# CONTENTS

# 1. Introduction

The *Palate examination: Identification of cleft palate in newborns* best practice guide provides recommendations for examination of the palate and cleft palate detection in babies. The best practice guide aims to improve the detection and the quality of healthcare provided by ensuring that all recommendations are based upon predetermined systematic methods to identify and evaluate evidence relating to specific review questions. In areas where no evidence was found a formal consensus method was undertaken to formulate recommendations.

The guidance was developed in partnership with the RCPCH and key partners (full acknowledgements can be found on the RCPCH website) and in accordance to the RCPCH standards for development of clinical guidelines in paediatrics and child health guideline manual[1].

While the best practice guide assists the practice of healthcare professionals, it does not replace their knowledge and skills.

# 2. Scope

## 2.1 Remit

The RCPCH in collaboration with key partners undertook the development of a best practice guide to increase the timely detection of cleft palate in babies. The scope was circulated to best practice guide stakeholders for comment before being finalised by the working group.

## 2.2 Population covered

Babies from birth to 28 days of age examined routinely as part of the newborn examination, usually within 72hrs of birth, in hospital, home, or at the general practitioner's (GP) surgery.

## 2.3 Target audience

The target audience for this guide is any healthcare professional who is likely to examine a newborn, more specifically, midwifery, neonatal and general paediatricians, general practitioners and health visitors, as well as more peripherally; dental, ear, nose and throat (ENT), and paediatric respiratory trainees, and allied professionals such as speech and language therapists, and paediatric dieticians.

## 2.4 Healthcare setting

Birthing units and their review clinics, GP's surgeries and their out of hours services, Health Centers and Children's Centers, Paediatric Walk-in Clinics, Accident & Emergency attendances, post-natal wards, special care baby units, neonatal units and home settings.

## 2.5 What this guideline covers

This guide covers:

(a) Routine postnatal examination of the palate.
(b) Identification of the cleft palate.

# 3. Developers and conflicts of interest

A working group was appointed to oversee the best practice guide development process. The group carried out the systematic searches, critical appraisal and data extraction of publications and informed the Delphi process. The RCPCH Clinical Standards team coordinated the development of the guide and provided methodological advice and support to the working group. The guide was drafted in consultation with the working group. The guide was not funded directly and instead developed through time and efforts volunteered from the working group and RCPCH clinical standards team. The group met every three months during the development of guideline. The working group declared all conflicts of interest which were recorded.

# 4. Aims and objectives

The best practice guide provides recommendations to health care professionals for optimal examination of the palate during the routine newborn examination to ensure early detection of cleft palate.

# 5. Developing the clinical questions

The working group formed the review questions based on the scope and prepared a protocol. The review question was developed in a framework of population, intervention, comparison and outcome for reviews of interventions to detect cleft palate. This was to guide the literature searching process, critical appraisal and synthesis of evidence, and facilitated the development of recommendations by the working group. The working group drafted the clinical question and this was validated by the RCPCH Clinical Standards team.

The clinical question used for the systematic review was:

1. What is the most reliable method of examining the palate during the newborn examination in order to detect a cleft palate?

The working group then drafted a further two clinical questions to aid the development of search strategies and literature searches for the review:

2. Is visual inspection compared to palpation/digital examination a more reliable method of detecting a cleft palate during the newborn examination?
3. Does visual inspection compared to palpation, performed during the newborn examination, reduce the incidence of delayed/missed diagnosis of cleft palate?

# 6. Identifying the evidence

The review questions formed the starting point for the systematic review of any relevant evidence. A total of three review questions were identified. All searches were conducted on core databases, MEDLINE, Embase, BNI and Maternity and Infant Care. Searches were limited to English language and there was no searching of grey literature, nor was hand searching of journals undertaken.

All searches were updated and re-executed within 8 weeks of the start of the stakeholder consultation to ensure the reviews were up-to-date. The process was completed by 31 May 2014 and no publications after this date were included.

