with cleft lip and/or palate and non-cleft velopharyngeal dysfunction. This is to ensure that they achieve an aesthetic and functional facial appearance, and to maximise oral feeding, hearing, speech development and psycho-social wellbeing.

The service will aim to improve the quality of life for people with cleft lip and/or palate (including non-cleft VPD) by:

- offering a safe, clinically effective and accessible service to patients with CLP and their families/carers
- supporting patients and their families/carers with high quality and appropriate information in a format that meets their individual needs
- providing patients with timely surgery, treatment and regular follow up in line with the clinical pathway described in this specification
- providing a high quality and evidence based service offering effective clinical interventions that ensure optimal clinical outcomes
- ensuring the entire care pathway is in place for patients
- facilitating autonomy and transition to adult care
- 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
- ensuring the CLP services are sensitive to the individual physical, psychological and emotional needs of patients and their families.

The objectives of this service specification are to:

- detail the specifications required to deliver a Cleft Lip and/or Palate service including Non-Cleft Velopharyngeal Dysfunction for all ages for people who are residents in Wales
- ensure minimum standards of care are met for the Cleft Lip and/or Palate service
- ensure equitable access to the service for Cleft Lip and/or Palate including Non-Cleft Velopharyngeal Dysfunction
- identify centres that can provide a service for Cleft Lip and/or Palate including Non-Cleft Velopharyngeal Dysfunction for Welsh patients
- improve outcomes for people accessing Cleft Lip and/or Palate including Non-Cleft Velopharyngeal Dysfunction services
- co-ordinate the total care of all children and adults from before birth to 20 years and sometimes for longer, as the patient will access the service indefinitely during adulthood
- ensure that the cleft lip and/or palate is/are well repaired and the child’s growth, development and function are maximised

- ensure arrangements are in place for ongoing care and treatment of adult patients where clinically indicated
- ensure that care is organised and provided in such a way that it:
    - respects the needs and wishes of the child, parent or guardian
    - recognises the nature of the original birth defect
    - optimises the psychological wellbeing of the patient and family
    - facilitates speech and language progress
    - ensures optimal hearing
    - optimises facial appearance
    - enables appropriate occlusal and dental growth
- work within the clinical protocols and treatment guidelines developed and agreed for the service.

1.5 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
    - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

- **WHSSC policies and service specifications**
    - Genetic Services (CP99), Service Specification (2016)

- **National Institute of Health and Care Excellence (NICE) guidance**
    - Otitis media with effusion in under 12s: Surgery, Clinical Guideline (CG60), February 2008.

- **Relevant NHS England policies**
    - NHS Standard Contract for Cleft lip and/or palate services including non-cleft velopharyngeal dysfunction (VPD) all ages. NHS England D07/s/a, 2013.

- **Other published documents**
    - Cleft Registry and Audit Network, CRANE Database, Annual Report

    - Cleft Lip and Palate Association (CLAPA) Report: Regionalisation of Cleft lip and palate services: has it worked? April 2007

    - DH Clinical Standards Advisory Group report into Cleft Lip and Palate 1998 DH Clinical Standards Advisory Group report into Cleft Lip and Palate 1998

- Department of Health, Getting the right start: National Service Framework for Children. Standard for Hospital Services. 2003

- SSNDS (3rd edition) No.23 Specialised Services for Children

- Welsh Assembly Government: All Wales Universal Standards for Children and Young People's Specialised Healthcare Services October (2008)

- Cleft lip and palate services - commissioning specialised services Health Service Circular, Department of Health, HSC 1998/238. December 1998,

2. Service Delivery

The Welsh Health Specialised Services Committee commission the services for cleft lip and/or palate and non-cleft velopharyngeal dysfunction for people resident in Wales, in-line with the criteria identified in this specification.

2.1 Access criteria

The service will accept inward referrals from primary, secondary, tertiary and community care clinicians for people who meet one of the following criteria:

- people with Cleft Lip and/or Palate (CLP) of any age
- people with non-cleft Velopharyngeal Dysfunction (VPD) of any age
- expectant mothers with a prenatal diagnosis of a baby with CLP.

Referrals will be handled by the receiving service according to the decisions made by the clinical director in conjunction with the multidisciplinary team.

The point at which a person with Cleft Lip and/or Palate requires treatment is a shared decision between the patient and their family/carer and their clinician.

2.2 Service Configuration

The Cleft Lip and/or Palate service will operate via a managed clinical network (MCN).

The Managed Clinical Network (MCN) delivers the service following the NHS standard contract for Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPD) all ages, NHS England service specification, D07/S/a, 2013[6]. The document identifies the key responsibilities and skill mix of the main team, led by a clinical director with a supporting care co-ordinator/manager, with each (MCN), treating a minimum of 80 – 100 new cleft births per year.

The network includes a hub and spoke delivery of services and relies on strong links with and coordination of local community services. Services may be delivered by hub clinicians in the centre or by outreach centres. Services can also be delivered by local specialist clinicians workings as prescribed by hub clinicians, for example SLT, dentistry, orthodontics, ENT/Audiology, this will be prescribed and coordinated by the hub for local delivery of the clinical pathway in a timely manner. The pathways are based on national policy and best practice and should be delivered according to the prescribed prescription for as long as considered necessary and within a timely manner, with no more than an 18 week wait.

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[6] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf

The specialist centre will provide advice, education and support for spoke and community services. The service will also strive to develop innovation in care delivery whenever possible and share these with the wider cleft care community.

Care covers pre-natal and post-natal diagnosis and advice including:

- training and education of all professionals who undertake new born exams, to ensure prompt initial post-natal diagnosis
- feeding advice
- corrective surgery including specialist and outreach nursing
- lip and palate repair
- speech assessment
- investigation and treatment/surgery
- children’s dentistry
- bone grafting
- orthodontics
- dento-alveolar surgery
- restorative dentistry including implant treatment
- rhinoplasty
- orthognathic surgery
- audiology/Ear Nose and Throat (ENT) (hearing and ENT problems)
- clinical psychology
- genetics
- revision treatment.

All oro-facial[7] clefts should be diagnosed at birth. Visual inspection of the palate takes place shortly after birth as part of the UK birth protocol but for CLP diagnosis must be within 24 hours not as in the UK birth protocols. Any diagnosis later than 24 hours is late and unacceptable as it prevents and/or delays the child and mother receiving the immediate care and advice they need.

The service will be safe, of high-quality and evidence-based in line with national policy and guidance. It will offer effective clinical interventions in an appropriate and timely care setting thereby ensuring a positive patient experience and optimal clinical outcomes.

Treatment will be co-ordinated through a dedicated multidisciplinary team of clinicians to achieve optimum outcomes. The team will work with locally identified specialist clinicians, such as Speech and Language Therapists (SLT’s), orthodontists, ENT surgeons and Audiologists, where possible or by the centre clinicians working with outreach services to ensure the care pathway is in place.

