



## ***Report: Development of Oral & Maxillofacial Surgery Services in the Eastern Health Board Region Publishing Body***

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In February 1999 a report into the development of oral and maxillofacial surgery services in the Eastern Health Board region was published. The terms of reference included a review of current and anticipated future needs, existing services and resources, identify shortcomings, and indicate any additional resources required.

We include here those sections of the report covering cleft lip and palate surgery services, under the following headings;

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## 3.2 The Management of Cleft Lip and/or Palate

### 3.2.1 Clinical Standards Advisory Group Review

The Clinical Standards Advisory Group (CSAG) was established in 1991 as an independent source of expert advice to the United Kingdom (UK) Health Ministers and to the National Health Service (NHS) on standards of clinical care, for access to and availability of services to NHS patients. Its investigations are carried out by members of relevant Royal Colleges and the faculties and co-opted experts.

During the early 1990 concerns emerged about variations, which appeared to predate the NHS reforms, in the standards of treatment of patients who have cleft lip and/or palate malformations, both within the NHS and between the UK and Europe. In response, the overall management of cleft lip and palate was examined by the CSAG and the findings published in 1998 in their 15th report.

The treatment of cleft lip and/or palate malformations presents serious problems for health-care delivery systems throughout the world, because successful treatment outcomes depend on personnel from a number of disciplines working together for each patient from birth to maturity.

#### 3.2.1.1 Epidemiology

Cleft lip and/or palate are the most common congenital abnormalities in the cranio-facial region with an incidence of approximately one in 700 births. The incidence of cleft lip and/or malformations in the UK and in most parts of Europe is fairly uniform. Based on the mandatory Danish reporting system, approximately 60% of all facial clefts are male and 40% are female, with 34% with isolated cleft lip, 39% combined cleft lip and palate and 27% cleft palate.

Clefting is now recognised as often being associated with syndromes, of which over 300 have been described. Many patients suffer from impaired facial growth, dental anomalies, speech disorders, poor hearing and difficulties in psychological well-being and in social relationships.

#### 3.2.1.2 Diagnosis

Cleft lip and palate is most frequently diagnosed in the delivery room or shortly after birth. It can now be diagnosed ante-natally by ultrasound scanning, but this will only show severe clefts of the lip and not of the palate.

#### 3.2.1.3 Management

The treatment of this condition may require multiple surgical procedures from birth to maturity and frequent outpatient attendances. Successful management requires multidisciplinary and highly specialised treatment from birth to the late teens. Care starts with neonatal nursing and highly specialised treatment and primary surgery, usually followed by further surgery, speech and language therapy, orthodontics, preventative, and restorative dental care, otolaryngology for hearing problems, and genetic and psychological counselling.

#### 3.2.1.4 Surgery

Primary surgery is of crucial importance to the long term success of the restoration of facial appearance and function. At present the majority of children born with clefts of the lip and palate undergo primary repair by plastic surgeons.

Surgeons from three specialties (plastic, oral and maxillofacial) perform primary repairs in the UK. An audit in 1994 by the Royal College of Surgeons (RCS) indicated that at least 74 surgeons at 45 centres were involved. One-third of surgeons in England involved in cleft surgery performed fewer than five primary lip or palate repairs per year. Only six surgeons dealt with more than 30 cases each year.

Advances in anaesthesia and intensive care have permitted the development of neonatal lip surgery at some centres, with the aim of restoring near normal appearance at the earliest time. This advantage must be weighed against the greater difficulties and increased risks of surgery and anaesthesia in the neonate.

#### 3.2.1.5 Orthodontics

A survey by the RCS in the UK also showed that 94% of consultant orthodontists who treat cleft patients deal with, on average, fewer than six new patients per year.

The survey also revealed that 80% of multidisciplinary clinics fail to maintain standardised records. Good case-management of cleft lip and/or palate patients in the first 10 years of life is especially important to the developing occlusion, and there is considerable evidence that initial care has a profound influence on the complexity and duration of later treatment.

Orthodontists suggested that the best outcome for the child's occlusion is more likely if a consultant orthodontist attached to a cleft team has the main responsibility for orthodontic diagnosis, record collection and treatment planning with routine and regular review. As a result of this survey, a network of regional co-ordinators was established by the Consultant Orthodontic Group to monitor orthodontic referral and care patterns for cleft lip and/or palate patients throughout the UK.

#### 3.2.1.6 Speech and Language Therapy

The Royal College of Speech and Language Therapists recommended that all children who have a cleft palate should be under the care of a speech and language therapist who has special expertise in cleft palate/palatal dysfunction and is a member of the cleft team to advise on the relationship of structure and speech. There is no established standard definition of "specialist" but there is a special interest group affiliated to the Royal College.

#### 3.2.1.7 Outcomes

The primary aims in the management of cleft lip and/or palate malformation are to produce normal facial appearance and function, and normal feeding, hearing and speech. Where treatment is provided in an effective, expert and co-ordinated manner outcomes can be extremely good. The provision of ineffective services is more costly because surgical procedures have to be repeated, and ancillary care such as speech and language therapy and orthodontics is protracted.

Data in clinical outcomes of cleft care is limited. In a historical survey of patients operated on in the late 1970s, clinical outcomes in the UK compared unfavourably with those achieved in Norway, Denmark and the Netherlands. For example, almost 50% of patients in one study area in the UK were judged to have surgically induced growth disturbance of such severity that major maxillofacial surgery would be required in the late teens to correct maxillary retrusion, compared to 6% in Norway. In the Eurocleft cross centre speech study, similar results for speech outcome were found. Hence, outcome of care were found to be superior in some overseas centres when compared to the UK.

### 3.2.1.8 Review of Clinical Standards

In July 1995 UK Health Minister asked CSAG to review the health needs of this group and existing clinical standards, to compare how care currently provided compares with these standards, to compare the effectiveness of care provided by high and low volume provider units, as measured in terms of clinical outcomes and other patient-centred measures, to report on current levels of access to units expected to achieve good outcomes and to suggest changes to existing clinical standards if necessary.