# 7. Reviewing and synthesising the evidence

Evidence relating to cleft palate detection was identified by two members of the working group by title screening and abstract screening the publications retrieved during the literature searches. Full papers were then obtained. Each study was reviewed by two reviewers and any relevant information extracted. Full papers were reviewed against pre-specified inclusion and exclusion criteria to identify studies that addressed the review questions in the appropriate population and reported outcomes of interest. Publications were critically appraised using checklists developed by the Institute of Health Economics[2] and key information about the study's population, methods and results were extracted using purpose built forms. Data extracted was then placed into an evidence table and the working group agreed studies for inclusion and exclusions from the review.

In line with the RCPCH standards for development of clinical guidelines manual[1] the type of clinical question would determine the highest level of evidence that may be sought. In assessing the quality of the evidence; each study received a quality rating using the SIGN level of evidence[3]. The evidence found in this review did not meet the inclusion criteria for the clinical questions. Therefore the working group undertook a Delphi consensus process.

# 8. Delphi process

For the best practice guide there was no substantial evidence in existence and so a two round Delphi consensus method was used to derive recommendations. This involved the participation of 16 healthcare professionals from specialities including midwives, nurses, cleft surgeons and neonatologists.

Participants rated a series of statements developed by the working group using a 1-9 scale (1 being strongly disagree, 9 strongly agree). Consensus was defined as 75% of rating falling in the 1-3 or 7-9 categories. Results and comments from each round were discussed by the working group and final recommendations were made according to predetermined criteria.

A total of 13 panellists participated in forming 6 recommendations. These statements were used to form the recommendations in the guide and were given a level of evidence according to the criteria developed by SIGN[3]. Full details of the consensus process are presented in appendix 3.

# 9. Developing recommendations

The working group held a meeting to agree upon the recommendations using the Delphi consensus results. Any statements that did not reach consensus during the Delphi process were reviewed and a consensus reached by the group. Delphi statements which had reached consensus were reviewed by the working group and considered using the below criteria:

- Relative value on the main objective of the clinical question
- Consideration of the clinical benefits and harms
- Consideration of the net health benefits and resource use
- Other considerations

This provided a clear translation of Delphi statements to recommendations and each recommendation in the best practice guide is accompanied by a paragraph with the rational.

# 10. Guideline consultation details

A three week stakeholder consultation took place between 14 July and 1 August 2014. During this time stakeholders were given the opportunity to comment on the best practice guide. All comments were collated and presented to the working group for discussion.

# 11. Parent, carer and patient participation

The working group included a parent of a child with a cleft palate who was able to feed into every aspect of the best practice guide development process. The working group and stakeholder representatives also included a parent, carer and patient information charity.

# 12. Guideline audit

The Clinical Effectiveness Unit of the Royal College of Surgeons (RCS) collect the date and time of the diagnosis of cleft palate for all babies referred to cleft teams. The timing of diagnosis is notified to the CRANE team at the RCS and entered on to the CRANE database. This allows the CRANE team to produce a report each year on the timeliness of diagnosis of cleft palate. The additional and separate documentation of visual examination of the palate at notification of a patient with cleft palate to the CRANE team will allow for audit of implementation of the guideline and assess the need for further education. Thus allowing researchers to:

- Establish whether the timing of detection of cleft palate improves following publication and dissemination of the guidelines
- Examine possible links between whether clefts of the palate are detected by routine newborn examination (which may not happen until 72 hours after birth) or precipitate an early newborn examination as a result of observations of clinical differences in the baby (such as slow feeding, or difficulty establishing feeding)

- Identify the clinical differences in babies with cleft palate that lead to early (<24 hours) detection of cleft palate.

In order for the addition of this data to the CRANE database to be viable discussions will need to be held with the CRANE team to ensure robust collection of data to ensure meaningful analysis.

# 13. Best practice guide update

It is recommended that this guidance is updated so that clinical recommendations take into account important new information. The evidence should be checked three years after publication, and healthcare professionals and patients views should be sought to assess whether all or part of the guidance requires updating. If important new evidence is published at other times it may be decided that a more rapid update of some recommendations is necessary.