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[7] Cleft Lip & Palate Association

Timely referral and treatment across the patient pathway (see annex i) will be required, as will close liaison with the patient's General Practitioner and General Dental Practitioner, and non-healthcare professionals, including school authorities. Treatment will need to be in line with national policies and guidance[8] (including the report of the Clinical Standards Advisory Group for Cleft Lip and/or Palate and subsequent Health Service Circulars), agreed care pathways and referral criteria (see annex i).

Services will be provided (where clinically appropriate) at times and ages as required by agreed clinical protocols[9], and within national waiting times on the basis of equity of access based on clinical need for the population served.

Key Elements of the Service

The provider will provide a comprehensive Cleft Lip and Palate care pathway that comprises of the following elements[10]:

- Prenatal and postnatal diagnosis
- Hospital and community paediatric care
- Pre and peri-natal specialist cleft nursing including support of newborn feeding and on-going assessment and management
- Genetic assessment and chromosomal studies
- Multi-disciplinary pre-surgery assessment
- Initial lip and/or palate surgery and post-operative assessment
- Paediatric dentistry including dental health education and oral promotion
- Alveolar cleft bone grafting and associated orthodontics
- Cleft-related dento-alveolar surgery
- Velopharyngeal dysfunction (VPD) investigations, therapy, surgery and/or prosthetics with follow-up
- Speech and language assessment and therapy
- Audiology and otology assessment and treatment for hearing problems
- Orthodontics
- Restorative dentistry including implants and prosthetics
- Orthognathic surgery/distraction osteogenesis techniques to correct cleft related jaw deformities, and associated orthodontics
- Rhinoplasty
- Cleft lip and palate revisions and fistula repair
- Psychological care for children, adults and their families

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[8] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf
[9] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf
[10] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf

- Revision treatment, which may include surgery, orthodontics and restorative dentistry, in adulthood
- Dental and orthodontic treatment
- Locally-provided services (e.g. health visitors, children's community services, education, speech and language therapy, primary dental care, CAMHS, Paediatric Psychology or adult mental health services) supported by the specialist cleft hub team

2.3 Service description

2.3.1 Facilities and Equipment

The provider should ensure that there is appropriate access to the following facilities and equipment:

Facilities

- Access to High Dependency Units (HDU)/Paediatric Intensive Care Units (PICU).
- Access to paediatric surgical area including recovery area.
- Dental clinics which facilitate orthodontics and paediatric dental services.
- Computer support which facilitates web based data entry for submission to the CRANE (Cleft Registry and Audit Network), database and Quality Dashboard[11].
- Congenital Anomaly Register and Information Service (CARIS)[12].This provides reliable data on congenital anomalies in Wales and can be used to inform the work of health services eg antenatal screening and is available via Health Intelligence Unit Public Health Wales.
- Appropriate facilities for multidisciplinary clinics (number and kind of rooms, play areas, waiting areas) and facilities must at least meet paediatric National Service Framework (NSF) standards[13].

Paediatric Services

- All children should be cared for in a suitable paediatric environment, as set out in "Welfare of Children and Young People in Hospital"[14].
- This policy has been supported by the Audit Commission in its report "Children First" and by the Parliamentary Select Committee.

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[11] CRANE Database - Home

[12] http://www.caris.wales.nhs.uk/home

[13] National service framework: children, young people and maternity services - GOV.UK

[14] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf appendix 1 page 40,41,42 and Appendix 2 page 63

General Paediatric care

- When treating children, the Service should follow the standards and criteria outlined in the Specification for Children's Services[15] .

Equipment

- Appropriate imaging equipment to facilitate the management and assessment of outcome of skeletal (including orthognathic) surgery and orthodontic treatment.
- Appropriate quality dental x-ray facilities which meet national standards.
- Access to videofluoroscopy.
- Equipment for nasendoscopy.
- Operating microscope.
- ENT Auriscopes.
- Dental sets.

2.3.2 Staffing

People with Cleft Lip and/or Palate have complex medical, emotional and social needs. The provider needs to ensure there is access to a broad range of professionals which is essential for delivering optimum and timely therapy (see table 1).

Table 1: Clinical and support staff required for Cleft Lip and/or palate service

The Multi-disciplinary Team	most of whom will be based at the Cleft centre/hub
Clinical Director	responsible for the service and to ensure that each discipline has sufficient staff to provide the service and to maintain high standards and skills
Care Co-ordinator	Based at Cleft Centre / Hub
Service Manager	
Lead Cleft Surgeons	who will devote a majority 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. Surgeons undertaking primary lip and palate repair should be treating not less than 30 new babies per year

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[15] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf Appendix 1 - (attached as Annex 1 and Appendix 1 Page 26

	notwithstanding the aim in HSC 1998 238 for 40-50 new babies per year per surgeon. New surgeons shall have met the requirements of a Training Interface Groups (TIG) approved cleft surgery fellowship training or equivalent.
Lead Paediatric Anaesthetist	with a special interest in cleft care
Lead Consultant in Paediatric Dentistry	with a special interest in cleft care
Lead Consultant Orthodontist	with major commitment to cleft care
Lead Specialist Speech and Language Therapist	with major commitment to cleft care
Lead Consultant Paediatrician/s	ensuring good paediatric surveillance and on-going paediatric care
Lead Consultant ENT surgeon and/or **Audiological Physician**	with paediatric otology experience with an interest in children's hearing.
Lead Clinical Nurse Specialist	
Lead Consultant Clinic Psychologist	
Lead Consultant Restorative Dentist	
Lead Consultant Clinical Geneticist	

Each service will have a lead/leads clinician who should have additional staff in their discipline/specialty, as are needed to provide the service.

The MDT will facilitate/encourage user involvement by including (a minimum of 2) patient representative(s) in their service development and review processes and meetings.

The hub MDT team will require the support of clinical photography, dedicated Information Technology (IT) support especially for archiving of records and to support general team activity, radiologists and radiographers, maxillofacial and orthodontic technicians, secretarial and clerical staff, and audit support staff. The spoke and community team will include local speech and language therapists, audiologists, orthodontists, local and community paediatricians, geneticists and ENT surgeons. There will also be close liaison with ultrasound diagnosticians and foetal medicine experts.

2.3.3 Transitional care arrangements

- Manage the transition into adult services for those with on-going needs for Cleft Lip and /or Palate care, ensuring that the young person understands their condition and is developing autonomy to manage their own healthcare.
- For those young people still requiring Cleft Lip and Palate team input at the age of 16+, transitional care arrangements will be delivered. Care for Cleft Lip and/or Palate Paediatric and Adult patients is delivered in large part by the same members of the clinical team and therefore transition is seamless, in this respect, from paediatric to adult care. However, consideration needs to be given to consent, decision making about treatment, information sharing and aspects of care such as appropriate clinics and wards for any admissions required.
- Transition involves a process of preparation of the young person and their family for their transition to adulthood and their transfer to adult services. This preparation should start from early adolescence, occurring from mid- to late teens, followed by full transfer into adult services from late teens to early 20s. The exact timing of each stage will ideally be dependent on the wishes of the young person but will need to comply with local resources and arrangements. The Transition process should be a flexible and collaborative process involving the young person, their family as appropriate and the Cleft Lip and Palate Service.

