

Cleft Lip & Palate PSP completed 2012															
Indicative Uncertainty		Why is there uncertainty?	What is person's age? 1	What is person's age? 2	Which types of treatments? 1	Which types of treatments? 2	Which types of treatments? 3	Which types of treatments? 4	Which types of treatments? 5	Original uncertainty	References to reliable up-to-date systematic reviews	Systematic reviews in preparation	Systematic reviews that need updating or extending	Ongoing controlled trials	Which outcomes?
Can stem cells be used to improve cleft palate repair (both primary and secondary)?	Uncertainties identified from patients' questions	No relevant systematic reviews identified	Any age		Vaccines and biologicals					Cleft Lip and or Palate Ranking 6				Cell Therapy for Craniofacial Bone Defects NCT01616953	Incidence of cleft lip and or palate; adverse effects or complications; quality of life; and cost
For infants born with cleft lip/palate what is the most effective care pathway for promoting mother/infant bonding?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Child / Adolescent		Service delivery										Bonding
How can reflux be treated best in babies with cleft lip/palate?	Uncertainties identified from carers' questions	No relevant systematic reviews identified	Child / Adolescent		Drug	Diet	Surgery								Incidence of reflux; adverse effects or complications; quality of life; and cost
How can we improve the diagnosis of cleft palate?	Uncertainties identified from clinicians' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Child / Adolescent		Diagnostic						Maarse W, Berg? S.J, Pistorius L, van Barneveld T, Kon M, Bruegem C, Mink van der Molen AB. Diagnostic accuracy of transabdominal ultrasound in detecting prenatal cleft lip and palate: a systematic review. <i>Ultrasound in obstetrics and gynecology: the official journal of the International Society of Ultrasound in Obstetrics and Gynecology</i> . 2010;35:4:495-502. Doddi NM, Eccles R. The role of anthropometric measurements in nasal surgery and research: A systematic review. <i>Clinical Otolaryngology</i> . 2010;35:4:277-83.			3D imaging of hard and soft tissue in orthognathic surgery NCT00285714	Diagnosis
In individuals with cleft lip/palate what is the most effective speech therapy to eliminate cleft type speech characteristics?	Uncertainties identified from clinicians' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Any age		Education and training	Physical therapies					Ponduri S, Bradley R, Ellis PE, Brookes ST, Sandy JR, and Niss AR. The management of otitis media with early routine insertion of grommets in children with cleft palate -- a systematic review. <i>Cleft Palate-Craniofacial Journal</i> . 2009 Jan 46: (1) 30-8. Hardin-Jones M, Chapman KL. Cognitive and language issues associated with cleft lip and palate. <i>Seminars in Speech &amp; Language</i> .2011;32:2:127-40. Lee AS, Law J, Gibbon FE, Lee ASY, Law J, Gibbon FE. Electropalatography for articulation disorders associated with cleft palate. <i>Cochrane Database of Systematic Reviews</i> 2009, Issue 3. Art. No.: CD006854. DOI: 10.1002/14651858.CD006854.pub2.				Articulation; adverse effects or complications ; efficacy; quality of life; and economic outcomes
In individuals with cleft lip/palate when is the most effective age to begin speech therapy?	Uncertainties identified from carers' questions	No relevant systematic reviews identified	Any age		Education and training	Physical therapies	Diagnostic			Cleft Lip and or Palate Ranking 4					Speech outcomes; adverse effects or complications
What are the educational, employment and personal (eg relationships) outcomes for individuals with cleft lip/palate during childhood, adolescence and in the long term?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Any age		Education and training					Cleft Lip and or Palate Ranking 2					Educational; personal and employment outcomes; adverse effects or complications; and costs
What are the factors that predict the psychological outcomes for individuals with cleft lip/palate?	Uncertainties identified from carers' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Any age		Psychological therapy						Klassen AF, Tsangaris E, Forrest GR, Wong KW, Pusic AL, Cano SJ, Syed I, Dua M, Kainth S, Johnson J, Goodacre, T. Quality of life of children treated for cleft lip and/or palate: a systematic review. <i>Journal of plastic, reconstructive &amp; aesthetic surgery</i> . 2012;65(5):547-57. doi: 10.1016/j.bjps.2011.11.004.		Eckstein DA, Wu RL, Akinbiyi T, Silver L, Taub PJ. Measuring quality of life in cleft lip and palate patients: currently available patient-reported outcomes measures. <i>Plastic &amp; Reconstructive Surgery</i> . 2011;128:5:519e-526e.	Psychological adjustment; adverse effects or complications; quality of life; and cost	
What can be done to improve the experience of families of a baby with cleft lip/palate at time of birth in hospital?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Child / Adolescent		Education and training										Families opinion and experience of support