# 14. Editorial independence

The best practice guide was developed without any external funding and the working group did not have any conflicts of interest.

# 15. Implementation

The best practice guide will be hosted on the Clinical Standards section of the RCPCH website, as well as stakeholder's websites which are listed below:

- Cleft Lip And Palate Association
- Community Practitioners and Health Visitors Association
- CRANE database
- BLISS
- British Society of Paediatric Dentistry
- Royal College of Nursing

## 15.1 Advice for implementation

To implement this guidance into your practice we suggest that this guidance is read by healthcare professionals who routinely carry out newborn examinations.

The RCPCH in collaboration with the CFSGBI are developing an educational resource to aid implementation of the guide across the healthcare profession.

# 16. Resource implications

It is not envisioned that these recommendations will have a substantial impact on local resources. The purpose of the recommendations is to aid healthcare professionals understanding of how to ensure a thorough examination of the newborn palate to ensure that any clefts are detected.

# 17. Reference list

1. RCPCH. (2006). Standards for development of clinical guidelines in paediatrics and child health, 3rd edition.
2. Moga C, Guo B, Schopflocher D, Harstall C. Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique. Edmonton AB: Institute of Health Economics. 2012.
3. SIGN (2011), a guideline developer's handbook. SIGN: Edinburgh.
4. Habel A, Elhadi N, Sommerlad B, Powell J. Delayed detection of cleft palate: an audit of newborn examination. Arch Dis Child 2006;91:238–240.

# Appendix 1: Search strategy (including selection criteria)

## Clinical questions

1. What is the most reliable method of examining the palate during the newborn examination in order to detect a cleft palate?

2. Is visual inspection compared to palpation/digital examination a more reliable method of detecting a cleft palate during the newborn examination?

3. Does visual inspection compared to palpation, performed during the newborn examination, reduce the incidence of delayed/missed diagnosis of cleft palate?

## Search terms

| P | I | C | O |
|---|---|---|---|
| Newborn<br>Infant | Visual inspection<br>Visualization<br>Physical examination<br>Inspection<br>Detection | Palpation<br>Digital examination | Cleft palate |

## Sources

- MEDLINE 1950 - present
- EMBASE 1980 – present
- CINAHL 1981 - present
- BNI 1992 – present
- Maternity and Infant Care 1971- present

Hand searching of reference lists from reviews and included papers.

## Inclusion criteria

**Population**

- Babies examined routinely as part of the newborn examination, usually within 72hrs birth, in hospital, home, GP surgery
- Infants from birth to 1 year to allow for delayed diagnosis of cleft palate

**Study design**

- Primary peer reviewed studies of delayed detection of cleft palate
- Systematic reviews of examination of the infant mouth

- Recommendations for examination of the newborn/infant mouth and palate from National associations and International bodies such as the American Academy of Pediatrics, WHO, etc.
- Any studies comparing visual and palpation methods for examination. Randomized controlled trials
- Case series
- Cohort studies
- Published abstracts
- Published in English language

## Exclusion criteria

**Population**

- Prenatal detection

**Study design**

- Studies that are methodologically flawed
- Case reports
- Personal practice, comments, letters and correspondence, book chapters, narrative reviews, conference proceedings

**Limits**

- No time limit
- English language only

## Search strategies

**Search History Medline(R) 1950 to 31 May 2014**

| | |
|---|---|
| 1. | exp INFANT,NEWBORN/ |
| 2. | exp INFANT/ |
| 3. | (visual AND inspection).ti,ab |
| 4. | visualisation.ti,ab |
| 5. | visualization.ti,ab |
| 6. | (physical AND examination).ti,ab |
| 7. | inspection.ti,ab |
| 8. | detection.ti,ab |
| 9. | palpation.ti,ab |
| 10. | (digital AND examination)ti,ab |
| 11. | exp CLEFT PALATE/ |
| 12. | 1 OR 2 |
| 13. | 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 |
| 14. | 11 AND 12 AND 13 |