2.3.4 Response time and prioritisation

The provider needs to ensure that all services are delivered in a timely manner and in accordance within the core standards for the service, which are identified in section 3. Treatment will be prioritised according to clinical need and where clinical need is the same, through chronological waiting list management provided this does not contravene agreed treatment protocols. Any diagnostic tests and investigations will be completed within any target dates established by NHS England and NHS Wales.

2.3.5 Information and Education

The provider needs to provide information, advice and support for a range of treatment options as set out in this service specification.

The provider needs to ensure patients receive a copy of all appropriate correspondence regarding their care.

The provider should offer all patients or their parents, and families and/or carers, opportunities to learn about their diagnosis and prognosis and the treatment options available to them. In some cases, more formal education may need to be offered, which could include members from the MDT providing a wider range of information according to the individual patient's needs, e.g. dental care, speech development, eating and drinking skills.

The provider should offer appropriate information covering advice, treatment and care to patients, general practitioners and patient groups that is non-discriminatory and culturally appropriate. The information should be in a format relevant to a patient's needs, taking into account any physical, sensory or learning disabilities.

The Clinical Nurse Specialists (CNS) in the Cleft team should offer information and training to maternity services in their area to promote early identification and referral.

The provider should ensure that patients, their families and/or carers are provided with information about local and national support groups and how to access them. It is recognised that these are a vital source of peer support, advice and information for patients. Signposting information can also be displayed within the provider's facilities.

2.3.6 Clinical Standards

Centres will contribute to and participate in regional and national audits and contribute data as required by CRANE (Cleft Registry and Audit Network database), the Quality Dashboard and the Tri/Quad centre audit groups[16].

The service will strive to contribute to clinical research and when possible basic research into aetiology of cleft lip and / or palate and the best means of treating the conditions. In particular the service will aim to collaborate with the Cleft Collective and National Institute for Health Research (NIHR) and NISCHR funded studies.

The service will work as a 'Hub and Spoke' model with all In rare cases because of major co-morbidities a child may need to have some aspects of cleft surgery carried out in another cleft centre. Whenever possible arrangements should be agreed so that these can be provided in those centres by the Wales cleft team surgeons and at an appropriate time the Welsh Centre should take over the cleft care of the patients.

Cleft surgery will take place at the specialist centres (Hub) and all core disciplines are centred at and directed from the Hub. It is recognised that the Hub may in fact include separate hubs for child and adult services but the service will be delivered by the same team.

The care pathway diagram for CLP is described in Annex I of this document. The precise pathway will vary with the cleft diagnosis, dependent to some extent on co-morbidity, geography and the way in which local and centre services are delivered.

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[16] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf

2.3.7 Clinical responsibility

The provider is responsible for all risks arising in connection with the provision of the Cleft Lip and Palate service (whether arising directly or indirectly) under the terms of this specification, provided that the provider has been enabled to provide and deliver the service.

All patients who are treated by the provider, whether in the main Cleft Lip and Palate centre or in local or community facilities, shall remain under the overall clinical CLP care of the hub. This includes outreach facilities, whether or not they are directly subcontracted.

Clinical management of eligible patients will be in line with the agreed care pathway.

The provider will coordinate any associated in-patient, day care and out-patient services to ensure continuity of care. Specialist Cleft Lip and Palate staff, equipment and care will be available irrespective of the care setting, for patients with Cleft Lip and/or Palate admitted to hospital.

2.3.8 Systems Management

Radiology systems

The provider will need to ensure that full access is available to the radiology picture archiving and communication system (PACS) in the hospitals where CLP patients undergo radiology investigations as part of their care.

PAS/HISS systems

The provider will need to ensure that full access is available to its Health Informatics Services (HISS) computing system or Patient Administration System (PAS).

2.4 Patient Pathway (annex i)

South Wales

Paediatric and Adult services

Children and adults with a Cleft diagnosis resident in South Wales access services which are delivered by the Cleft team at Morriston Hospital, Swansea Bay UHB as part of the South Wales South West managed Clinical Network. These services are delivered from the current staffing configuration for the South Wales as detailed in annex iii.

North Wales

Paediatric and Adult Services

Children and adults resident in North Wales access services through The North West, Isle of Man and North Wales Operational Delivery Network. The current staffing configuration for the Network is detailed in annex ii. These services are delivered across Alder Hey Children's Hospital and Aintree University Hospital. Ongoing outpatient treatment is provided as close to the patients home as possible in the three main acute hospitals in North Wales. (Glan Clwyd, Wrexham Maelor and Ysbyty Gwynedd)

2.5 Interdependencies with other services or providers

A proportion of patients with Cleft Lip and/or Palate conditions may have single or multiple medical/congenital conditions and treatment may need to be developed in conjunction with other clinical priorities.

Co-located services

Services that need to be provided on the same site as CLP surgery are:

- Paediatric ENT airway support or appropriate protocols for paediatric airway support
- Paediatric Critical Care, generally high dependency but in some cases access to Paediatric intensive care (PICU) will be required. In general, access to or written protocols for retrieval to PICU will be required.
- Specialised Paediatric Anaesthesia.

Independent Services

Members of the multidisciplinary team (MDT) who do not need to be based at the centre but need to be readily available are:

- Restorative dentistry
- Genetics

Patients with Cleft Lip and/or Palate often also have other medical conditions, particularly congenital cardiac anomalies, other craniofacial anomalies etc. It is therefore essential that strong clinical links are made with service areas managing those co-morbidities.

Related Services

Local Service Provision

The service prescribed in this specification relies on local services to deliver some elements of the CLP pathway. The services described in Appendix 1 will often be commissioned at a local level to support the nationally commissioned CLP services.

Those services are integral to the service and commissioning must be seamless so that there is no disruption to full delivery of the entire care pathway as described by the hub CLP team. Examples of these services are as follows:

- Local Paediatric Services e.g. Health visitors, School nurses, SLT, Dentists, Audiology/Hearing services
- General Practitioners, General Dental Practitioners and community services
- Mental Health Services e.g CAMHS, paediatric psychology and adult mental health services
- Secondary and Tertiary provider clinicians and specialist nurses
- Patient Transport Services

NHS Non Specialised Health care

- Patient's GP
- Patient's GDP
- Paediatric inpatient facilities – play therapists, Community Paediatricians, Community SLT, Local Mental Health Services

Non NHS Services

- Local Education
- Social Care Services
- Children's Centres-Support Groups
- Charitable Organisations
- Service User representatives

2.6 Exclusion Criteria

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

2.7 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.8 Patient Pathway (Annex i)

Techniques in cleft care have advanced over recent years and adult patients who have received surgery in the past sometimes require further specific intervention from the CLP teams to optimise previous procedures.

