

SPECIALISED SERVICES NATIONAL DEFINITIONS SET (2nd Edition)

Cleft Lip and Palate Services (all ages) - Definition No. 15

Preface

36 specialised services are covered by the Specialised Services National Definitions Set (2nd edition).

The definitions were developed through national working groups (one for each service). Many clinicians, hospital managers, finance and information staff and commissioners were directly involved in working group meetings and many more provided comments during the consultation stages. Some of the definitions have been endorsed by the relevant national organisations.

The definitions identify the activity that should be regarded as specialised and therefore subject to collaborative commissioning arrangements. The definitions provide a helpful basis for service reviews and strategic planning and enable commissioners to establish a broad base-line position and make initial comparisons on activity and spend. It should be noted that, currently, many of the definitions have coding gaps and other information problems as well as a lack of agreed standard service currencies; further work is needed in these areas.

Production of the Specialised Services National Definitions Set is an iterative process. Over time new specialised services will be provided by the NHS whilst other services will become more commonplace and cease to be specialised.

Each definition is divided into two sections.

Section A provides descriptions of the various services covered. In most definitions, the existing pattern or model of service provision is described as well as the clinical service. Each definition includes a list of relevant national guidelines, such as DoH or Royal College of Publications, and identifies any national databases containing health outcomes information. Section A also includes sections on finance and information, examines the best way of identifying the relevant activity in information systems and acknowledges any coding gaps or difficulties. Most of the definitions include a recommended standard currency for the service (eg. banded bed days).

Section B includes specific issues considered to be important by the working group concerned. The views expressed in Section B are those of the particular working group and do not necessarily represent opinion within the DoH or the NHS. Resolving these issues is not within the remit of the definitions project.

It should be noted that the definitions are not service specifications nor do they prescribe service models or set service standards. Where national standards for a service already exist these may be referred to in the definition but specific decisions regarding the planning and procurement of a specialised service are matters for NHS commissioners themselves to address. Inclusion of a treatment or intervention in a definition should not be taken to mean that there is established evidence of clinical or cost effectiveness.

Comments and suggested improvements to the definitions are very welcome and can be sent to the email address: specialised.services.defins@doh.gsi.gov.uk

Section A

1. General Description

This clinical speciality can be defined as cleft lip and/or palate plus velopharyngeal insufficiency (VPI). There is a range of conditions within the definition, from a simple notch of the upper lip to a full bilateral cleft of the lip and hard and soft palate resulting in a very disabling malformation. Successful management of patients born with cleft lip and/or palate requires multidisciplinary, highly specialised treatment from birth to early adulthood followed by a lifetime commitment to the maintenance of oral health. With increasing antenatal diagnosis, contact with the specialist team often begins before birth with counselling. Treatment itself starts with neo-natal nursing and primary surgery, usually followed by several episodes of further surgery sometimes into adulthood. Speech and language therapy, orthodontics, preventive and restorative dental care, audiology and otolaryngology for hearing problems and genetic and psychological counselling are all essential parts of the package of care. Significant numbers of affected children also have co-existing additional medical complications and syndromes.

The main recommendation from the Clinical Standards Advisory Group (CSAG) in their report on cleft lip and/or palate was that the expertise and resources for cleft lip and palate services should be concentrated within a small number of designated centres throughout the UK. The designated centres ('hubs') would also have 'spoke' arrangements to ensure that accessibility was optimal without compromising the quality of care. This recommendation was accepted by the government and HSC (1998) 198 identified cleft lip and palate services as a national priority for the new arrangements for commissioning specialised services.

Specialised services commissioning groups are at present confirming the designated cleft centres in England. This process is expected to continue throughout 2001/02 and beyond. Where new centres have been designated, new-born babies with clefts should only be referred to these units. Patients already undergoing treatment may however continue to receive non-surgical care in their existing units provided these remain viable and are fully integrated into the clinical network managed from the designated centre. If for any reason existing centres are not part of the new network of care, their records will nevertheless need to be transferred or otherwise available to the designated centre.

2. Rationale for the Service being included in the Specialised Services Definitions Set

As stated above, cleft lip and palate services have been designated as a national priority for specialised services commissioning since 1998. The CSAG report identified serious problems with the organisation of cleft lip and palate services and linked this with the poor health outcomes that were being achieved in the UK. A major implementation programme is now underway which requires national and local co-ordination.