**Search History: Maternity and Infant Care 1971 to 31 May 2014**

| | |
|---|---|
| 1. | Cleft palate.de. or cleft palate.mp..de. (463) |
| 2. | (examination or inspection or palpat* or detection).mp. [mp=abstract, heading word, title] |
| 3. | (infan* or bab*).mp. [mp=abstract, heading word, title |
| 4. | 1 and 2 and 3 |

**Database: Maternity and Infant Care <1971 to 31 May 2014**

| | |
|---|---|
| 1. | cleft palate.mp. or Cleft palate.de |
| 2. | Physical examination and Infant - newborn).de |
| 3. | 1 and 2 |
| 4. | ((examination* or detecting or diagnosis or palpation or digital examination or visual inspection or inspection) not prenatal not antenatal).mp. [mp=abstract, heading word, title] |
| 5. | (newborn or infant or neonate).mp. [mp=abstract, heading word, title) |
| 6. | 1 and 4 and 5 |

**Database: Maternity and Infant Care <1971 to 31 May 2014**

| | |
|---|---|
| 1. | cleft palate.mp. or Cleft palate.de. |
| 2. | (Physical examination and Infant - newborn).de. |
| 3. | 1 and 2 |

**Search History Embase 1980 to 31 May 2014**

| | |
|---|---|
| 1. | EMB.EXACT("physical examination") AND EMB.EXACT("cleft palate") AND EMB. EXACT("newborn") AND human(yes) |
| 2. | ti(examination) AND ti(cleft palate) AND ti(newborn) AND human(yes) |
| 3. | emb(examination) AND mjemb(cleft palate) AND emb(newborn) AND human(yes) |
| 4. | emb(physical examination) AND mjemb(cleft palate) AND emb(newborn) AND human(yes) |

**Search History CINAHL to 31 May 2014**

| | |
|---|---|
| S1 | (MM "Cleft Palate") |
| S2 | (MM "Physical Examination") |
| S3 | Visual and inspection |
| S4 | Digital AND examination |
| S5 | detection |
| S6 | inspection |
| S7 | S2 OR S3 OR S4 OR S5 OR S6 |
| S8 | S1 AND S7 |

**Search History BNI 1992 to 31 May 2014**

| | |
|---|---|
| 1. | Exp NEONATES/ |
| 2. | Exp INFANTS/ |
| 3. | (visual AND inspection).ti,ab |
| 4. | visualisation.ti,ab |
| 5. | visualization.ti,ab |
| 6. | (physical AND examination).ti,ab |
| 7. | inspection.ti,ab |
| 8. | detection.ti,ab |
| 9. | palpation.ti,ab |
| 10. | (digital AND examination)ti,ab |
| 11. | exp CLEFT PALATE/ |
| 12. | 1 OR 2 |
| 13. | 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 |
| 14. | 11 AND 12 AND 13 |
| 15. | 11 AND 13 |
| 16. | 11 and 12 |

**Search History Medline(R) 1946 to week 31 May 2014**

| | |
|---|---|
| 1. | cleft palate.mp. or Cleft Palate/ |
| 2. | limit 1 to yr="1950 -Current" |
| 3. | Infant, Newborn/ |
| 4. | Physical Examination/ |
| 5. | 2 and 3 and 4 |
| 6. | neonate*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 7. | 3 or 6 |
| 8. | 1 and 4 and 7 |
| 9. | (Diagnosis or visual inspection or examination or palpation or detecting).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 10. | Prenatal Diagnosis/ |
| 11. | ((Diagnosis or visual inspection or examination or palpation or detecting) not prenatal).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 12. | 2 and 7 and 11 |

**Database: Ovid MEDLINE(R) <1946 31 May 2014**

| | |
|---|---|
| 1. | Cleft Palate/ |
| 2. | (infan* or bab*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 3. | (examination or inspection or palpat* or detection).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 4. | 1 and 2 and 3 |
| 5. | postnatal.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier] |
| 6. | 4 and 5 |