2.9 Service provider/Designated Centre

North Wales Service

The North West, Isle of Man and North Wales Operational Delivery Network (ODN)

Alder Hey Children’s Hospital
Prescot Road
Liverpool
L14 5AB

Aintree University Hospital
Lower Lane
Liverpool
L9 7AL

Outpatient treatment is provided by the three main acute hospitals in North Wales (Spoke centres)

Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
Rhyl
LL18 5UJ

Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
LL13 7TD

Ysbyty Gwynedd
Penrhosgarnedd
Bangor Gwynedd
LL57 2PW

South Wales Service

South Wales and South West Managed Clinical Network (MCN)

Morriston Hospital - (Hub/Centre)
Swansea Bay University Health Board
Heol Maes Eglwys
Morriston
Swansea
SA6 6NL

Bristol Dental Hospital
Lower Maudlin Street
Bristol
BS1 2LY[17]

2.10 Tertiary Referral Management

Referral Management is a tool used to monitor, direct or control patient referrals. A robust Referral Management system will allows for scrutiny of all new out-patients referrals and ensure referrals that can be treated in Wales are considered by the appropriate organisation and where appropriate redirected to Welsh providers.

Occasionally, patients who require CLP services all require treatment by supra regional services for other conditions. In this instance the patient will be re-directed by the CLP clinical gate-keeper.

The Clinical Gatekeeper is a nominated clinician through whom all elective non urgent specialist referrals pass. The preferred clinician will receive referrals from colleagues and assess whether the care can be provided within Wales, and within existing WHSSC commissioning and service specification policies. If treatment outside of Wales is required the Clinical Gatekeeper is authorised to commit funding on behalf of WHSSC, provided it is within commissioning policies and within the preferred directory of English Trusts (available at www.whssc.wales.nhs.uk).

The process from time to time and without delay enable second opinions to be provided both for welsh patients to centres outside Wales, and for patients from outside Wales to obtain second opinions from within Wales.

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[17] The Bristol Dental Hospital forms part of the South Wales and South West Clinical Network however it is only patients from the South West of England that access services here.

3. Quality and Patient Safety

The provider must work to written quality standards as documented in this service specification and provide monitoring information to the lead commissioner. The quality management systems must be externally audited and accredited and the commissioners will support the clinical director of the service to facilitate this.

The centre must enable patients, carers and advocates informed participation and be able to demonstrate this. Provision should be made for patients with communication and language difficulties and for children, teenagers and young adults.

The service will provide a safe, cost effective, high quality specialised service for people with Cleft Lip and/or Palate to improve their quality of life by[18]:

- providing a personal service, sensitive to the physical, psychological, intellectual and developmental needs of the patients and their family/carers
- ensuring equity of access to services for those with Cleft Lip and/or Palate taking into account a patient’s location and the distance they travel
- offering informed choice to people with Cleft Lip and/or Palate
- ensuring an appropriate transition to adult care
- ensuring effective communication and support between patients, their family / carers and the service providers
- ensuring the Service has a formal appointment policy and follow-up process in case of non-attendance
- the Service should have a clear written policy for children who do not attend 2 successive appointments in order to ensure that no child is disadvantaged. This should be based on a team discussion, agreement on action which may include a letter or direct approach to parents/carers and if this does not resolve the situation may require referral to social agencies. In all such cases the paramount interests of the child must be placed first. In principle, no child will be discharged from the service for non-attendance or non-compliance with treatment in order to ensure that children are not disadvantaged.
- since service delivery in some disciplines (e.g. speech and language therapy) is often delivered locally, the commissioners will ensure that the lead provider/cleft centre has the means to ensure such delivery to the service standards and to cleft centre prescription whether the service is funded locally or centrally.

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[18] NHS Standard Contract D07/s/a for cleft lip and/or palate services including non-cleft velopharyngeal dysfunction (VPD) all ages.

- none of the services listed in this service specification will be subject to prior approval whether for children or adults.

The service will offer effective clinical interventions in an appropriate and timely care setting thereby ensuring a positive patient experience and optimal clinical outcomes.

3.1 Key Performance Indicators (Quality Dashboard)

Service Outcomes

The aims of treatment of CLP are to ensure that children and adults:

- who have a cleft lip repair, have a good aesthetic and functional result
- who have CLP and especially palatal cleft repair, have good palate function to produce good speech, normalised hearing and optimal dento-facial development.
- patients should be able to function well socially and without disadvantage.
- With non cleft Velopharyngeal Dysfunction have improved speech.

In some of these areas of clinical outcome, robust and validated outcome measures have been developed and are in routine use through local, regional, national and international audit.

This service specification includes 42 Standards of Care (section 3.2), which relate to process and clinical outcome in the management of Cleft Lip and/or Palate and non-Cleft Velopharyngeal Dysfunction. The outcome measures referred to in this document are all ones, which are robust and have been validated. Unfortunately, there are some clinical areas, where such outcome measures are not yet adequately developed anywhere in the world (for example, assessment of the result of lip repair) but work is on-going especially in the UK Cleft Special Interest Groups of the Craniofacial Society of Great Britain and Ireland and nationally in the CRANE project team to develop these measures.

The NHS England Clinical Reference Group, in conjunction with the UK NHS Cleft Development Group developed a quality dashboard that contains measures reflecting elements of the MDT’s Cleft care. All CLP outcomes are in Domain 2 of the NHS Outcomes Framework (Enhancing quality of life for people with long-term conditions).

Domain 2 – Enhancing quality of life for people with long term conditions

1.	• Outcome: 100% of families are supported by the CLP Clinical Nurse specialist (CNS) at an early stage following diagnosis. • Measures: % of parents contacted by the Cleft team CNS within 24 hrs of notification of an antenatal diagnosis of CLP % of families that receive a visit from a Cleft team CNS for advice within 24 hours of first referral at birth or first diagnosis after birth.
2.	• Outcome: All babies with CLP receive initial lip and palate surgery at the optimal time to achieve 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 13 months in the absence of specific clinical reasons for delay (e.g. syndromes, co-morbidity and approved research).
3.	• Outcome: 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.
4.	• Outcome: All children with CLP at 5 years of age will have dental health which is at least as good as that of children without CLP in their region. • Measure: Average dmft and treatment index scores of 5 year old children with any cleft (from 5th birthday and before 6th birthday).
5.	• Outcome: Children with CLP achieve good quality, intelligible speech between the age of 5 and 6 years. • Measures: % of children between 5 years of age and before 6 years of age whose speech has no evidence of a structurally related problem and who have not had VP surgery or fistula repair for speech (green outcome on CAPS A section 3 & 4 - % of children between 5 years of age and before 6 years of age who have no cleft speech characteristics (CSCs) which require therapy (with green outcomes on CAPS A section 7a).
6.	• Outcome: Children with UCLP have good maxillary growth and achieve good facial appearance. • Measure: The 5 year Olds' Index as indicator of maxillary growth in patients with complete UCLP (either no Simonart's band or a band <5mm in height).
7.	• Outcome: All children with CLP achieve psychological well-being. • Measure: % of all children with clefts and their families born in a designated year who have been screened for psycho-

	social issues by a specialist cleft clinical psychologist at least once before the child's 6th birthday and a plan made to address any issues that arise.
8.	• Outcome: All children requiring alveolar bone grafting 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 alveolar bone grafting between 7 years and before 9 years of age. • The Kindelan score (defined) 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.
9.	• Outcome: All children with CLP will have acceptable appearance in their permanent dentition. • Measure: Mean Peer Assessment Rating (PAR) scores for completed orthodontic cases in the permanent dentition presented as % PAR difference for the measured cohort for all cleft types in a designated year.