3. Links to other Services in the Specialised Services Definitions Set

Some cleft lip and palate activity will take place within a number of different specialties in the Specialised Services Definitions Set, including genetics, paediatric plastic surgery and paediatric oral and maxillofacial surgery. Cleft lip and/or palate may be an important part of a syndrome. Established communication links with other paediatric specialised services such as cardiac, renal, craniofacial, etc., are an important part of the care of these children. The cost of provision for these specialised services should be attributed to their specific definition set - e.g: paediatric neurosurgery. The cost of provision of the cleft care for the patient will be attributed to this definition. A small number of severely affected babies may require NICU support whilst those undergoing complex surgery and prolonged anaesthetics may require short stays in PICU. The majority of cases do not need this specialist level of associated support.

4. Detailed Description of Specialised Activity

The following description of the service and the required standards of care, which is not intended to be comprehensive, is drawn from the CSAG report (1998) and HSC 1998/238.

Comprehensive Service - Children with clefts require care that is provided by a multi-disciplinary team, which includes specialist counselling, specialist cleft nursing, plastic surgery, maxillofacial surgery, orthodontics, dental care, speech and language therapy, otology/audiology, clinical genetics, psychology, prosthetics and developmental paediatric services. The specialist team needs also to be available to provide advice and training to all the hospitals within the network.

Co-ordination - All treatment should be undertaken by the team from a designated specialist centre, at which certain important tasks (registration of cases, record keeping, treatment planning and multidisciplinary audit) are also performed. A specialist centre must be co-located on a single site with a major centre of paediatric care, but appropriate provision needs to be made for the 16+ age-group. Training of other professions throughout the network and in the community in appropriate aspects of cleft care is an important responsibility of the central team. Regular communication between the centre team and all parts of the network is crucial.

Surgery - Primary lip and palate repair and revision, pharyngoplasty, alveolar bone grafting, surgical exposure of teeth, and jaw osteotomies should be performed only by surgeons who have specialised knowledge and training in the management of cleft lip and palate. These surgeons will be devoting the majority of their time to this work and perform at least the minimum volume of operations specified in the CSAG report. Surgical technique, timing and sequencing should conform to established protocols unless new alternative procedures are introduced as part of a methodologically sound and ethically approved trial. Decisions to perform secondary operations should be reached within a multidisciplinary forum. Bone grafting and osteotomies should not be performed before joint surgical/orthodontic discussion, nor should pharyngoplasty be performed before joint surgical/speech and language evaluation, including nasendoscopy /videofluoroscopy where appropriate. Surgical records should include photographs and a detailed anatomical description of the pre-operated cleft, augmented by dento-facial casts obtained at the time of primary surgery.

Orthodontic treatment -Such treatment should be performed only by experienced orthodontists who have specialised knowledge and training in the management of cleft lip and palate and are frequently involved in this work. The majority of orthodontic treatment

will normally be provided locally, though co-ordinated by the specialist centre. Treatment may be concentrated into a pre-bone graft phase in the mixed dentition, followed by alignment of the permanent dentition, including pre-surgical preparation if orthognathic surgery is required in older patients. Additional early treatment should be carried out only when it is essential to facilitate surgery. It is an important duty of the orthodontist to feed back to the surgeon information on patients who have surgically related growth disturbance not already noted so that inappropriate surgical practices may be altered. Orthodontic audit records should not duplicate those obtained during audit of other clinical care, and should be fully accessible to the specialist centre.

Dental care – A named member of the cleft lip and palate team should ensure that dental health education, fluoride supplementation and dental attendance are maintained throughout childhood. Children with clefts should have priority access to a consultant in paediatric dentistry. Adolescents and adults requiring advanced restorative care, including crown and bridgework, dental implants and obturators, should have priority access to a consultant in restorative dentistry.

Speech and language therapy – A specialist speech and language therapist from the central team should carry out early counselling and diagnostic assessments, and provide any necessary therapy directly or through liaison with a local therapist. In addition some children may need access to a therapist specialising in dysphagia. The speech and language therapists also have a key role in reporting outcomes following speech-related surgical or prosthetic procedures.