### 3.2.1.9 Research Strategy

Rather than examining services for patients with the range of cleft conditions of the lip and palate the group decided to measure the outcomes of 5 and 12 year-old children with complete bony unilateral cleft lip and palate (UCLP). This group requires the skills of the complete multidisciplinary team, is a relatively numerous, well defined and homogenous sub-group and therefore provided a valid basis for comparison.

The research group visited the 57 centres identified at which cleft children were children. Written submissions and oral presentations were obtained to increase the understanding of optimum standards of care required. A parent survey was undertaken by the Cleft Lip and Palate Association (CLAPA). Seventeen cleft centres, both high and low volume units and operators, were visited by the Committee in a wide geographical area. Two overseas visits were made to Nantes in France and Oslo in Norway.

### 3.2.1.10 Key findings

In most of the literature, emphasis has been placed on the surgical timing and technique preferred for primary lip and palate closure. Unfortunately, this may have contributed to the view, shared by some parents and clinicians, that clefting is a cosmetic problem, similar to surgically closing a wound, rather than a long term multidisciplinary commitment to resolving a complex anatomical, physiological and functional problem over many stages. As shown in Box 3.8, the wide variation in practice in cleft care may reflect the absence of a strong evidence base and the influence of strongly held views of clinicians which are based on 'intuition' and personal preferences.

As shown in Box 3.9, multi-disciplinary, highly specialised services are required from the time of diagnosis continually until the patient is at least 20 years of age. A minimum of three operations are normally required for patients with unilateral cleft lip and palate: one to repair the lip, one to repair the palate and one to repair the alveolus. A co-ordinated team approach involving all relevant specialties is essential for the care of cleft lip and palate patients. The minimum standards suggested by the Royal College of Surgeons of England Cleft Steering Group provide guidelines on which future developments might be based.

Box 3.8 CSAG Report - results of literature review.

No national or internationally agreed treatment regimen for the presurgical orthopaedic /orthodontic management. Broad spectrum of early care has two extremes - interventionist (consider occasional/routine use of "correction plates") or non-interventionist (consider "feeding plates" or other devices usually unnecessary prior to surgery). No strong evidence that early orthopaedic intervention is better than non-interventionist approach.

Usual timing for repair of cleft lip is between 6-12 wks but some centres advocate repair in the first few days of life. Aims of surgery are to produce a lip of good length, which looks good, is not tight and functions as normally as possible. A good initial repair may reduce the need for later revision surgery.

Cleft palate usually repaired at 3-18 mths to get earliest normal palatal activity, assist speech development and reduce food regurgitation. Some suggest delaying repair to 5-8 yrs minimises facial growth disruption.

Palatal repair does not guarantee good function of the Eustachian tube and otitis media (glue ear) is not uncommon. Practice in relation to ventilation tube insertion varies.

50% require speech and language therapy to achieve good speech and language competence, mainly in the first 7 yrs.

Poor quality of much speech research with little use of randomised controlled trials fuels the controversies about speech outcome in cleft care.

Dental care of crucial importance to the success of later treatment as many advanced orthodontic and surgical procedures only offered if the teeth are in good condition with a high standard of oral hygiene.

Early orthodontics is minimised. Alveolar bone grafting at about 9 yrs has greatly improved orthodontic and dental outcomes. Definitive orthodontics is appropriate once most permanent dentition has erupted.

Appearance of anterior teeth may be improved by restorative techniques.

Secondary surgery may be required to improve appearance or speech (experienced team of crucial importance).

In early adulthood, orthognathic surgery may be required to correct significant facial deformity.

Psychological support should be an intrinsic part of the overall treatment plan.

Generally agreed that care should be delivered by a team of committed individuals working well together to agreed protocols which are regularly reviewed with all treatment decisions based on evidence. Regular audit of outcomes with inter-unit comparison is crucial, with sufficient patient numbers to allow for the many confounding factors

Box 3.9 CSAG Report - the provision of cleft care from birth to maturity.  
Summary of clinical care.

Birth-3 mths: Member of cleft team should assess the child within 24 hrs to explain the management programme and reassure parents; an identified member should be available to give ongoing support and counselling; provide specialist advice on feeding and nursing (also by phone); home visit; introduce the cleft team; lip repair by 3 mths.

4-18 mths: Closure of palate between 12-18 mths, with ENT assessment; dental health education.

18 mths-5 yrs: Regular OPD review, especially speech and language therapy and ENT assessment; routine dental care; surgical revision of lip and nose and velopharyngeal surgery if indicated; full set of records at 5 yrs.

6-10 yrs: Orthodontic assessment; alveolar bone graft between 9-12 yrs; address speech and hearing problems; routine dental care; full set of records at 10 yrs.

11-20 yrs: Continue orthodontic and paediatric/restorative dental care as indicated; assess and plan orthognathic and nasal revisional interventions; full set of records at 15 yrs at conclusion of treatment.

Ideally, same team should provide care throughout.

Minimum standards (based on the Royal College of Surgeons of England Cleft Steering Group)

Comprehensive service: Team should involve specialised counselling and nursing, plastic and OMFS, orthodontics, dental care, speech and language therapy, otology/audiology, clinical genetics, developmental paediatrics.

Co-ordination: All treatment undertaken from a regional centre with a paediatric setting where certain important tasks (registration of cases, record keeping, treatment planning and multidisciplinary audit) are also performed, and regular instructional courses for non-team members are held.

Counselling and nursing: (As described above).

Surgery: Primary surgical procedures should be performed only by experienced surgeons who have received extended training in cleft management and are frequently involved in this work (suggested minimum of 30 new cases per operator per year) using agreed guidelines. Decisions about secondary operations should only occur following joint discussion by appropriate team members.

Orthodontics: Should be performed only by experienced orthodontists who have received extended training in cleft management and are frequently involved in this work (suggested minimum of 30 new cases per operator per year). A primary duty of the orthodontist is to feed back to the surgeon information on patients who have surgically related growth disturbance so that inappropriate surgical practices may be altered.

Dental care: A named member of the team should ensure that dental health education, fluoride supplementation and dental attendance are maintained, and that priority access to care is provided.