3.2 Clinical Standards

The service will need to meet the following standards[19]:

Antenatal Care Standards

Core Standards

1.	Parents will be contacted by a cleft team Clinical Nurse Specialist within 24 hours of receiving the referral.
2.	Parents will be offered a visit from a CNS at an appropriate and negotiated time and place.
3.	A record will be kept by the cleft team of the outcome of the pregnancy (including, as appropriate, cleft type) for all antenatal referrals.

Recommended standards

4.	The regional team will agree protocols with, and provide information to, each 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

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[19] https://www.england.nhs.uk/wp-content/uploads/2018/08/Cleft-lip-and-or-palate-services-including-non-cleft-velopharyngeal-dysfunction-all-ages.pdf.

5.	The Clinical Nurse Specialist 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 cleft team • Counselling and support • Appropriate feeding preparation and plan for immediate postnatal period • Verbal and written information re cleft treatment and management • Contact with a family of a child with a similar diagnosis (ideally a trained CLAPA parent contact with a similar diagnosis if available) • Written information about CLAPA

Post Natal & Infant Care Standards

Core Standards

6.	A Clinical Nurse Specialist should visit the mother and baby within 24 hours of receiving the referral.
8.	A feeding plan should be devised and documented which supports the mother's preference for feeding at the first visit.
9.	All babies should have a nationally-recognised feeding assessment prior to the introduction of assisted feeding.
10.	All parents to be offered: • Counselling and support • Verbal and written information re cleft treatment and management • Contact with a family of a child with a similar diagnosis (ideally a trained • CLAPA parent contact with a similar diagnosis if available) • Written information about CLAPA
11.	All parents will be offered the opportunity of visiting the ward at the surgical centre prior to any surgery being undertaken
12.	Parental consent will be sought to register the details of the baby onto CRANE (Cleft Registry and Audit Network database), and to hold data on the baby and his/her parents on local cleft databases.

Recommended Standards

13.	An electric breast pump should be offered to all mothers who need one, for as long as they need it, without charge.
14.	A Clinical Nurse Specialist shall visit all babies at home within one week of discharge
15.	Arrangements must be in place to monitor parental satisfaction with the early care of the child and the effectiveness of the initial

	interventions, for example through a validated satisfaction questionnaire.

Additional Recommended Standards for Maternity Services

16.	All babies born with Cleft Lip and/or Palate should be diagnosed by birth.
17.	All babies are to be referred by relevant professionals to the cleft team within 24 hours of diagnosis.

Care and Facilities for Children & Young People Standards
Core Standards

18.	All babies with clefts will be fully assessed clinically by a Paediatrician for the presence of other congenital malformations and investigated further if required.
19.	All children and young people receiving cleft care should be treated in an appropriate paediatric environment, the general features of which are set out in the National Service Framework for Children 2003.
20.	All families of children with a cleft will be offered assessment by and will have access to support from a member of the Cleft Clinical Psychology team before the first operation is carried out.

Additional Recommended Standards for Paediatric Services

21.	Babies and children with cleft involvement will have regular, local, paediatric follow up to ensure appropriate growth and development, especially in the first 24 months of life.

Cleft Surgery Standards

Core Standards

22.	Cleft surgeons must have appropriate experience and training and a proven commitment to cleft care. They will devote a majority 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.
23.	Surgeons undertaking primary lip and palate repair should be treating not less than 30 new babies per year notwithstanding the aim in HSC 1998 238 for 40-50 new babies per year per surgeon. The number of new babies treated over a period (e.g. 3 years) will be considered. New surgeons shall have met the requirements of a TIG approved cleft surgery fellowship training or equivalent.
24.	With regard to cleft surgery in general and the need to devote a majority 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 surgery, ABGs,

	orthognathic surgery, speech surgery, and revisions, will be considered.

25.	All cleft surgeon(s) will participate in audit 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.
26.	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.
27.	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 alveolar bone grafting. 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 alveolar bone grafting procedure.
28.	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.

ENT & Audiology Service Standards

Core Standards

29.	All children with a cleft palate should have their hearing assessed by a clinician trained in paediatric audiology before the gestational age of 10 months (in addition to the national newborn 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, again at school entry and at 5 years and 10 years of age. **NB:** In some cases follow up care may be provided by non-prescribed, locally commissioned ENT and Audiology services.
30.	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.
31.	All children with persistent conductive hearing loss must receive careful review by a clinician expert in otoscopy.

Speech & Language Therapy Standards

Core Standards

32.	For patients 5–11 years of age each centre will collate data as laid down by the Lead SLT Group in order to strive to achieve the National Standards for Speech for children with cleft palate (+/- cleft lip/alveolus) relating to process (10.4–10.7) and outcome (10.8–10.12) (see Appendix 4)

Recommended standards

33.	For patients 10–11 years of age each centre will collate data as laid down by the Lead SLT Group in order to strive to achieve the National Standards for Speech for children with cleft (+/-cleft lip/alveolus) relating to process (10.4 – 10.7) and outcome (10.8–10.12) (see Appendix 4)

Dental Health Standards

Core Standards

34.	All children born with a cleft lip and/or palate will receive preventive dental advice and support by the time the child is six months of age and will have treatment if needed arranged or provided to aim to ensure that their level of dental disease is the same as or better than the average in their local community.
35.	All children born with a cleft lip and/or palate 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.
36.	1. 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 being to determine the degree of dental abnormality and provide protection of defects to prevent further deterioration and for aesthetic improvement if indicated prior to change to high school. 2. Planning and provision of longer term restorative solutions should 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 recognized that later assessments for adults and treatment will be required in some if not many cases.

Recommended Standard

37.	For children who have completed orthodontic treatment the Peer Assessment Rating (PAR) score should be applied to start and finish of

	treatment models. The change in PAR scores should relate favourably to any established National Standards.

Clinical Psychological & Counselling Services Standards

Core Standards

38.	All parents and children with clefts will be regularly assessed and offered psychological support if needed.

Recommended Standard

39.	The Lead Clinical Psychologist will ensure that all children with cleft lip and/or palate have audit records collected in line with national audit recommendations. National and international comparisons will be made and the service will meet any clinical need identified including clinical psychology therapy sessions.