**Ovid MEDLINE(R) <1946 to 31 May 2014**

| | |
|---|---|
| 1. | cleft palate.mp. or Cleft Palate/ |
| 2. | limit 1 to yr="1950 -Current" |
| 3. | Infant, Newborn/ |
| 4. | Physical Examination/ |
| 5. | 2 and 3 and 4 |

# Appendix 2: Evidence table

| Paper | Aims of study | Study type/ timeframe | Study population | Method of palate examination | Quality of study | Main results | Comments |
|---|---|---|---|---|---|---|---|
| Habel 2006[4] | To identify prevalence of delayed detection of cleft palate and associated factors that could lead to improved identification at newborn examination | Retrospective audit of case notes<br>1988 - 2001 | All patients (N=344) with cleft palate only (i.e. not with cleft lip) referred to Great Ormond Street (GOS) and Plastic Surgery Centre at St Andrew's, Billericay<br><br>Sample characteristics;<br>61% of 344 female | Method of initial detection was not recorded. | Low quality<br>The study was rejected as there was no description of recruitment of participants/ patients or description of outcome measures. | **Age at detection:**<br>N=344 cases audited, of which n=316 yielded information about day of detection.72% detected day 1<br>**Shape:**<br>assessed in 207 at operation<br>Broad U shaped more often detected on day 1 compared to narrow V-shaped<br>91/115 (79%) vs. 39/92 (42%) [p<0.001]<br>**Parental Questionnaire**:<br>This found delay was associated with breathing difficulties on day 1 (p=0.015), feeding problems and nasal regurgitation after that (p< 0.001).<br>**Junior Hospital doctor survey:**<br>in 23 referring units, 14 taught palpation only, 9 combined visual and palpation. Isolated cleft palates (ICP) not detected day 1 was 37% compared with 23% if Syndromic cleft palates (SCP) (p <0.05). Data was from 254 cases seen in detail.<br>**Delivery location:**<br>Home delivery 12 of 13 delayed. No significant difference between DGH and tertiary units. | The results mentioned one of the authors contacted a doctor at each of the referring units to ask how they currently examined the palate, what method was advised locally and whether they were given specific training. This does not provide any information about how the babies with cleft palate in the study were examined |

# Appendix 3: Delphi process

## 1. Rules of Delphi

All Delphi consensus methods must follow three rules:

- Anonymity of participants
- Statistical analysis of responses
- Iteration (allowing participants to change their views in subsequent round)

Beyond these rules Delphi processes can vary. The specifics of the process should be laid down from the start of the first round. For this Delphi process the specific rules were as follows:

| | |
|---|---|
| **Number of rounds** | There will be two rounds |
| **Definition of consensus** | A nine point Likert scale will be used for panellists to provide their responses to statements. Consensus agrees will be defined as 75% of panellists selecting 1, 2, 3 on the Likert scale. Consensus disagrees will be defined as 75% of panellists selecting 7, 8, 9 on the Likert scale |
| **Panel size** | The panel must be multidisciplinary and include at least two representatives from each speciality |
| **Panel knowledge base** | There will be no literature sent to participants as any evidence sent out could bias responses |

## 2. Delphi panel

| Name | Speciality | Round 1 | Round 2 |
|---|---|---|---|
| Helen Robson | Nursing | ✓ | ✓ |
| Karine Latter | Nursing | ✓ | ✓ |
| Anne Crawford | Nursing | ✓ | ✓ |
| Anne Lomax | Midwifery | ✓ | ✓ |
| Stephanie Michaelides | Midwifery | ✓ | ✓ |
| Belinda Ackerman | Midwifery | ✓ | ✓ |
| Helen Baston | Midwifery | ✓ | ✓ |
| Cathy Rogers | Midwifery | ✓ | ✓ |
| Felicity Mehendale | Cleft surgeon | ✓ | ✓ |
| Alistair Smyth | Cleft surgeon | ✓ | ✓ |
| Norma Timoney | Cleft surgeon | ✓ | ✓ |
| Bob Welch | Neonatologist | ✓ | ✓ |
| Peter Fowlie | Neonatologist | ✓ | ✓ |

## 3. Instructions from Likert scale

Each participant received the same instructions for each round. Their responses were recorded on a Likert scale to allow statistical analysis.