Contd.:

3.9 contd.:

Speech and language therapy: A specialist speech and language therapist should carry out counselling and diagnostic assessments and ensure the provision of necessary therapy (suggested minimum of 30 new cases per operator per year). A primary duty of the therapist is to feed back to the surgeon information on patients who have surgically related speech impairment so that inappropriate surgical practices may be altered.

Otology/audiology: the otologist should co-ordinate ongoing audiometric evaluation and ensure any required procedures are carried out with other surgical episodes to minimise the need for multiple anaesthetics.

Genetics: All parents and patients should have access to genetic counselling with back-up of a genetics laboratory.

Psychology: All parents and patients should have access to suitably trained psychologists.

Developmental paediatrics: The team should liaise with the appropriate clinician.

Communication: The team should undergo regular consumer audit, wear name badges, provide families with written reports of multidisciplinary assessments etc.

Audit and research: The team should participate in multicentre audits and in national and international research.

Records: Team should maintain integrated and standardised records which are also suitable for audit and research.

Support groups: The team should liaise closely with local parent support groups and put parents in touch with the organisation at an early opportunity.

Relevant records for clinical management for the specialties of orthodontics, plastic surgery, oral and maxillofacial surgery, speech and language therapy, ENT surgery, patient satisfaction and psychological outcome are required. In any guidelines produced, there should be standards for record keeping that facilitate the performance of inter-centre audit, reduce the exposure of patients to unnecessary radiographs, and to avoid unnecessary duplication of records. The ages recommended (5, 10, 15 and 20 years) for the timing of records are coincident with those of the Craniofacial Anomalies Register (CARE).

The quality of outcomes for cleft repair can vary considerably and may be related to surgical techniques, the skill of individual surgeons or the treatment programme of the centre. The extended duration of the treatment and outcome measurement pose methodological difficulties. Retrospective study requires information on primary management practices over many years and presupposes the existence of clearly described treatment guidelines. In a European study of six centres, it was reported that the small number of surgeons at two centres with high personal caseloads achieved the best results.

To compare clinical outcomes in the UK with other European countries, centres in Oslo and Nantes were visited. The approach to cleft care, evaluation and inter-centre collaboration varied greatly. The main findings of the site visits and the opinions and experiences of parents were obtained using a postal questionnaire carried out by the Cleft Lip and Palate Association.

Information on the number of children born with a cleft lip and/or palate suggest that the incidence of cleft lip and/or palate malformations is about 1:700 live births. However, the voluntary reporting system to the Office of National Statistics may lead to an underestimate, and the reorganisation within the NHS may lead to variations in the level of completeness of recording. The lack of reporting of cleft births and the absence of a national database posed difficulties in undertaking meaningful audit of the outcome of cleft care. In Northern Ireland, considerable efforts have been made to create a reliable database. A process audit involving 5 and 12 year-old children was carried out. Fifty-seven units at which primary repair was performed in the UK were identified. Lack of standardisation of record keeping and data bases posed major difficulties in obtaining the required data. The results of the process audit are shown in Box 3.10. In comparison to the 'best practice' standards described above, major variations in the delivery of cleft care were describes.

Box 3.10 CSAG Report - visits abroad, client satisfaction, process and outcome indicators.

(A) Visit to the Oslo (Norway) and Nantes (France) cleft centres.

Both centres receive 50-80 new patients per year from large catchment areas.

At both centres, very few feeding plates are used and pre-surgical orthopaedic treatment is not practised.

Cleft management varies greatly between the centres.

In Oslo, guidelines are agreed and adhered to, a multidisciplinary approach is considered fundamental, the treatment plans are long term, documentation is meticulous, and follow-up is long term. An oral and maxillofacial surgeon is not a full-time member of the team, but is involved if orthognathic surgery is required. Impressions for study models, radiographs and photographs are taken. The centre is involved in inter-centre collaboration, research and audit within Europe and North America. Travel and accommodation are provided at no cost to parents. Service centralisation was considered efficient in terms of cost as well as quality of service.

In Nantes, written guidelines were not available, measurements of internationally recognised outcomes had not been used. Serial measurements had not been undertaken.

Photographs were used for assessment, pre-surgery model impressions were not taken. All surgical procedures on the same patient were carried out by the same surgeon. There was little formal contact with other cleft units in France.

(B) Views of parents on the treatment of their children (n=102).

Most parents were satisfied with most services.

Concern was expressed on the lack of information for parents, the lack of non-specialist staff knowledge in cleft care, especially for feeding and pain control, lack of continuity of care, some poor co-ordination of services, lack of communication within departments, and lack of privacy for significant discussions with staff.

One in three parents referred to the insensitive way they were informed about their child's cleft.

Two-thirds of mothers achieved successful feeding patterns, mainly by trial and error.

8 in 10 parents were satisfied with their stay in hospital at the time of their child's operation.

9 in 10 parents who responded were pleased with the first meeting with the surgeon and care the child received.

Contd.:



3.10 contd.:

(C) Process audit

Primary cleft repairs were undertaken by plastic, oral and maxillofacial, or paediatric surgeons.

Most cleft teams held one multidisciplinary satellite clinic in addition to those held at the team base.

While 70% of units were said to have active databases, only 50% were able to provide names of new referrals etc.

In addition to the minimum procedures (primary lip repair, palate repair and alveolar bone grafting) over 50% of 5 year olds and almost 80% of 12 year olds had undergone additional revision procedures, while 15% of 12 year olds had yet to undergo alveolar bone grafting. Mean number of general anaesthetics for 5 year olds was 2.6 (range 2-7), and 3.8 (range 1-9) for 12 year olds.

Approximately 65% of 5 and 12 year olds had received speech and language treatment.

Approximately 50% of both 5 and 12 year olds had neonatal appliances fitted.

Almost 90% of 12 year olds had received orthodontic treatment.

By 5 years, approximately 60% had at least one set of grommets inserted.

(D) Outcome audit

Almost 40% of 5 and 12 year olds had poor or very poor dental arch relationship.

70% of 12 year olds had a poor skeletal relationship.

Alveolar bone grafting (ideally at 9-11 years) had not been performed in 16% of 12 year olds - of those who had been grafted over 40% were unsuccessful.

By 12 years 20% had poor lip appearance and 42% had poor nasal appearance.