Genetic Services Standard

Core Standard

40.	All patients (and their parents) will be offered a referral to the Clinical Genetics service when appropriate and at discharge from the Cleft team.

Audit Records and Post-Infant Patient/Parent Satisfaction

Recommended Standard

41.	The standard record set should be available, or else the reason for non-collection recorded, for 100% of all cleft individuals at each age band. Patient and Parent satisfaction questionnaires will be used to assess the team's performance in adolescence and at the end of routine care.

Adults Returning to the Service

Core Standard

42.	Any adult who has missed out on the care pathway should be assessed and treated according to the Clinical Service Specification in so far as that is clinically possible and appropriate regardless of age, according to clinical need and in an appropriate environment.

3.3 Other Applicable Standards

- Standards as set out in Annex 1 and Appendix 1 of NHS standard contract for Cleft Lip and/or Palate Services including Non-Cleft Velopharyngeal Dysfunction (VPN) all ages, NHS England service specification, D07/S/a, 2013.

- NHS Wales, Health and Care Standards, April 2015.

- Welsh Government, National Standards and Outcomes Framework for Children and Young People in Wales, 2019.

- Department of Health, National Service Framework for Children, Young People and Maternity Services, Core Standards, October 2004.

3.4 Other quality requirements

- the provider will have a recognised system to demonstrate service quality and standards
- the service will have detailed clinical protocols setting out nationally (and local where appropriate) recognised good practice for each treatment site
- the quality system and its treatment protocols will be subject to regular clinical and management audit
- the provider is required to undertake regular patient surveys and develop and implement an action plan based on findings.

3.5 Clinical Governance

The provider will provide and ensure that all staff adheres to its policies, procedures, and clinical guidelines as agreed with commissioners.

Every patient must have a named consultant responsible for their care. A member of the team will be offered as a keyworker to support families throughout the clinical pathway if required.

3.6 Data collection for the Cleft Registry and Audit Network database (CRANE Database)

All Hubs providing Cleft care are required to submit information to CRANE. This database is commissioned by NHS England and NHS Wales and produces both annual and interim reports. Commissioners are able to request specific queries to CRANE to aid commissioning. CRANE data analysis is also reported to the national UK Cleft Development Group which is responsible for CRANE and who use the information to drive quality services and interrogate variation. The following outcomes are collected: details of diagnosis and appropriate/timely referral from maternity units to

Hubs; key outcome indicators at 5 years of age, including facial growth, speech, dental disease and overall growth with height and weight data. Additional key indicators are also being developed and included for a variety of ages including 10, 15 and 20 year olds.

In addition, the CRANE Project Team also produces analyses of data from the Hospital Episode Statistics (HES), the database on all NHS hospital admissions in England and Patient Episode Data Wales (PEDW) for all NHS hospital admissions in Wales. These data are used to provide additional information including: hospital and surgeon volumes for surgical procedures; number of hospital admissions and length of stay in hospital; readmission rates; emergency admission rates. This will develop further to include reporting outpatient episodes of care.

4. Performance monitoring and Information Requirement

4.1 Performance Monitoring

WHSSC will be responsible for commissioning services in line with this policy. This will include agreeing appropriate information and procedures to monitor the performance of organisations.

For the services defined in this policy the following approach will be adopted:

- Service providers to evidence quality and performance controls
- Service providers to evidence compliance with standards of care

WHSSC will conduct performance and quality reviews on an annual basis to review the service utilisation and improve on any aspects of the service as required.

Service monitoring meetings/Network Board Meetings

The provider and service commissioner (WHSSC) will meet on a quarterly basis at a performance meeting to review the service utilisation and on an annual basis where a representative of service users will be invited to this meeting.

A WHSSC representative is a member of the Network board and will attend meetings at least on an annual basis.

4.2 Key Performance Indicators

The providers will be expected to monitor against the full list of Quality Indicators derived from the service description components described in Section 3.2.

The provider should also monitor the appropriateness of referrals into the service and provide regular feedback to referrers on inappropriate referrals, identifying any trends or potential educational needs.

In particular, the provider will be expected to monitor against the following target outcome:

- The provider will ensure that all services are delivered in a timely manner and in accordance with national standards. Treatment will be prioritised according to clinical need and where clinical need is the same, through chronological waiting list management provided this does not contravene agreed treatment protocols.

- It is proposed that WHSSC will work with the service to develop a further set of Key Performance Indicators (KPIs) to measure the improvements to the quality of service as required (Appendix 2).

4.3 Date of Review

This document is scheduled for review before 2023 where we will check if any new evidence is available.

If an update is carried out the policy will remain extant until the revised policy is published.

5. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

6. Putting Things Right: Raising a Concern

6.1 Raising a concern

Raising a Concern Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

6.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient’s Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

Annex i Patient Pathway

	Ante-natal	Birth to 8 wks	9 wks - 2 yrs	3 - 7 years	8 years – 14 years	15 – 21+ years	> 21 yrs returning
Local Obstetric Units	• Ultrasound scan diagnosis, confirmed if necessary by foetal medicine specialist • Local obstetric unit to contact Cleft Team within 24 hours of diagnosis	• Local maternity unit to contact Cleft Team within 24 hours of birth					
Main 'Hub' Cleft Centres (including MDT clinics organised by the Hub at Spokes)	• Contact by Cleft Clinical Nurse Specialist (CNS) within 24 hours of referral. • Provide printed information • Negotiate face to face meeting • offer contact with CLAPA	• CNS visit within 24 hrs of referral • Specialist feeding assessment and management, printed information, offer Cleft Lip And Palate Association **(**CLAPA**)** referral	• Lip repair at 3-6 months • Palate repair 6-12 months • Refer for local Audiology for assessment and management of cleft palate • Speech and language assessment usually at 18	• Psychological support offered 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	• 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	• Definitive orthodontic care • Full MDT clinic and records at 15 and 20 years • Offer Genetic referral • Team assessment for Orthognathic surgery if indicated	• Continuation of/or return to care from previous period • Adult patients returning for care may require • Speech and Language assessment and therapy • Lip and/or Nose

	Ante-natal	Birth to 8 wks	9 wks - 2 yrs	3 - 7 years	8 years – 14 years	15 – 21+ years	> 21 yrs returning
		• Meet Cleft team and/or Multi-disciplinary Team (MDT) Baby clinic before any cleft 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	months, and management • Paediatric dentist for dental health education/ advice by 6 months of age and direction / liaison with appropriate general dental care	• Paediatric Dentistry advice and/or intervention if necessary • Later investigation (e.g. nasendoscopy and videofluoroscopy) for speech problems if necessary and this may be required at any stage in the care pathway	Orthodontic treatment • If required, pre-ABG orthodontic care followed by Alveolar Bone Grafting completed before 12 years – follow-up at 6 months post-op • Full MDT and records at 10 years • Speech and Hearing checked and managed if palatal involvement • Definitive Orthodontic care • Paediatric Dentistry if necessary	• Planning and pre-treatment for skeletal surgery • Orthognathic surgery and associated Orthodontics if indicated • Revisional surgery if indicated (nose, lip) • Paediatric to Restorative Dentistry as indicated • Completion of Post-Orthognathic surgery records and Speech assessment • Speech revision surgery if indicated	revisional surgery • Speech revision surgery • Palatal fistula repair • Orthodontics • ABG if not done previously • Orthognathic surgery • Clinical Psychology • ENT and hearing assessment and treatment • Restorative dentistry