**So what do I have to do?**

This is Round 2 of the Delphi process. You will need to complete the following questionnaire 30 May and 13 June. In total the questionnaire should take no longer than 5 minutes to complete.

**How do I complete the questionnaire?**

This questionnaire contains statements followed by a 9 point scale on which you can indicate your agreement with that statement.

For each statement, you must decide how much you agree with the statement by selecting the number that indicates your level of agreement.
1 = Strongly disagree - 9 = Strongly Agree

Following each statement and scale there is a comments box for you to include reasons for your rating and/or alternative wording.

**What about confidentiality?**

All results from the questionnaire will remain anonymous and other participants will have no access to your answers.

**What now?**

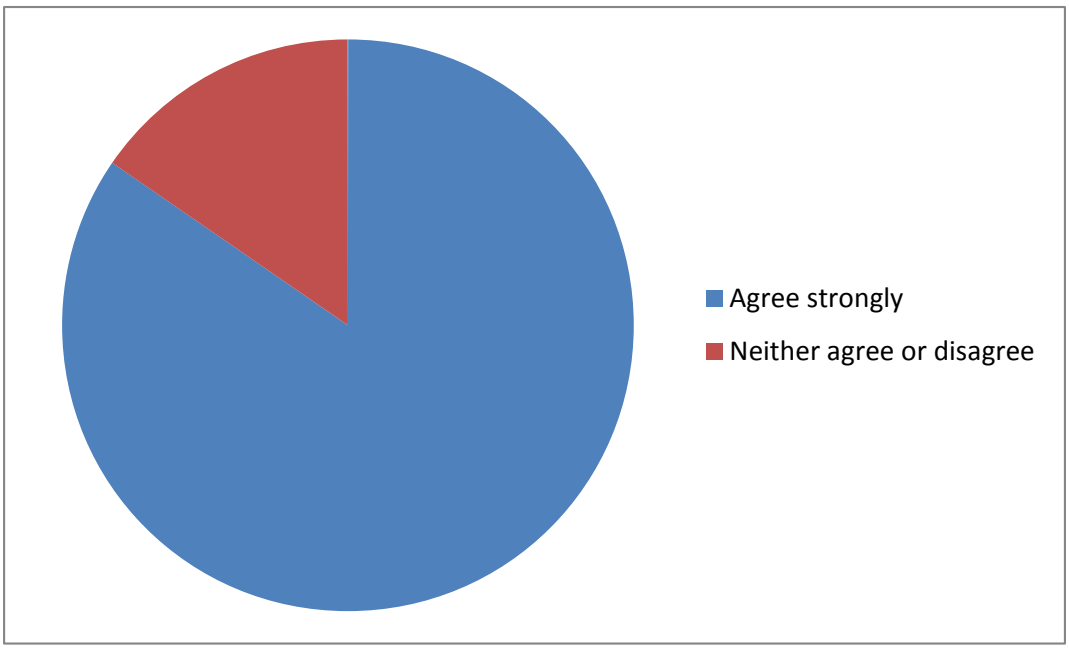
Please click on the button at the bottom of the page to get started and remember please do not consult colleagues before selecting your response.

## 4. Round one statements and results

The statements from round one are presented below along with a pie chart of participants responses and any comments made by the panel. The comments were used to re-phrase any statements which had not reached consensus.

Please note comments from Delphi panellists have been spell checked for eligibility, however the content of the comments have not been changed.