Speech was difficult to understand in almost 20% of 5 year olds and 4% of 12 year olds.

Hypernasality occurred or had occurred in almost 30% of 5 and 12 year olds.

Only 67% of the 5 year olds and 53% of the 12 year olds had a completely successful outcome of secondary velopharyngeal surgery.

Mild or moderate degree of hearing loss was detected in approximately 20% of 5 year olds and 15% of 12 year olds.

One-third of 12 year olds admitted to being teased about their cleft.

Parents and 12 year old patients were generally satisfied with the outcome of care provided.

There were significant residual treatment needs in surgery, speech therapy, hearing and dental care.

An outcome of cleft care was carried out using a range of accepted measurement techniques. The outcome of cleft care was far from optimal for a significant proportion of the patients.

In relation to an illustrative sample of 17 cleft units across the UK visited by the CSAG Committee, the assessment of purchasers covered strategic planning, service specification, specific contracts and quality. With one or two exceptions, the results were disappointing. The majority of scores were 0 (no action) or 1 (active discussion). Only four purchasers had carried out some form of population-based needs assessment. Quality of services, with few exceptions, were not monitored.

Assessment of providers was wider varying. Only two units achieved 'good' rating overall. In only two units was it considered that the range of experience and facilities equated to that of the best centres in Europe (suggesting that only 6-8 units throughout the UK were likely to rank as centres of excellence). There was very little systematic data gathering for the purposes of audit or research. In only one centre

had clinical outcome audit been conducted. The centre with the best score from the assessment by CSAG visitors also had the best outcomes in dental arch relationship and speech for both 5 and 12 year olds.

The effectiveness of care provided by high and low volume provider units and high and low volume operators (5 or more per year) was compared, although a thorough analysis of volume and outcome was not feasible due to the small number of high volume operators and poor overall results. Four outcome indicators in 12 year olds were used - dental arch relationship, skeletal relationship, and the success of alveolar bone grafting and speech. Most surgeons performed only one or two primary repairs on unilateral clefts per year. Primary surgery carried out four or more weeks after birth had a better outcome than if carried out in the neonatal period. Indicators for a good speech outcome were significantly associated with high volume operators. While the overall outcomes of alveolar bone grafting were poor, oral and maxillofacial surgeons tended to produce results superior to that of plastic surgeons.

Wide variations in the training and experience of cleft team members indicated the need to review cleft training needs. It was suggested that training should be based in high volume units.

#### 3.2.1.11 Implications of the CSAG findings

Good epidemiological information on the incidence and prevalence of disease is essential for the calculation of health needs. The voluntary and locally organised cleft databases in the UK would not appear to be satisfactory sources of such data, and the strategic planning of services on a population basis was considered underdeveloped. The ad-hoc development of cleft teams with variable multidisciplinary input who manage small numbers of cleft referrals was considered less than optimal.

The outcome studies indicate that the quality of cleft care in the UK to be far from optimal, with little evidence of any significant improvement over time. Cleft patients were found to have significant unmet needs and behind schedule for some essential procedures. The number of referrals to the numerous cleft teams was low, with the great majority of cleft surgeons operating on very few cases over time. The general absence of an intrinsic 'quality culture' or the systematic collection of standardised and detailed data suitable for audit, and the inability to perform intra and inter-unit evaluation and comparison, together with the wide variations in the timing and choice of procedures may have contributed to these findings.

The key to the provision of a quality service would appear to be the concentration of skills and resources through the centralisation of the major services in cleft 'hubs'. At the hub, truly multidisciplinary teams could provide continuity of care and expertise could remain honed by the treatment of higher volumes of patients according to standardised guidelines, and where there was ongoing monitoring to maintain and improve the quality of care. Provision of some services (such as orthodontics or speech and language therapy) in 'spokes' could improve access for patients.

The evidence-based refinement of best practice guidelines can only be achieved if research designs meet the rigours of contemporary health technology assessment. Given the relative infrequency of the condition, ongoing and detailed audit, with multi-centre collaboration offers the only path for the advancement of clinical knowledge in cleft care.

The surgery of clefts falls at the interface between specialties, particularly plastic surgery and oral-maxillofacial surgery. Claims are made by both specialties both to the privilege of operating on cleft

children and for greater expertise in the field. While competition can raise standards, it can, by fragmentation, lead to impaired training and low volume operating which may be against the interest of the child. Hence, the specialties involved should agree to delineate the areas of expertise, on training pathways, training locations, and numbers of trainees. The specialist training for cleft surgery in properly structured programmes, geared to match the availability of future posts, should be based in high volume centres with a clearly documented commitment to excellence. However, to designate a centre as a proper training unit, there would require to be sufficient referrals to support two major cleft surgeons and one trainee. Programmes for specialist training and accreditation for orthodontists and speech and language therapists in cleft care are required.

Cleft care should be provided by fully integrated multidisciplinary teams, with continuity of care given from birth to adulthood. Each team member should have the right degree of specialisation relevant to cleft care. Core team members are the cleft surgeon, orthodontist, and speech and language therapist, supported by a range of other professionals.

Expert, timely and comprehensive advice to parents and non-cleft team staff members, especially in the early period following the diagnosis, is essential. This role may be ideally undertaken by a specialist nurse. Co-ordinating all the activities to keep the team focused on the needs of the patient over the treatment period is the crucial role of the cleft team co-ordinator, and who should also be the facilitator of audit and research. It is important that the cleft team should work in partnership with voluntary cleft support groups.

The quality of surgery and the number of cases treated per year is of paramount importance, although high volume does not necessarily imply high quality. The variety of surgery required for cleft patients is wide.

Although the exact size of an effective cleft unit will remain a matter of debate, a unit with two cleft surgeons receiving approximately 80-100 new cleft cases (of all types) per year may provide the ideal environment for training, audit and research for all members of the multidisciplinary team. Furthermore, to ensure direct access to other related services, a cleft centre should be adjacent to other specialised paediatric centres. Accessibility for patients/families should also be included in the equation. In the UK, such considerations would conclude that the resources of the existing 57 cleft units should be concentrated into 8-15 centres.