	Ante-natal	Birth to 8 wks	9 wks - 2 yrs	3 - 7 years	8 years – 14 years	15 – 21+ years	> 21 yrs returning
Local Care		• Paediatric surveillance for co-morbidity & syndromes • Neo-Natal 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 • Local Paediatric follow-up to ensure continued surveillance for co-morbidity and syndromes including appropriate referral to other specialist services	• Later Speech and language 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- paediatric and restorative dental care in close liaison with 'centre'	
Primary Care		• Dental health education in	• Dental health education in	• Routine preventative	• Routine preventative	• Regular dental care	• Regular dental care

	Ante-natal	Birth to 8 wks	9 wks - 2 yrs	3 - 7 years	8 years – 14 years	15 – 21+ years	> 21 yrs returning
		liaison with main centre	liaison with main centre • Routine child health surveillance	dental advice and treatment	dental advice and treatment		

Annex ii Staffing Configuration

Current staffing configuration for the North Wales Regional Network.

Current staffing configuration for The North West England, The Isle Of Man & North Wales Cleft Lip and Palate Network
Staff
Consultant
Cleft Clinical Nurse Specialist
Cleft Co-ordinator
Medical Secretary
Paediatric Dentistry - Consultant Sessions
Orthodontics Sessions
Clinical Psychology
Speech and Language Therapist

*band may change depending on skill mix at the time
** sessions are held at AH

Paediatric and Adult services

Children resident in North Wales access services which are delivered by Cleft Lip and Palate Service based at Alder Hey. These services are delivered from the current staffing configuration detailed above.

Current staffing configuration for the South Wales Managed Clinical Network.

Speciality/Discipline
Chief Executive
Medical Director
Surgery Clinical Director
Directorate General Manager
Directorate Finance Manager
Clinical Director
South West Eng Clinical Director
Lead Cleft Surgeon
Lead Cleft Surgeon
Paediatric Anaesthetist
Anaesthetist
Lead Cleft Orthodontist
Lead Paediatric Dentist
Lead Paediatrician (Neonatal)
Lead Paediatrician
Lead Speech & Language Therapist
Deputy Lead SLT
SLT
SLT

SLT
SLT
SLT Assistant and audit assistant
Lead Consultant Clinical Psychologist
Highly Skilled Clinical Psychologist
Assistant Psychologist
Cleft Coordinator
Lead Clinical Nurse Specialist
Clinical Nurse Specialist
Clinical Nurse Specialist
Senior Dental Nurse (Cardiff)
Senior Dental Nurse (Swansea)
Lead Medical Geneticist
Foetal Medicine
ICT Officer
Team Secretary
Medical Secretary
Clerical Officer
Clerical Officer
Clerical Officer
Clerical Officer
Lead for ENT and Hearing
Audiology (Swansea)
Audiology (Cardiff)
Restorative Dentist (Swansea)
Restorative Dentist (Cardiff)
Orthodontist (Newport)
Orthodontist (Abergavenny)
Orthodontist (Swansea)
Orthodontist (Cardiff)
Orthodontist (Cardiff)
Orthodontist (Cwm Taf Morgannwg)
Audiovestibular Physician(Cardiff)
ENT Surgeon (Cardiff)
Audiology (Newport)
ENT Surgeon (Newport)
Audiology (Bridgend)
ENT Surgeon (Bridgend)
Audiology (Swansea)
ENT Surgeon (West Wales)
Audiovestibular Physician (West Wales)
ENT Surgeon (Cwm Taf)
Audiology (Cwm Taf)

* = sessions funded from Cleft service (WHSSC) + sessions funded by ABM as presumed - pre-existing resource
**= sessions unfunded by Cleft service but funded locally
Local = locally resourced

Annex iii Codes

Code Category	Code	Description
ICD10	Q302	Fissured, notched and cleft nose
	Q351	Cleft hard palate
	Q353	Cleft soft palate
	Q355	Cleft hard palate with cleft soft palate
	Q357	Cleft uvula
	Q359	Cleft palate, unspecified
	Q360	Cleft lip, bilateral
	Q361	Cleft lip, median
	Q369	Cleft lip, unilateral
	Q370	Cleft hard palate with bilateral cleft lip
	Q371	Cleft hard palate with unilateral cleft lip
	Q372	Cleft soft palate with bilateral cleft lip
	Q373	Cleft soft palate with unilateral cleft lip
	Q374	Cleft hard and soft palate with bilateral cleft lip
	Q375	Cleft hard and soft palate with unilateral cleft lip
	Q378	Unspecified cleft palate with bilateral cleft lip
	Q379	Unspecified cleft palate with unilateral cleft lip
OPCES Should be OPCS4	F031	Primary closure of cleft lip
	F032	Revision of primary closure of cleft lip
	F291	Primary repair of cleft palate
	F292	Revision of repair of cleft palate
	V123	Transcranial repair of craniofacial cleft and reconstruction of cranial and facial bones HFQ
	V124	Subcranial repair of craniofacial cleft and reconstruction of cranial and facial bones HFQ
		ABG,

Other procedures not unique to CLP		Harvest of BG- Harvest of bone graft LF1 Ost -Le Fort 1 maxillary osteotomy
		DO LF1- Distraction Osteogenesis for LF1 osteotomy
		LF2 Ost- Le Fort 2 midface osteotomy
		DO LF2- Distraction Osteogenesis for LF 2 osteotomy
		Dental extractions
		Exposure of teeth

Annex iv Abbreviations and Glossary

Abbreviations

ABG	Alveolar Bone Graft
AWMSG	All Wales Medicines Strategy Group
BCLP	Bilateral Cleft Lip and Palate
CLP	Cleft Lip and Palate
CLAPA	Cleft Lip and Palate Association, a parent/ patient group
CNS	Clinical Nurse Specialist
CP	Cleft Palate
CRANE	Left Registry and Audit Network database
ENT	Ear Nose and Throat
HDU	High Dependency Units
IPFR	Individual Patient Funding Request
MDT	Multi Disciplinary Team
NSF	National Service Framework
PAR	Peer Assessment Rating
SLT	Speech Language Therapy
UCLP	Unilateral Cleft Lip and Palate
VPD	Velopharyngeal dysfunction
WHSSC	Welsh Health Specialised Services

Glossary

Alveolar cleft bone graft
Insertion of bone graft into gap in the alveolar bone where the cleft is.