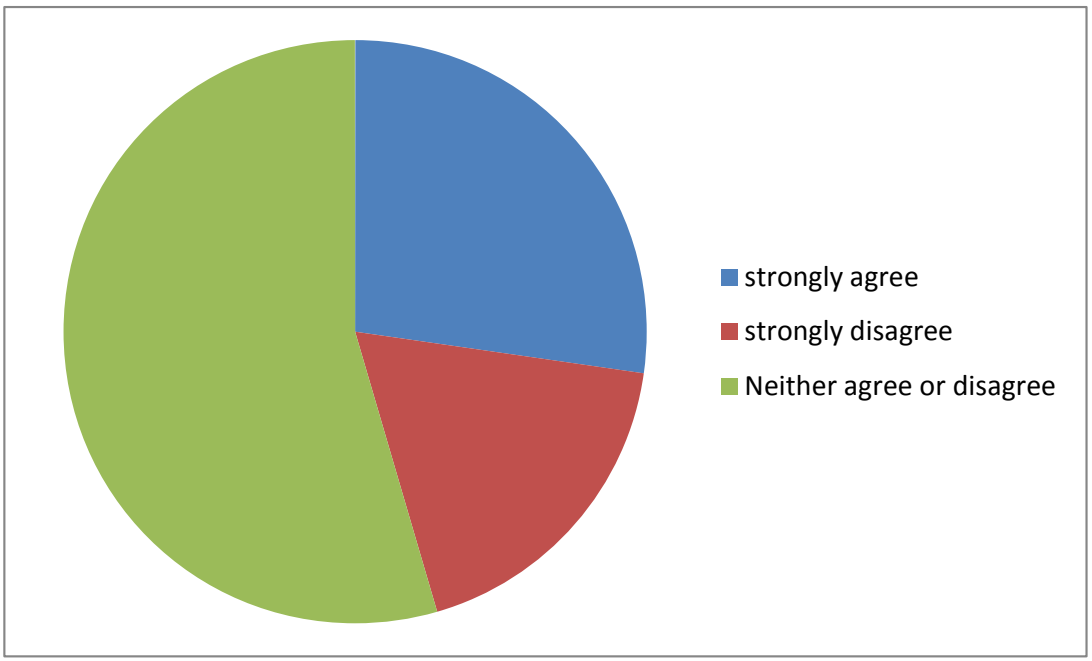
**1. Examination of the palate should take place during the newborn examination**




Consensus achieved: 85% strongly agree

| Response | Comments |
|---|---|
| Strongly agree | Examination of the hard and soft palate should take place during the full examination of the newborn |
| Strongly agree | with the addition of soft and hard palate |
| Strongly agree | is essential component of the NBE |
| Strongly agree | Some babies are discharged within a few hours of birth and may appear to be feeding well but will usually struggle after 24 hour period. The palate then appears to be only palpated which means that many get missed for days, weeks and months causing feeding difficulties, weight loss and sometimes readmission to hospital |
| Neither agree nor disagree | Word change: Examination of the full palate (hard and soft palate) should take place during the newborn examination. An intact palate or a cleft palate should be diagnosed at the earliest opportunity. Examination of the palate is more likely to be performed when part of a structured examination of the newborn. If it is not a requirement of the newborn examination then it is more likely to be overlooked or assumed that 'somebody else will do it'. Early diagnosis will allow early referral to cleft teams, facilitate appropriate oral feeding methods and allow early imparting of accurate information to parents. I would favour a protocol which requires the initial provisional diagnosis of cleft palate to be confirmed by another member of the medical team responsible for that child's care at the earliest opportunity. The provisional and subsequent confirmed diagnosis of cleft palate must be clearly documented in the records. |
| Neither agree nor disagree | delay in diagnosis of soft palate clefts can lead to feeding difficulties, poor weight gain, and unnecessary parental worry |