A truly multidisciplinary centre should include the staff as shown in Box 3.11. There should be close liaison with a psychologist, geneticist, paediatric dentist and a restorative dentist, and good communication with non-team staff caring for cleft patients. Cleft teams should work to common guidelines. For any cleft unit, it was considered essential that outcomes should be externally assessed on an ongoing basis, using appropriate methodologies. To allow this to occur, detailed and standardised record keeping across all disciplines is imperative.

**Box 3.11** The multidisciplinary cleft team.  
 2 surgeons each undertaking at least 40-50 cases annually  
 1 surgeon undertaking bone grafts and orthognathic surgery  
 1-2 orthodontists and speech language therapists with a major commitment to cleft care  
 1 co-ordinating ENT surgeon/audiological physician  
 1-2 paediatricians with a major commitment to cleft care  
 1 co-ordinator/manager  
 1 specialist nurse

### 3.2.2 Cleft care: life after CSAG

In 1998, Williams and Markus responded to the CSAG report on cleft care in the UK. They agreed that there was absolutely no doubt that an untenable situation existed regarding cleft care in the UK, and in remedying the situation a pragmatic approach should be adopted.

The comparison with a centre in Oslo was commended, but it was felt that comparisons with other major centres should have been included. While Oslo is a centre of excellence, it was one of two centres serving a population of 5.5 million in a country that was culturally, morphologically, economically, and geographically quite different from the UK and with logistical problems that were not comparable to anything in the UK, therefore producing measurable outcomes that were considerably different from the UK experience.

The authors agreed that not only must the number of centres and surgeons be reduced, it must also be ensured that any centre providing cleft care meets strict criteria on which successful outcome could be judged on an ongoing basis. In the past a mushrooming of cleft centres has occurred with many surgeons often involved in treating an increasingly lower number of patients. In the last decade, the OMFS speciality had become involved as a direct response to perceived inadequacies of service provision by a local population.

If a centre is to do justice to children with this deformity, it must have a strict management protocol, a method for accurate data-collection and an ability to meet predetermined criteria for successful outcome as well as a commitment to participation in regular externally assessed audit.

They advocated that the highest quality of cleft care must be made available, which meets the requirements of population demands and expectations, is not unreasonably expensive, but at the same time, does not suffer the diseconomies of scale and does not duplicate or waste resources at district or supra-district level. A viable alternative would be for an amalgamation and defined association between geographically close units of demonstrably high levels of care, similar to the approach suggested in the Calman and Hine report for the organisation of cancer services.

The needs of trainees could be met by the establishment of formal rotations or links between centres both in the UK and overseas. Manpower predictions could be difficult, especially in small specialties. A large reduction in the number of trainees could occur but it should reflect the need for future cleft team members to be selected and trained in numbers that are related to the potential needs.

### 3.2.3 Scottish Cleft Lip and Palate Needs Assessment, 1998

The Scottish Needs Assessment Programme (SNAP) Oral Health Group commissioned a review of the Scottish cleft services in 1997. Representation on the SNAP group included members of the Scottish Cleft Lip and Palate (SCALP) group. SCALP is a forum in which most health professionals providing cleft services can meet on a regular basis. Preparation of the SNAP report coincided with the CSAG report.

Approximately 100 cleft lip/palate infants are born in Scotland each year. The Scottish population is characterised by a particular predilection to congenital malformations including orofacial clefting and has

the highest rate of isolated clefting of all the European Central Registry for Congenital Malformation and Twins (EUROCAT) centres.

Cleft care took place in six centres with considerable variations in the composition cleft teams and workloads of individual team members (e.g. surgical caseloads varied from 2 to 26 cases per year). There was a general lack of information on treatment outcomes and on how they compared to centres in the UK and elsewhere.

Core recommendations included a reduction of the number of cleft teams from six to two, where skill and resources would be concentrated into centres of excellence (see Box 3.12).

**Box 3.12 SNAP Report, 1998 - key recommendations**

Further research required to determine the possible protective effect of folic acid and other micronutrients in orofacial clefting and to identify the possible effect of other environmental and nutritional factors and how they interact with certain genes to predispose to orofacial clefting.

The national SCALP registry and database was strongly supported as a tool for monitoring activity, assessing outcomes and audit and should be properly resourced.

Research required into the health needs of adults who have partially treated or untreated orofacial clefts.

Need to ensure appropriate training from the cleft team for clinicians who make the initial diagnosis and other health professionals who are involved in care at an early stage.

Staff in maternity units should have rapid access to the cleft team so that a designated team member can visit without delay.

Cleft patients should have access to a full range of specialist care during the progress of their treatment.

Cleft centres without a comprehensive team (as defined by the Royal College of Surgeons criteria) should be able to demonstrate that satisfactory alternatives are in place.

Mechanisms should be in place to ensure effective communication between the cleft team and community services including the community paediatricians.

Written reports on individual cases should be provided to parents when requested and, possibly, where treatment is particularly complex. Sessions available for professionals working in cleft teams should be reviewed with a view to ensuring optimum input, including services delivered in the community.

Patient records should be collected systematically and according to SCALP criteria and minimum data set, with cleft teams co-ordinating the record keeping, assessment and treatment of adult cleft patients.

Audit and research should be conducted on a prospective multicentre basis to enable proper assessment of process and treatment outcome. Local Cleft Lip and Palate Association (CLAPA) groups should be involved in the production of regular consumer audit.

Effective psychological support for cleft patients and their families should be available and further research into this aspect of care is required.

Cleft teams should ensure that patients should have the benefit of a co-ordinated dental disease prevention programme from birth - possibly delivered by a dental hygienist in the cleft team.

There should be a staged move towards no more than 2 cleft teams in Scotland whilst maintaining a network of high skill levels locally. This would fit with the concept of a managed clinical network as envisaged in the Acute Services Review.

Many issues need to be addressed in implementing the recommendations. In particular, the recommendations on service reconfiguration have operational implications which need to be supported by an economic appraisal.

## Section 4.2 Cleft Services

Approximately 75 children with cleft lip and palate are born in Ireland each year, of whom about 55 (75%) are managed in the Eastern Health Board region. Professional staff involved in the care of cleft patients in the region have taken cognisance of the findings and recommendations of the recent CSAG report of cleft care in the United Kingdom ( see Section 3.2).