Cleft Lip and/or Palate
Cleft Lip and /or Palate is a congenital anomaly resulting from failure of fusion of embryological parts forming the lip, nose and palate.

Cleft Registry and Audit Network (CRANE)
This is an NHS database which collects information about all children born with cleft lip and/or cleft palate in England, Wales and Northern Ireland.

Individual Patient Funding Request (IPFR)
An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Velopharyngeal dysfunction
Abnormality of nasal speech (resonance) due to failure of normal function of the sphincter between the soft palate and the pharynx (back of the throat)

Welsh Health Specialised Services Committee (WHSSC)
WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Appendix 1 – NHS England Standard for Cleft Lip and/or Palate services

This extract has been taken from the NHS England D07 document for Cleft Lip and/or Palate services[20]. The guidelines to local care are mandatory.

Local Care Guidelines

The service described in this specification relies on local CCG/local authority commissioned services to deliver some elements of the CLP pathway. It is possible that some of the services described in this appendix will be commissioned at a local level to support the nationally commissioned CLP services.

The service will work as a 'Hub and Spoke' model with all cleft surgery taking place at the specialist centres (Hub) and all core disciplines being centred at and directed from the Hub, notwithstanding that some centres are twin site.

Services may be delivered by Hub clinicians in the centre or by outreach, but to reduce travelling for patients who live distant from the centre, may be delivered by local specialist clinicians working as prescribed by hub clinicians, for example in SLT, dentistry, orthodontics, ENT/Audiology. Those services for cleft related care in those specialties/disciplines will be prescribed and coordinated by the Hub for local delivery of the clinical pathway in a timely and appropriate manner. These pathways will be based on national policy, guidelines and best practice. Such therapy should be delivered according to prescription by the hub cleft team for as long as considered necessary in the prescription and within timely fashion (no more than 18 weeks wait).

Orthodontics

Orthodontic treatment of patients with clefts should be considered in two broad categories:

1. Clefts not involving the alveolus: Orthodontic treatment for patients where the cleft does not involve the alveolus, or where it is anticipated that the orthodontic treatment will not require to be integrated significantly with surgery or other MDT care, may be provided at the Cleft Centre or locally by a suitably trained Consultant Orthodontist with the agreement of the Lead Cleft Orthodontist.

2. Clefts involving the alveolus: For patients with clefts involving the alveolus or where it is anticipated that treatment needs to be integrated with care provided by other members of the Multi-disciplinary Team, such as orthognathic surgery, speech and

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[20] https://www.england.nhs.uk/wp-content/uploads/2013/06/d07-cleft-lip.pdf page 43

language therapy, it is more appropriate for treatment to be provided by one of the following:

- Lead Cleft Consultant Orthodontist
- A Post-CCST Specialty Trainee (in the final two years of training leading to consultant post) under the supervision of the Lead Cleft Consultant Orthodontist
- A local Consultant Orthodontist participating in hub or outreach CLP clinics or a Post-CCST Specialty Trainee being supervised by them and in close co-operation with the Lead Cleft Consultant Orthodontist
- Under a shared care arrangement with a local Consultant Orthodontist where significant amounts of the care are provided by the Lead Cleft Consultant Orthodontist with perhaps alternate appointments provided locally.

Orthodontic treatment of patients with CLP is not currently included in the first three years of orthodontic specialist registrar training. Consequently, treatment for these patients is provided either by a Consultant Orthodontist or under supervision by Post-CCST Specialty Trainees in Orthodontics. It is not appropriate for specialist practitioners, dentists with a special interest, or orthodontic therapists to treat patients with a cleft whose treatment is outside their training.

The provision of orthodontic treatment for patients with clefts, with or without alveolar involvement, must be agreed by the Cleft MDT and in those cases which will involve orthognathic surgery, that team must include the Cleft Surgeon/s who will carry out the orthognathic surgery, a team speech and language therapist and a team clinical psychologist.

Any local orthodontics will be provided in timely fashion and in no case will any patient wait longer than 18 weeks to start treatment. The treatment will conform to the overall cleft care pathway and will be guided by the Lead Cleft Consultant Orthodontist.

Speech and Language Therapy

The local speech and language therapy provided by specialist cleft link therapists or generalist community therapists will be appropriate to the needs of the individual child or adult and within 18 weeks RTT. Advice, support and guidance will be given to local therapists as required by the specialist speech and language therapists working at the cleft surgical centre.

ENT and Hearing

It is recognised that most ENT and Hearing investigation and treatment for cleft children will be carried out by local secondary services in ENT, Audiological Medicine and Audiology. Each locality should have designated individuals who have these responsibilities for cleft children and who will liaise closely with the central cleft team.

All children, regardless of whether they have a cleft palate, will undergo a New Born Hearing Screen locally within 1-3 days of birth.

All children with a cleft palate should also have their hearing assessed by a clinician trained in paediatric audiology between 8-10 months of age. They should receive follow-up audiological care and appropriate audiometric assessments not less frequently than once a year for the first 3 years, again at school entry and at 5 years and 10 years of age. In many centres the audiological and otological assessments for 5 and 10 year olds will be carried out at their respective Cleft MDT clinics (if not already performed locally). Local results will be shared with the cleft team for audit purposes.

All families of children with a cleft palate (including cleft lip and palate) should receive information about the risks of hearing loss and how to look out for it before the child is 10 months old.

All children with persistent conductive hearing loss must receive careful review by a clinician expert in otoscopy.

Dentistry

It is expected that the majority of dental care for cleft children and adults will be delivered locally through the general dental services and community dental services. It is important that children with CLP receive good and regular dental care and liaison with the cleft team and especially the specialist in paediatric dentistry will facilitate this.

Appendix 2 – All Wales Key Performance Indicators

Investment	**Outcome measures**
Cleft Surgeon	• Waiting times for VF and NCVPD patients • Waiting times for outpatient appointments • Waiting time for surgery for adults and NCVPD
Nursing	• Number of babies visited in 24 hours • Audit the number of beds saved following pre-assessment clinic
Paed Dentistry	• Measure the improvement in Decayed Missing Filled Teeth (DMFT) score • Number of appointments to those children with greater need
ENT	• Improvement in the monitoring of ear/hearing problems
Orthodontic	• Waiting time for Orthodontic treatment
Psychology	• Number of additional clinics where a psychologist is present • Number of additional children, families and adult patients receiving psychological support in clinics • Number of psychological support offered outside of clinics • Number of Mental Health Screens undertaken for children with 22q • Number of Additional Interventions
Speech and Language Therapy	• Number of children waiting for therapy intervention • Waiting time from speech assessment to VF (palatal investigation clinic) • Waiting time from VF to surgery • Number of NCVPD referrals
Administration	• Audit the time the appointment is sent to patients • Audit the timescale for typing medical notes