# Measuring Outcomes in Cleft Lip and Palate Treatment

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**KEYWORDS**

• Cleft lip • Cleft palate • Cleft surgery • Evidence base • Outcomes measurement • Outcome data

**KEY POINTS**

- Outcome measurement is essential to document quality and to facilitate improvement.
- Cleft surgeons should choose outcome measures that are valid, reliable, practical to implement, and broadly adopted.
- New measures are under development, and existing measures will continue to evolve in all aspects of cleft care. Measures should focus on outcomes most relevant to patients and include input from providers and health care purchasers.

*If you can not measure it, you can not improve it.*

*—Lord Kelvin*

## WHY MEASURE OUTCOMES?

Once the sole purview of clinical and health-services research, *outcome assessment* has become a core component of clinical practice. Generally speaking, outcome measurement may be used for accountability, quality improvement, and health-system design (eg, resource allocation, purchasing decisions, and policy development) (**Box 1**). *Accountability* refers to the demonstration that a particular surgeon's or team's results are within accepted standards. *Quality improvement* is a process of combining domain expertise with knowledge of systems, variation, and psychology to effect meaningful improvement. Originally developed in the manufacturing and service industries, quality improvement is now widely applied to health care delivery systems.[1]

It is intuitive that regularly reviewing one's outcomes is useful and instructive for improving patient care. For some time, the American Board of Medical Specialties' Maintenance of Certification process has required demonstration of quality-improvement practices in an individual's clinical practice.[2] However, it is important to underscore that routine collection and reporting of clinical outcomes are increasingly emphasized in the public sphere. There is a growing movement to tie reimbursement to outcomes, and organizations such as the Leapfrog group and the Agency for Healthcare Research and Quality have advocated public reporting of these data. The American College of Surgeons' National Surgical Quality Improvement Program was conceived as a volunteer program to help hospitals monitor specific clinical outcomes (particularly the so-called never events) that are already being tied to reimbursement. Recently, the Centers for Medicare and Medicaid Services announced its intention to require a proven level of performance to be eligible for payment.[3] In the future, payers will be increasingly

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**Box 1**
**Applications of outcome measurement in health care**

- Accountability
  - Accreditation
  - Quality assurance
  - Public reporting
- Quality improvement
  - Improve clinical care
  - Research
  - Board certification
- Health-system design
  - Resource allocation
  - Value-based purchasing
  - Policy development

sensitive to objective data on outcomes when deciding where care should be directed and when negotiating fees.

## OUTCOMES ASSESSMENT AND QUALITY IMPROVEMENT REQUIREMENTS IN CLEFT CARE

Specific to cleft care, the American Cleft Palate Association (ACPA) established minimum requirements for accreditation.[4] These requirements include that "the Team has mechanisms to monitor its short-term and long-term treatment outcomes" by documenting "its treatment outcomes, including base-line performance and changes over time" and conducting "periodic retrospective or prospective studies to evaluate treatment outcomes."[4] Similar requirements exist in the United Kingdom.[5] To date, the ACPA offers no specific recommendations regarding *which* outcomes should be assessed, nor *how* these data are to be collected, analyzed, and interpreted. Consequently, the onus is on each cleft team to conceive and develop its own system of outcomes assessment, monitoring, and quality assurance.

## OUTCOMES ASSESSMENT IN THE LITERATURE

Cleft lip and palate treatment has been the subject of innumerable studies in the surgical, medical, and allied health literature. Most of the evidence base is level IV and level V evidence—that is, most data derive from case series, experiential reports, and expert opinion. Few papers have been subjected to the rigors of contemporary clinical trial design or systematic review and metanalysis.

Some outcome data do exist. Perhaps the most complete early report was a 1984 study by Bardach and colleagues[6] describing the long-term esthetic, dental, facial growth, and speech outcomes of 45 patients with unilateral cleft lip and palate. In 1987, the Third International Symposium on Early Treatment of Cleft Lip and Palate initiated a collaborative investigation, in which cephalograms and treatment records from 15 international centers were reviewed to evaluate the effects of individual treatment protocols on facial growth.[7] Attendees from the symposium later developed novel measures for objective comparison of treatment outcomes, such as the Great Ormond Street, London, and Oslo (GOSLON) yardstick for assessing dental arch alignment[8] and a validated instrument for rating nasolabial esthetic results.[9]

In the late 1980s and early 1990s, Eurocleft was founded to study treatment outcomes from 6 European cleft centers.[10–14] The Eurocleft study included Caucasian children with nonsyndromic, complete unilateral cleft lip and palate. Initial outcomes of interest were dental arch alignment, midfacial growth and facial profile, and nasolabial esthetics. Follow-up studies also considered orthognathic outcomes at skeletal maturity, speech, burden of care, and patient satisfaction.[15–20] Results are summarized in **Table 1** but highlighted much disparity in protocols and outcomes between centers. Results of the Eurocleft studies kindled a desire for quality improvement in the cleft-care community at large. With funding from the European Union, a registry of European cleft teams was created. It issued a policy statement that delineated practice guidelines for the treatment of children with clefts and that recommended minimum recordkeeping standards for teams. EUROCRAN was conceived to help organize clinical and genetic research and to foster collaboration.[21,22] Many of the Eurocleft researchers also participated in the World Health Organization's (WHO) development of an international strategy to craniofacial research, bringing Eurocleft's quality-improvement aims to a worldwide audience.[23]

In response to poor outcomes obtained by British centers participating in the Eurocleft studies, the Clinical Standards Advisory Group (CSAG) performed an audit of all 5- and 12-year-old children in the United Kingdom with unilateral cleft lip and palate. Results were poor across all measures (see **Table 1**).[24–27] CSAG proposed specific methods for restructuring the cleft-care-delivery process and created specific service specifications for providers. Based on