The National Cleft Lip and Palate Centre is located in the OMFS department in St. James's Hospital. The centre has overall responsibility for the tertiary management of all cleft lip and palate patients and for the joint orthodontic and orthognathic management of all patients referred for maxillofacial surgery.

The centre operates on a “hub and spoke” basis. The core activities of the centre are shown in Box 4.1. Patients from outside the Eastern Health Board region are assessed, monitored and reviewed in the Centre and the basic orthodontic work is performed in the local health centres of the health boards under the care of an orthodontist. Patients from the Eastern Health Board region are managed at the centre itself.

Sources of referral include paediatricians, plastic surgeons and orthodontists.

The Centre is serviced by a single consultant with no full time junior staff.

It was suggested that additional consultant or specialist orthodontic input with relevant support staff is required.

At present there are two separate cleft teams located in North and South Dublin, with the consultant orthodontist working with both teams.

Primary surgery is performed by two cleft (plastic) surgeons who have specifically trained in cleft surgery and craniofacial surgery. Primary surgery is carried out at Temple St. and Crumlin paediatric hospitals. Care is provided by a multidisciplinary team including an orthodontist, speech and language therapists, a paediatric dentist, otolaryngologists and OMF surgeons.

Multidisciplinary clinics are held in the two children's hospitals and St. James's Hospital where the orthodontic and maxillofacial departments are located and secondary surgery is undertaken by both plastic and OMF surgeons.

### Box 4.1 Activities of the National Cleft Lip and Palate Centre.

- New baby record collection (study models, advice for parents & occasionally pre-surgical orthopaedics)
- Taking of impressions of babies undergoing surgery at Temple St. and Crumlin Hospitals.
- Preparatory orthodontic treatment prior to alveolar bone grafting.
- Post graft orthodontic treatment in early teens.
- Joint orthodontic/surgical planning and presurgical orthodontic preparation for all clefts patients requiring corrective jaw surgery in late teens.
- Combined clinics with other specialties involved in the “Cleft Team”.
- Facial growth is monitored: at age 14 or 15 years a decision is made whether or not routine or more complex orthodontic procedures may be required prior to any orthodontic surgery at 18 years of age.
- An on-call service to the three Dublin maternity hospitals.
- Close working relationship with the OMFS unit which provides the necessary cleft surgical services such as bone grafting, removal of supernumerary and impacted teeth, exposure of canines and orthognathic / craniofacial surgery.
- Orthognathic and orthodontic preparation for craniofacial or difficult orthodontic cases which benefit from treatment within the Centre.

A rationalisation of the management of cleft patients in the region in a manner that provides the best possible service to patients is the agreed aim, together with the fullest use of best practice guidelines. The quality culture is very much part of the cleft management philosophy, and includes participation in the Eurocleft project and the Cleft Special Interest Group of the British Association of Plastic Surgeons.

As described above, the trauma and oncology services at two major acute general hospitals make heavy demands on the OMFS team. Significant delays in the provision of elective OMFS surgery continue to occur, including surgery required by cleft patients at the National OMFS Centre.

Ideally, minor oral surgical procedures required by cleft patients should be performed on a day care basis. However, without a dedicated day care facility many of these cases are being deferred due to the unavailability of beds or theatre space. Where fixed appliances remain in place for excessive periods, caries, gum disease and root shortening can result. It was suggested that some patients with private medical insurance could opt to avail of private care with a view to minimising the waiting period for OMFS surgery. Access to a dedicated day care OMFS service in the region was considered essential.

Prosthodontics is a highly specialised branch of dentistry which covers the spectrum of crown and bridgework, implantology, and the provision of obturators and prostheses for oncology patients who have undergone ablative surgery. . A typical cleft patient would have had multidisciplinary treatment over an 18 year period. Most cleft patients at this stage would have defects in the anterior part of the dental arch. All such patients require complex restorative procedures to finalise their treatment. These procedures can be the most important stage in finally overcoming the social stigma associated with cleft lip and palate in terms of the overall physical and psychological rehabilitation of these patients. Currently there is no structural restorative dental service available to these patients. The appointment of a consultant restorative dentist as a member of the Cleft Team was suggested.

At present, there is no national register of infants with a cleft lip or palate in Ireland. It was pointed out that a national register and database of cleft patients is essential for the purposes of clinical audit and strategic planning of services. An appointment of a dedicated Cleft Co-ordinator to compile and maintain the database, to liaise with other members of the cleft team, to co-ordinate multidisciplinary clinics and to advise parents on the different stages of treatment was suggested.

It was indicated that approximately 60% of cleft cases may require orthognathic surgery, although improvements in primary surgical techniques may eventually reduce this figure. An increased demand for OMFS and orthodontic services is envisaged in subsequent years as a result of the increasing number of orthognathic cases presenting for treatment to the National OMFS unit. This trend was considered to have manpower implications for both orthodontists and OMF surgeons.

Craniofacial surgery is required for patients with rare and complex congenital and acquired conditions due to trauma or neoplasia affecting the head, face and jaws. The majority of these patients are children who are usually less than two years old and have severe congenital abnormalities (for example craniosynostosis, Crouzon's syndrome and Apert's syndrome).

A craniofacial surgery service includes a full assessment (primarily imaging) and complex surgical management. It was suggested that a truly multidisciplinary team approach to the provision of craniofacial surgery in the Board's region was required. It was suggested that an OMF surgeon with expertise in orthognathic and reconstructive jaw surgery, working in a collaborative approach with other

surgical colleagues, can significantly contribute to the development of this service, especially with regard to the management of severe trauma in both children and adults.

Section 5.1.8 Cleft lip and palate

Also 5.2 Hospital case-mix in the EHB region (paragraph)

In the public sector, cleft surgery accounted for 1% of discharges in head and neck surgery nationally, and for 3% in the Eastern Health Board region. The majority of discharges were coded to the specialty of plastic surgery (Table 5.8). Management of cleft cases took place primarily in the Board's region with 150 (85%) discharges annually, 30 (15%) in the Southern Health Board region, with a small number being managed in the Western Health Board region (Table 5.9). The volume of cleft surgery carried out in the private sector was relatively small.