What can be done to prevent cleft lip/palate?	Uncertainties identified from carers' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Any age		Diagnostic					De-Regil LM, Fern7ndez-Gaxiola AC, Dowswell T, Pe7a-Rosas JP. Effects and safety of periconceptional folate supplementation for preventing birth defects. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD007950. DOI: 10.1002/14651858.CD007950.pub2			Incidence of cleft lip and/or palate; adverse effects or complications; quality of life; and cost
What exposures pre- and during pregnancy increase the risk of having a baby with a cleft?	Uncertainties identified from carers' questions	No relevant systematic reviews identified	Child / Adolescent		Diagnostic								Incidence of cleft lip and/or palate; adverse effects or complications; quality of life; and cost
What interventions would enhance the educational outcomes for children with cleft lip/palate?	Uncertainties identified from patients' questions	No relevant systematic reviews identified	Child / Adolescent		Education and training				Cleft Lip and or Palate Ranking 7				Educational achievements at all ages; adverse effects or complications; and costs
What is the best feeding method for babies with cleft lip/palate, including those with syndromes (including breast feeding, nasogastric tubes and weaning times?)	Uncertainties identified from clinicians' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Child / Adolescent		Diet					Bessell A, Hooper L, Shaw WC, Reilly S, Reid J, Glennly AM. Feeding interventions for growth and development in infants with cleft lip, cleft palate or cleft lip and palate. Cochrane Database of Systematic Reviews 2011, Issue 2. Art. No.: CD003315. DOI: 10.1002/14651858.CD003315.pub3.			Adverse effects or complications; growth; development; quality of life; change from birthweight"; body length"; and economic outcomes
What is the best protocol for primary repair of the lip and palate, including technique/timing and sequence?	Uncertainties identified from clinicians' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Child / Adolescent		Surgery				Cleft Lip and or Palate Ranking 3	Guo, J., Li, C., Zhang, Q., Wu, G., Deacon, S. A., Chen, J., Hu, H., Zou, S., and Ye, Q. Secondary bone grafting for alveolar cleft in children with cleft lip or cleft lip. Guo J, Li C, Zhang Q, Wu G, Deacon SA, Chen J, Hu H, Zou S, Ye Q. Secondary bone grafting for alveolar cleft in children with cleft lip or cleft lip and palate. Cochrane Database of Systematic Reviews 2011, Issue 6. Art. No.: CD008050. DOI: 10.1002/14651858.CD008050.pub2 - van Hout WM, Mink van der Molen AB, Breugem CC, Koole R, Van Cann EM. Reconstruction of the alveolar cleft: can growth factor-aided tissue engineering replace autologous bone grafting? A literature review and systematic review of results obtained with bone morphogenetic protein-2. Clinical Oral Investigations. 2011 15: (3) 297-303.	Furlow Palatoplasty With Tensor Tenopexy for Otitis Media NCT01535131 Timing of primary surgery for cleft palate (TOPS) NCT00983551 The management of otitis media with effusion (OME) in children with cleft palate: a feasibility study (MOMENT) <a href="http://www.nets.nhr.ac.uk/projects/hta/0816702">http://www.nets.nhr.ac.uk/projects/hta/0816702</a>	Articulation; adverse effects or complications ; efficacy; growth; development; quality of life; major congenital abnormality; structural-morphological birth defect;	
What is the best treatment for otitis media with effusion (OME - glue ear) in individuals with cleft lip/palate?	Uncertainties identified from clinicians' questions	Reliable up-to-date systematic reviews have revealed important continuing uncertainties about treatment effects	Any age		Drug	Physical therapies	Devices			Ponduri S, Bradley R, Ellis PE, Brookes ST, Sandy JR, and Niss AR. The management of otitis media with early routine insertion of grommets in children with cleft palate -- a systematic review. Cleft Palate-Craniofacial Journal. 2009 Jan 46: (1) 30-8.	Furlow Palatoplasty With Tensor Tenopexy for Otitis Media NCT01535131	Number of episodes, days per episode and per year with nasal symptoms; proportion of people with recurrent episodes of nasal symptoms (nasal symptoms are defined as nasal discharge with or without obstruction as observed by the parents or physician); nasal obstruction alone; patient having three or more episodes of nasal symptoms in a period of six months, or four or more episodes in a period of 12 months	
What is the best way to manage infants with Cleft lip and/or palate undergoing primary surgery before, during and after in hospital?	Uncertainties identified from patients' questions	No relevant systematic reviews identified	Child / Adolescent		Surgery				Cleft Lip and or Palate Ranking 9			Furlow Palatoplasty With Tensor Tenopexy for Otitis Media NCT01535131 Efficacy of Oral Versus Intravenous Acetaminophen for Primary Pediatric Cleft Palate Repair NCT01500109 Timing of primary surgery for cleft palate NCT00983551 An investigation for the optimal timing of a cleft palate repair NCT00779961	Adverse effects or complications; efficacy; growth; development; quality of life; pain; feeding; medication use; use of arm splints; and economic outcomes