Otology/audiology – The cleft lip and palate team should include an otologist who is responsible for the co-ordination of regular audiometric evaluation. Wherever possible, placement of grommets and other procedures should be co-ordinated with the performance of other surgical episodes to minimise the need for multiple anaesthetics. Otherwise, however, such procedures are not normally to be included within the specialised package of care.

Clinical genetics – The cleft lip and palate team should include a geneticist/dysmorphologist who has access to a genetics laboratory. All parents and patients should be offered the opportunity of access to genetic counselling.

Psychological counselling – The cleft lip and palate team should include a psychologist who has been suitably trained in counselling. All patients and parents should be assessed at times of transition and have access to counselling where indicated.

Paediatric development medicine – For each patient, the cleft lip and palate team should provide information to the child's consultant community paediatrician and to his or her general practitioner and general dental practitioner. Any suspicion of developmental or growth delay should be notified early to enable appropriate investigations to be undertaken.

Clinical audit and research – The cleft lip and palate team should participate in multi-centre audits and in national and international research.

Records – The cleft team should maintain integrated records which are also suitable for audit and research and have facilities for appropriate data capture, as outlined in CSAG.

All appropriate data must be submitted regularly to the national Cranio-facial Anomalies

Register (CARE) as required.

Communications with patients and parents and parental support – Effective and sympathetic communication with patients and parents is a central requirement of proper care. The team should subject itself to regular consumer audit, wear name badges at all times and provide families with written reports of multi-disciplinary assessment. The team must maintain effective relations with the local parents' support group (usually the Cleft Lip & Palate Association), put parents or prospective parents in touch with it at the earliest opportunity, and ensure that appropriate and timely information is always available. Appropriate and convenient accommodation must be provided for parents during in-patient episodes.

5. Recommended Units of Currency/ Approach to Costing

It has not been possible to agree a set of standard currencies for cleft lip and palate services to date. There is broad support for a package of care approach but no consensus about the different packages. Some people favour separate packages for different conditions e.g. cleft palate alone, cleft lip alone, cleft lip and palate and bilateral cleft lip and palate. Others favour a breakdown by age groupings - e.g. birth to 18 months and 18 months to 17 years.

It is important that more time is spent considering this issue before a decision is made. It is suggested that providers continue to use their current currencies until a standard set emerges at a later stage.

Any set of packages of care will need to take into account the following aspects of treatment and care, whether provided from the hub site or outreach clinics:

- Prenatal diagnosis and counselling
- Perinatal specialised cleft nursing
- Primary repair
- Routine follow-up, including outcome assessment
- Paediatric dentistry including dental health education and oral health promotion
- Alveolar bone grafting and associated orthodontics including exposure of the canines where required
- VPI investigations
- VPI surgery, including therapy and post-operative assessment
- Speech assessment and associated specialist speech therapy
- Definitive orthodontics (which could have several levels of care depending on case complexity)
- Orthognathic surgery/distraction osteogenesis techniques
- Lip revisions
- Palate revisions
- Rhinoplasty
- Restorative dentistry including implants and prosthetics
- Associated compensatory surgery such as lower lip revisions and vestibuloplasty
- Genioplasty
- Support from central team to networked hospitals

6. Approach to Identifying Activity in Information Systems

The existing coding systems do not allow full identification of all of the activity for these patients, and will not support the new arrangements for commissioning or provision. A new specialty code within the HES system needs to be created for the sole purpose of describing the care received by patients with cleft lip and/or palate. Until the new code is available, inpatient activity can be located in information systems by using the codes in Appendix 1. Outpatient activity, notably in orthodontics and speech therapy, and in paediatric dentistry and adult restorative care, both at the centres designated and in the networked hospitals, should also be included.

7. National Standards, Guidelines and Protocols

The criteria for commissioning cleft services are clearly set out by the Government in the Health Service Circular (HSC) 1998/238, Cleft Lip and Palate Services, Commissioning Specialised Services, which is based on the CSAG report.

