

Minimum standards for the management of cleft lip and palate: efforts to close the audit loop

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Key words: Cleft lip and palate; Clinical standards; Low-volume operators; Audit

Intercentre audit in the late 1980s revealed poorer outcomes for facial growth for British patients with cleft lip and palate than equivalent patients in northern Europe. A subsequent survey of the surgical practices in England and Wales, under the auspices of the Surgical Audit and Epidemiology Unit, revealed the widespread involvement of low-volume operators in cleft care, a tendency for low-volume operators to have an incomplete network of associated professionals, and non-standardised record keeping protocols. Recommendations for minimum standards of care for children born with cleft lip and palate were produced by a multidisciplinary steering group. A further investigation is planned to determine their validity and to provide a baseline for future audit cycles.

Clefts of the lip and/or palate occur with a frequency of around 1 per 700 births and may significantly influence appearance, speech, hearing and psychological well-being. Approximately 750 new cases are born in England and Wales each year. Rehabilitation requires multidisciplinary care from birth until maturity. Outcome can be remarkably good when this is provided

in a skilled and coordinated manner, and remarkably bad when it is not.

Initiation of the present audit cycle

In 1989 a comparative clinical audit was carried out in which the outcomes of cleft surgery in the North West of England and in London were compared with those in Denmark (Copenhagen), the Netherlands (Amsterdam), Norway (Oslo) and Sweden (Stockholm) (1, 2). The audit was conducted on the records of consecutively treated 10-year-old children with repaired complete unilateral cleft lip and palate whose primary surgery had been performed in the late 1970s. Except for speech, outcomes were evaluated by panels blinded to the origin of cases. In summary, the English cases compared unfavourably. Based on dental arch relationships, almost half of the cases from the North West of England were likely to need orthognathic surgery. This compared badly with cases from Denmark and Norway where only 6% of cases were thought to require osteotomy.

Evaluation of protocols revealed minor differences in operative choices but major differences in surgeon case load, and the concentration of ancillary expertise into a small team, in one case a single national team (3). Furthermore, the Danish and Norwegian children had been exposed to less expensive and burdensome protocols with fewer surgical episodes. Subsequent surveys of cleft centres in the United Kingdom (4,5) suggested that the diversification of surgical care

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revealed in the international study was representative of the national picture.

Supplementary work in the Surgical Audit Unit

Given the above findings, the establishment of a multi-disciplinary steering group on cleft lip and palate was a natural step when the College audit activities became established in 1990–1991. The group completed four tasks:

- 1 A national survey of surgical activity, team structure and record keeping;
- 2 Preparation of, with consumer involvement, a set of Recommendations for Minimum Standards of Care (Appendix I);
- 3 Definition of minimum data sets for audit purposes, including the development of consumer satisfaction questionnaires; and
- 4 Preparation of an information booklet for parents.

Challenges to the process of change

The Steering Group's survey highlighted the widespread involvement of low-volume operators in cleft care, a tendency for low-volume operators to have an incomplete network of associated professionals, and non-standardised record keeping protocols (6). For example, in 1992 over two-thirds of cleft surgeons undertook less than 10 lip repairs. This figure is also true for palate repairs. Though changes are already occurring in parts of the country within some surgical specialties, some occasional operators may, however, be disinclined to forfeit an interest in this work. Furthermore, there is potential for a turf war between the four surgical disciplines (plastic, oral and maxillofacial, ENT and paediatric) who presently undertake cleft repairs. Thus, the most challenging element of the Steering Group's recommendations is the proposal for the key participants in care to treat not fewer than 30 new cases per year. This figure was argued on four grounds; proficiency, infrastructure, audit and research.

Proficiency

Complete clefts of the lip and palate, especially those occurring bilaterally, represent the greatest technical challenge for the surgeon and are associated with the poorest outcomes. A surgeon who receives 40 new cases per year will, on average, repair a complete unilateral cleft once per month and a complete bilateral cleft every 3 months (Table I). However, with five referrals per year, the mean interval between these operations would increase to 8 months and 2 years, respectively. Threshold numbers for competence can never be calculated precisely, but for other forms of surgery recommended minimum numbers have been estimated (7,8).