What is the best way to prevent tooth decay in children with cleft lip/palate?	Uncertainties identified from carers' questions	Existing relevant systematic reviews are not up-to-date	Child / Adolescent		Education and training	Physical therapies	Diagnostic				Hasstlof P, Twetman S. Caries prevalence in children with cleft lip and palate—a systematic review of case-control studies. International Journal of Paediatric Dentistry. 2007;17:5:313-9.	Oral health; adverse effects or complications; and costs	

What is the impact of having a baby born with cleft lip/palate on maternal/child attachment?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Child / Adolescent		Diagnostic					Cleft Lip and or Palate Ranking 8			Relational development in children with cleft lips and palates: influence of the waiting period prior to the first surgical intervention and the parents' psychological perception of the abnormality NCT00993993	
What is the impact of parenting approach on the outcomes for children with cleft lip/palate?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Child / Adolescent		Diagnostic									Psychological adjustment; educational achievement; social achievement adverse effects or complications; quality of life; and cost
What is the most effective intervention for children with cleft lip/palate to minimise the impact of bullying?	Uncertainties identified from carers' questions	No relevant systematic reviews identified	Child / Adolescent		Education and training	Psychological therapy								Psychological adjustment
What surgical outcomes are important to patients with cleft lip/palate and are they met?	Uncertainties identified from clinicians' questions	No relevant systematic reviews identified	Any age		Surgery								Furlow Palatoplasty With Tensor Tenopexy for Otitis Media NCT01535131 Efficacy of Oral Versus Intravenous Acetaminophen for Primary Pediatric Cleft Palate Repair NCT01500109 Timing of primary surgery for cleft palate NCT00993551 An investigation for the optimal timing of a cleft palate repair NCT00779961 3D imaging of hard and soft tissue in orthognathic surgery NCT00285714 Relational development in children with cleft lips and palates: influence of the waiting period prior to the first surgical intervention and the parents' psychological perception of the abnormality NCT00993993	Presentation; adverse effects or complications; acceptability to patient and carer; costs;
What types of psychological intervention (individual therapy, community or school based) and at what time (from diagnosis to adulthood) are most helpful for patients with cleft lip/palate and their families?	Uncertainties identified from clinicians' questions	Existing relevant systematic reviews are not up-to-date	Any age		Psychological therapy					JLA CLAPA Ranking 1			Bennett ME, Stanton ML. Psychotherapy for persons with craniofacial deformities: can we treat without therapy? Cleft Palate-Craniofacial Journal. 1993;30;4:406-410 Collett B, Speltz ML. A developmental approach to mental health for children and adolescents with orofacial clefts. Orthodontics and craniofacial research. 2007;10;3:138-48. Relational development in children with cleft lips and palates: influence of the waiting period prior to the first surgical intervention and the parents' psychological perception of the abnormality NCT00993993	Articulation; adverse effects or complications; efficacy; development; quality of life; major congenital abnormality; structural-morphological birth defect; birthweight*; preterm delivery* (delivery before 37 completed weeks gestation); stillbirth; mild congenital abnormality; structural-morphological birth defect requiring medical intervention but with good life expectancy (such as congenital dislocation of the hip or undescended testis); low Apgar score (less than 7 at 5 minutes); and economic outcomes
Which protocols of cleft care produce the best results?	Uncertainties identified from patients' questions	No relevant systematic reviews identified	Any age		Education and training								Furlow Palatoplasty With Tensor Tenopexy for Otitis Media NCT01535131 Efficacy of Oral Versus Intravenous Acetaminophen for Primary Pediatric Cleft Palate Repair NCT01500109 Timing of primary surgery for cleft palate NCT00993551	Articulation; adverse effects or complications; efficacy; growth; development; quality of life; major congenital abnormality; structural-morphological birth defect; birthweight*; body length*; foetal growth restriction*; or other outcomes related to foetal growth; preterm delivery* (delivery before 37 completed weeks gestation); stillbirth; mild congenital abnormality; structural-morphological birth defect requiring medical intervention but with good life expectancy (such as congenital dislocation of the hip or undescended testis); low Apgar score (less than 7 at 5 minutes); and economic outcomes