Associated documentation includes:

- HSC 1998/198 set out the arrangements for commissioning specialised services in 1999-2000
- HSC 1998/087 announced the establishment of an implementation group to develop a commissioning framework for services for children born with a cleft lip and/or palate
- HSC 1998/002 covered the Clinical Standards Advisory Group (CSAG) report on cleft lip and/or palate together with the Government's response

Endorsement:

This Definition has been endorsed by:

- The British Association of Oral and Maxillofacial Surgeons

Section B

Note: The views expressed in the following section are those of the working group and do not necessarily represent opinion within the Department of Health or the NHS

8. Issues to be Noted Regarding this Service/Definition

The National Cleft Implementation Group is overseeing the process of designating all the specialist centres and the appointments of the new team members including the surgeons. These teams will be the centres of managed clinical networks that will include a number of local hospitals providing locally accessible care for cleft patients as fully integrated members of the network. The potential for using "tele-medicine" as part of the care of these patients is high.

It is important to analyse and cost the activity in the networked hospitals, especially orthodontics and speech therapy, but also psychology, restorative dentistry, medical genetic services etc, to ensure that the whole service is properly funded and seamless. It will be important to do this not only for the estimated 700 new cases / per annum but also for the approximately 10,000 patients under current care or review.

Appendix 1: Cleft Lip and Palate – attributable codes

Note: The codes listed need to be tested and amendments may be necessary.

ICD 10 codes

F80.1	Specific developmental disorders of speech and language
K00	Disorders of tooth development and eruption
K01	Embedded and impacted teeth
K02	Dental caries
K07	Dento-facial anomalies (including malocclusions)
Q35	CLEFT PALATE
Q35.1	Cleft hard palate, unilateral Cleft hard palate NOS
Q35.3	Cleft soft palate, unilateral Cleft soft palate NOS
Q35.5	Cleft hard palate with cleft soft palate, unilateral Cleft hard palate with soft palate NOS
Q35.6	Cleft palate, medial
Q35.7	Cleft uvula
Q36	CLEFT LIP
Q36.0	Cleft lip, bilateral
Q36.1	Cleft lip, medial
Q36.9	Cleft lip, unilateral, cleft lip NOS
Q37	CLEFT PALATE WITH CLEFT LIP
Q37.0	Cleft hard palate with cleft lip, bilateral
Q37.1	Cleft hard palate with cleft lip NOS, Cleft hard palate with cleft lip, unilateral
Q37.2	Cleft soft palate with cleft lip, bilateral
Q37.3	Cleft soft palate with cleft lip NOS, Cleft soft palate with cleft lip, unilateral
Q37.4	Cleft hard and soft palate with cleft lip, bilateral
Q37.5	cleft hard and soft palate with cleft NOS, Cleft hard and soft palate with cleft lip, unilateral,
Q37.8	Unspecified cleft palate with cleft lip, bilateral
Q37.9	Unspecified cleft palate with cleft lip, unilateral
Q38.8	Other congenital malformations of pharynx
Z46.4	Fitting and adjustment of orthodontic device
Z82.7	Family history of congenital malformations etc.
Z87.7	Personal history of congenital malformation deformities and chromosomal abnormalities

OPSC 4 Codes relating specifically to clefts	
F03	CORRECTION OF DEFORMITY OF LIP
F03.1	Primary closure of cleft lip
F03.2	Revision of primary closure of cleft lip
F29	CORRECTION OF DEFORMITY OF PALATE
F29.1	Primary repair of cleft palate
F29.2	Revision of repair of cleft palate
F29.8	Other specified
F29.9	Unspecified
F30	Secondary repair of palate
F32	Other operations on palate
Other OPCS 4 codes which relate to clefts if an appropriate ICD code is linked	
D14.2	Myringoplastey nec
D15	Drainage of middle ear
E02	Rhinoplasty Lengthening of columella
E03	Septum of nose
E21.1	Pharyngoplasty
E21.2	Pharyngoplasty using posterior pharyngeal flap
E21.3	Pharyngoplasty using lateral pharyngeal flap
E21.8	Other specified
E21.9	Unspecified
E25	Diagnostic endoscopic examination of the pharynx
F11	Preprosthetic oral surgery
F11.2	Augmentation of alveolar ridge
F11.5	Endosseous implant into the jaw
F14	Orthodontic operations
F14.5	Surgical exposure of tooth
V10	Maxillary Osteotomies
V13.2	Alveolar bone graft to the maxilla
V16	Mandibular Osteotomies Genioplasty
Y71.3	Revisional operations NOC