Table I. Operating frequency for unilateral and bilateral cleft lip and palate cases for cleft surgeons accepting different rates of new referrals annually (based on data from the Oslo Cleft Lip and Palate Archive (13))

<i>Total referrals annually</i>	<i>CUCLP annually</i>	<i>CUCLP mean interval (months)</i>	<i>CBCLP annually</i>	<i>CBCLP mean interval (months)</i>
40	12	1	4	3
30	9	1.5	3	4
20	6	2	2	6
10	3	4	1	12
5	1.5	8	0.5	24

CUCLP Annually = The number of cases of unilateral cleft lip and palate referred per surgeon

CUCLP Mean Interval = The interval between referrals of unilateral cleft lip and palate cases

CBCLP Annually = The number of cases of bilateral cleft lip and palate referred per surgeon

CBCLP Mean Interval = The interval between referrals of bilateral cleft lip and palate cases

Regionalisation of services would certainly make the attainment of a case load minimum of 30 referrals for primary surgery and bone grafting (approximately 50% of cases) entirely feasible. Surgeons undertaking primary cleft repairs are committed to the long-term surgical care of these children and a sufficiently high case load of primary repairs is necessary to generate adequate numbers for maintaining proficiency for secondary procedures.

Audit

Cases of unilateral clefting are the only homogeneous subgroup upon which meaningful audit can be conducted, preferably at age 10 years and beyond (3). Measures of dental arch relationship provide one sensitive indication of substandard practice (9) and detection of a mean difference of 0.5 scale points (ie the difference observable between good and moderate outcome, or moderate and poor outcome in the Eurocleft Study), requires 42 cases (1). Even if differences were detectable at age 5, the point at which the first audit could be performed for a surgeon who receives 40 new cases per year would be reached 8.5 years after appointment. For a surgeon receiving five new referrals per year, 33 years would have to pass—more than the length of a consultant's career. At present the majority of cleft centres in England and Wales would not be able to critically audit current practices.

Infrastructure

The Recommendations for Minimum Standards for Cleft Care includes recommendations for surgical and other facilities that cleft patients should have access to, including the provision of psychological support. All

major clinical decisions, for example the need for alveolar bone grafting or the surgical correction of velopharyngeal insufficiency, should be made jointly by the relevant clinicians.

Research

The widespread call for evidence-based care emphasised in the recent NHS Research and Development Initiative (10) presents a challenge to cleft teams. Present reviews of the evidence for selecting treatment protocols (11,12) reveals virtually no dependable data at controlled trials level. Regionalisation of services is a prerequisite for multicentred clinical trials, given the low occurrence for clefts.

Future plans to maintain momentum

While the concentration of cleft care in centres with high-volume operators creates an optimum environment for good practice (outcomes can be measured at statistically meaningful levels), this alone provides no guarantees. The burden of proof, it seems, will be on the proponents for change. Consequently, the Steering Group's next cycle of audit will include comparisons of care between centralised and decentralised arrangements and between high- and low-volume operators. This national study, commissioned by the Clinical Standards Advisory Group, will include children who received primary surgical care at the start of the present decade, so establishing a baseline against which progress in achieving improved outcomes can be determined by future audit.

It is also recognised that centralised, high-volume centres may, over time, become complacent and inward-looking. Thus, the Steering Group will develop a system of peer review among regional centres. Since it is not assumed that any surgical discipline has a natural right to perform primary surgery, maxillary osteotomy or alveolar bone grafting, the Steering Group will also focus future efforts in establishing training pathways for future aspirants to cleft surgery and other clinical disciplines such as orthodontics.

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Received 27 October 1995

Appendix I

Recommendations for Minimum Standards for the Care of Children with Clefts of the Lip and/or Palate

**ROYAL COLLEGE OF SURGEONS OF ENGLAND
SURGICAL AUDIT UNIT**

CLEFT LIP AND PALATE STEERING GROUP

MINIMUM STANDARDS FOR THE CARE OF CHILDREN WITH CLEFTS OF THE LIP AND/OR PALATE

Introduction

1. About 750 new patients with cleft of lip and/or palate are born annually in England and Wales.
2. Cleft of lip and/or palate can result in a wide variety of disabilities, including difficulties in breathing and feeding after birth, poor learning, poor speech, dental anomalies, impaired facial growth and problems with psychological wellbeing and social relations.
3. A cleft may sometimes be one feature of a syndrome or genetically determined disorders affecting more than one system in the body.
4. In many patients, treatment and clinical surveillance needs to continue throughout childhood and adolescence.
5. The cleft itself, and its functional and developmental consequences require treatment by members of several medical specialties and allied professions.