As shown in Figure 5.4, approximately 23 babies with cleft lip/palate would be expected to be born in the Dublin region annually, eight in the Cork region, four in the counties of Wicklow, Limerick and Galway, three in Donegal and two or less in all the other counties.

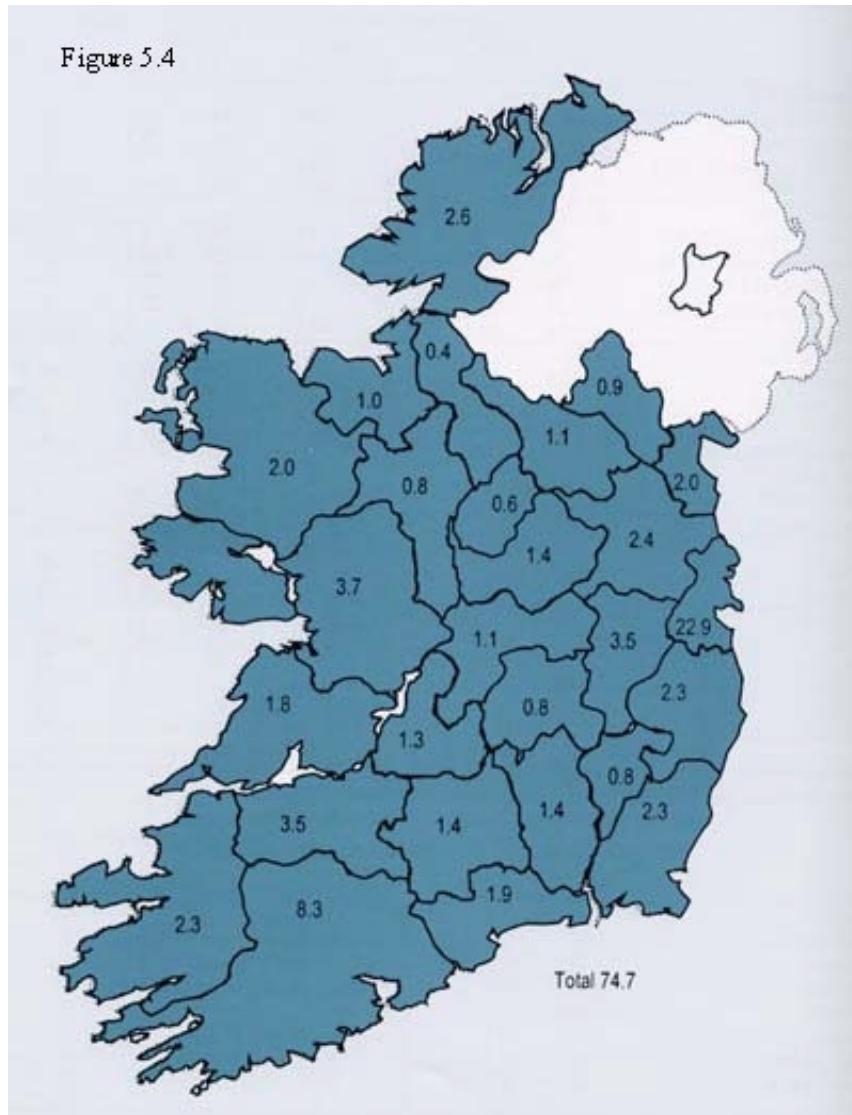




Table 5.8. Cleft lip and palate discharges by type, specialty, sex and age group in the public and private sectors (averaged over 1996-1997)

	Eastern Health Board				Ireland			
	HIPE		VHI		HIPE		VHI	
	n	%	n	%	n	%	n	%
<b>Diagnosis (ICD)</b>								
Cleft palate (749.0)	53	35.2	10	35.8	68	38.2	11	35.5
Cleft lip (749.1)	43	28.6	10	37.7	43	24.2	11	35.5
Cleft lip and palate (749.2)	54	36.2	7	26.4	67	37.6	9	29.0
Total	150	100.0	27	100.0	178	100.0	31	100.0
<b>Procedure (ICD)</b>								
	(n=						(n=	
	144)						171)	
Nose repairplastic (21.8)	14	9.7	2	7.5	14	8.2	2	8.1
Plastic repair mouth (27.5)	29	20.1	11	41.5	29	16.9	12	38.7
Palatoplasty (27.6)	38	26.4	2	7.5	52	30.3	4	11.3
Facial bone graft (76.91)	28	19.5	0	0	40	23.3	8	25.8
Other	35	24.3	12	43.5	36	21.3	5	16.1
<b>Admission type</b>								
Inpatient	138	91.7	24	90.6	166	93.0	29	91.9
Day case	12	8.3	3	9.4	12	7.0	2	8.1
<b>Specialty</b>								
Oral-maxillofacial surgery	2	1.7	5	20.8	3	1.4	7	21.0
Oral surgery	-	-	0	0	-	-	0	0
Dental surgery	2	1.3	0	0	15	8.7	0	0
Plastic surgery	146	97.0	12	79.2	160	89.9	24	79.0
<b>Sex</b>								
Male	86	57.1	16	58.5	105	58.7	18	56.5
Female	64	42.9	11	41.5	73	41.3	13	43.5
<b>Age group</b>								
0-9	64	42.6	10	37.7	76	42.7	12	37.8
10-19	72	47.8	12	45.3	86	48.0	13	41.9
20-29	12	8.3	2	5.7	13	7.6	2	6.5
30+	2	1.3	3	11.3	3	1.7	4	13.8

Table 5.9. Source of referral and location of hospital by health board region for management of cleft lip and palate (averaged over 1996-1997). Rate = number discharges/1000,000 total population.