The Royal College of Surgeons Steering Group on Cleft Lip and Palate therefore recommends the following as minimum standards:

1. **Comprehensive Service** - Children with clefts require care from a Team - including specialised counselling, specialised nursing, plastic surgery, maxillo-facial surgery, orthodontics, dental care, speech and language therapy, otology/audiology, clinical genetics, developmental paediatrics. The Steering Group stresses the importance of team work between these specialties.
2. **Coordination** of all treatment by the Team from a single regional centre where registration of cases, record keeping, treatment planning and multi-disciplinary audit are undertaken. The regional centre should have a paediatric setting. The Team should hold regular instructional courses for non-team members e.g. health visitors, midwives, paediatricians, speech and language therapists.
3. **Neonatal Counselling** - An experienced professional under the direction of the Team should assess the child on the first day of life and provide parents with reassurance and information on the future programme of management. Similar antenatal counselling should be provided in the event of foetal diagnosis. An identified member of the Team should be available to give further information support and counselling as necessary.
4. **Neonatal Nursing** - A Nurse Specialist in the Team should give early instruction to the mother on feeding and nursing. Continuing care in the community by the Specialised Nurse should include the availability of advice by telephone and home visit. Separation of mother and child should be kept to an absolute minimum.
5. **Surgery** - Primary lip and palate repair and revision, pharyngoplasty, alveolar bone grafting, surgical exposure of teeth, and jaw osteotomies should be performed only by experienced surgeons with extended cleft lip and palate training and a frequent involvement in this work. The Steering Group recommends 30 new cases per operator per year as a minimum involvement for primary surgery. Further rationalisation will be desirable to ensure appropriate concentration of skills for secondary procedures such as alveolar bone grafting, surgical correction of VPI and maxillary osteotomy. Annual experience should not fall below 20 cases for alveolar bone grafting and for VPI surgery and maxillary osteotomy 15 cases, possibly including some non-cleft subjects, is the recommended minimum.

Surgical technique, timing and sequencing should conform to well-tried protocols unless new alternative procedures are introduced as part of an ethically approved surgical trial. Decisions to perform secondary operations should be reached in a multi-disciplinary forum. Bone grafting and osteotomies should not be performed before joint surgical/orthodontic discussion, nor pharyngoplasty before joint surgical/speech and language evaluation including nasendoscopy/videofluoroscopy. Surgical records should include photographs and detailed anatomical description of the pre-operated cleft, preferably augmented by dento-facial casts obtained at the time of primary surgery.

6. **Orthodontics** - Orthodontic treatment should be performed only by experienced Orthodontists with extended cleft lip and palate training and frequent involvement in this work. The Steering Group recommends 30 new cases per orthodontist per year as a minimum involvement. Treatment should be concentrated into a pre-bone graft phase in the mixed dentition (only if necessary), and permanent dentition arch alignment. Additional early treatment should be carried out only when essential for facilitating surgery. It is a primary duty of the orthodontist to feed back to the surgeon information on patients with surgically related growth disturbance so that inappropriate surgical practices may be remedied. Orthodontic audit records should not duplicate those obtained for clinical care.
7. **Dental Care** - Dental health education should be commenced by a named member of the Team. The Cleft Team should ensure that dental health education, fluoride supplementation and dental attendance is maintained throughout childhood. Children with repaired clefts should have priority access to a Consultant in Paediatric Dentistry where necessary. Adolescents requiring advanced restorative care including crown and bridgework, dental implants and obturators should have priority access to a Consultant in Restorative Dentistry. If this Consultant is not a Team member, access should be available for treatment planning at an early enough stage to be able to influence outcome.
8. **Speech and Language Therapy** - A Specialist Speech and Language Therapist should carry out early counselling and diagnostic assessments, and provide necessary therapy directly or through liaison with a local Therapist. The Standing Committee recommends 30 new cases per year as a minimal involvement for the team therapist. It is a primary duty of this individual to feed back to the surgeon information on patients with surgically related speech impairment so that inappropriate surgical practices may be remedied, and to report outcome following speech related surgical or prosthetic procedures.
9. **Otology/Audiology** - The Cleft Team should include an Otologist responsible for the coordination of regular audiometric evaluation. Wherever possible placement of grommets and other procedures should be coordinated with other surgical episodes to minimise the need for multiple anaesthetics.
10. **Clinical Genetics** - The Team should include a Geneticist/Dysmorphologist with access to a Genetics Laboratory. Patients with any possibility of syndromic association must have timely appraisal. All parents and patients should be offered the opportunity of access to genetic counselling.
11. **Psychological Counselling** - The Team should include a Psychologist or a professional in the Team suitably trained in counselling skills. All patients and parents should be assessed at times of transition and have access to counselling where indicated.
12. **Paediatric Developmental Medicine** - For each patient, the Team should provide information to the Consultant Community Paediatrician of the child's district of residence. Any suspicion of developmental or growth delay should be notified early to allow appropriate investigations to be undertaken.
13. **Audit and Research** - The Cleft Team should subject itself to regular consumer audit, wear name badges, provide families with written reports of multi-disciplinary assessment, and take other measures to adhere to the "Patients' Charter". The Team should participate in multi-centre audits and in national and international research.
14. **Parent Support Group** - The Team should maintain good relations with the local Parent Support Group and put parents in touch with this organisation at an early opportunity.