Region	Source of referral				Location of hospital			
	HIPE		VHI		HIPE		VHI	
	n	%	n	%	n	%	n	%
Eastern	49	27.5	12	38.7	150	84.6	27	85.5
South Eastern	32	17.7	3	9.7	0	0	0	0
Southern	19	11.0	3	11.3	27	14.9	3	12.9
Mid-West	18	10.1	3	9.7	0	0	0	0
Western	13	7.3	2	6.5	1	0.5	1	1.6
Midland	18	10.4	4	12.9	0	0	0	0
North Western	9	5.1	1	1.6	0	0	0	0
North Eastern	20	11.0	3	9.7	0	0	0	0
Other	-	-	0	0	0	0	0	0
<b>Total</b>	<b>178</b>	<b>100.0</b>	<b>31</b>	<b>100.0</b>	<b>178</b>	<b>100.0</b>	<b>31</b>	<b>100.0</b>

## 5.2 Hospital case-mix in the EHB region

The largest number of discharges for cleft lip and palate were St. James's Hospital (70 discharges per year), Crumlin Hospital (44 discharges) and Temple St. Hospital (27 discharges). Approximately 70% of the cleft discharges from St. James's and Crumlin Hospitals were referred from outside the Board's region, compared to less than 50% from Temple St. Hospital.

## Section 7.4 Development of cleft care services

Given an incidence of cleft lip and palate of one in 700 births (see Section 3.2.3), approximately 75 cases occur in Ireland annually. Approximately 55 (75%) of these patients are managed in the Eastern Health Board region. Primary cleft care is provided by two plastic surgeons at two paediatric hospital locations, with secondary surgery being carried out by two plastic and two OMF surgeons providing largely independent services in North and South Dublin. From a regional perspective the service lacks an integrated and co-ordinated approach and the management of care has not been subject to ongoing quality review.

Although St. James's Hospital is designated as the National OMFS and Cleft Centre, the involvement of the Centre in cleft care is limited, and delays in the provision of OMFS care at the Centre to cleft patients can sometimes occur. Similar delays were not reported at the paediatric hospitals where the primary surgery is carried out.

The CSAG review of cleft care in the UK (Section 3) was very critical of the overall quality of service when the outcome of patient care was studied. The reasons included the following:

- Fragmentation of the service.
- Care provided in low volume units or by low volume operators.
- Absence of the support of a full multidisciplinary team.

It is considered essential that due cognisance be given to the issues raised in the CSAG report as they relate to cleft care in this country (see Section 3).

Based on the key conclusion of the CSAG report, the management of cleft patients should be organised as follows:

- Care should be centralised in a ‘cleft hub’ where highly skilled staff and resources can be concentrated.
- Some services available in ‘spokes’ to increase accessibility.
- Cleft care should be provided by two surgeons, each undertaking approximately 40-50 cases annually, with one surgeon undertaking bone grafting and orthognathic surgery.
- Support should be provided by a truly multidisciplinary team to provide continuity of care from birth to adulthood.
- Cleft care should be provided in line with agreed best practice guidelines.
- The cleft hub should participate in ongoing quality review with multi-centre collaboration.
- The presence of a Cleft Co-ordinator in the team is an essential component in the provision of an integrated cleft service.

In light of the CSAG report, professionals in the Board’s region are already taking steps to implement key recommendations as were described in the report (see Section 4.2). Such progress augers well for the provision of a quality cleft service in the region.

The CSAG report described the complex relationship between the specialties of plastic and OMFS surgery in the management of cleft patients. To resolve the matter, it was recommended that the respective professional bodies should review the cleft service and agree to delineate the areas of expertise so as to optimise the cleft service in the region and clarify training needs. These recommendations are considered to be equally applicable to the cleft services in the Board’s region.

The general underdevelopment of a ‘quality culture’ with systematic collection of standardised and detailed data appropriate for cleft quality review in the Board’s region, poses a barrier to the achievement and the demonstration of a service of optimum quality. However, this issue is already under review within the region. To allow for the monitoring of the timeliness and quality of care provided to cleft patients, a computerised national cleft database, compatible with international standards, is required.

Consideration should be given to developing a system under the auspices of the relevant specialty group whereby surgeons and other members of the cleft team can travel to other centres (whether in this country or abroad) to ensure that their skills remain at the highest level of proficiency through managing a sufficient volume of patients on an on-going basis. Such an arrangement would demonstrate the commitment to delivering a quality service, while maintaining the expertise in the cleft team through the relevant specialty.

#### 7.4.1 Recommendations

It is recommended that:

1. The core cleft services in the Health Board's region should be organised into a highly integrated regional team (hub) based in a paediatric environment with two surgeons each undertaking approximately 45 cases (or approximately 50% of all cases) annually, and with bone grafting and orthognathic surgery each undertaken by one surgeon (or alternatively by two surgeons each undertaking approximately 50% of these procedures) as justified by the volume of cases and supported by quality indicators.
2. The plastic and OMFS consultants in the region, together with their respective professional bodies, should agree to a methodology for integrating their combined expertise so as to provide a fully integrated quality cleft service for the region.
3. Cleft care should be provided by a fully integrated and truly multidisciplinary regional team with each member having a major commitment to cleft care (including a cleft co-ordinator, orthodontics, prosthodontics, speech and language therapy, ENT surgery/audiology, paediatrics) with close liaison with a psychologist, geneticist, paediatric dentist, and good communication with non-team staff caring for cleft patients and voluntary cleft support groups, so as to provide continuity of care from birth to adulthood.
4. A regional Cleft Co-ordinator should be appointed to the National Cleft Lip and Palate Centre as an immediate priority, with a brief that should expand to include a national dimension.
5. Some aspects of cleft care (such as orthodontics and speech and language therapy) could be provided in 'spokes' to improve access for patients.
6. Cleft care should be provided in line with agreed best practice guidelines.
7. A retrospective quality review of cleft care in the Eastern Health Board region should be carried out to provide a foundation for ongoing quality review and to assist in the planning and delivery of a quality cleft service.
8. The cleft team should participate in ongoing quality review with multi-centre and international collaboration.
9. A computerised cleft database compatible with international requirements should be introduced and integrated on a national basis.
10. Where indicated, a mechanism should be developed to ensure that the skill base of the cleft team is maintained at the highest level e.g. through attachments of cleft team members to other centres (whether in this country or abroad).
11. Services to cleft patients provided by all specialties should be co-ordinated in the Eastern Health Board region and nationally.
12. To ensure universal access to quality services, the provision of cleft care on a national basis should be reviewed in light of the developments in the Board's region.