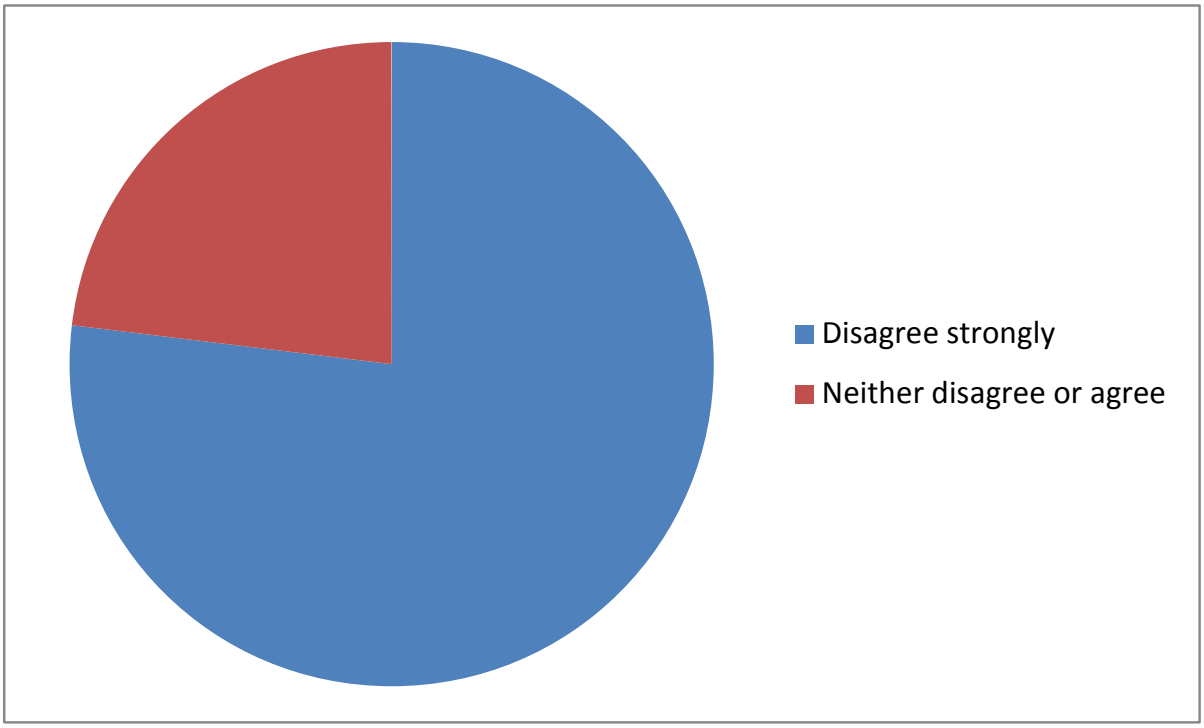
**2. Palate examination should be carried out by visual inspection alone**




Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | Visual inspection must be carried out to visualise the uvula |
| Strongly agree | Only if carried out using a good pen torch and a tongue depressor, with assistance of a second person when necessary |
| Neither agree nor disagree | it is not always possible to visualise the palate, although this is preferable |
| Neither agree nor disagree | Visual is the gold standard but if a baby will not open mouth I have had to palpate but am aware this is not accurate and merely a guide. |
| Neither agree nor disagree | The issue here is not whether visual inspection is appropriate or not or a good diagnostic test or not but rather whether it can be done with a single person examining the baby. To double up and have 2 individuals per newborn examination is not practical in majority of settings and it may not be possible safe to inspect the palate properly with single examiner. |
| Neither agree nor disagree | Palpation is ok as long as it is done alongside a visual inspection as well |
| Neither agree nor disagree | This only holds if a complete view of the palate is obtained and this can be difficult to achieve.<br>Word change: Examination of the full palate (hard and soft palate) should be carried out by visual inspection alone. Visual examination of the palate in a newborn with an adequate light source and including depression of the tongue to visualise the posterior palate is the most reliable and accurate method to diagnose the presence or otherwise of a cleft palate. Other methods of clinical examination such as palpation are much less reliable and contribute nothing further to the diagnosis of cleft palate which has been established by visual inspection. |
| Strongly disagree | Examination should be carried out by both visual inspection and palpation |

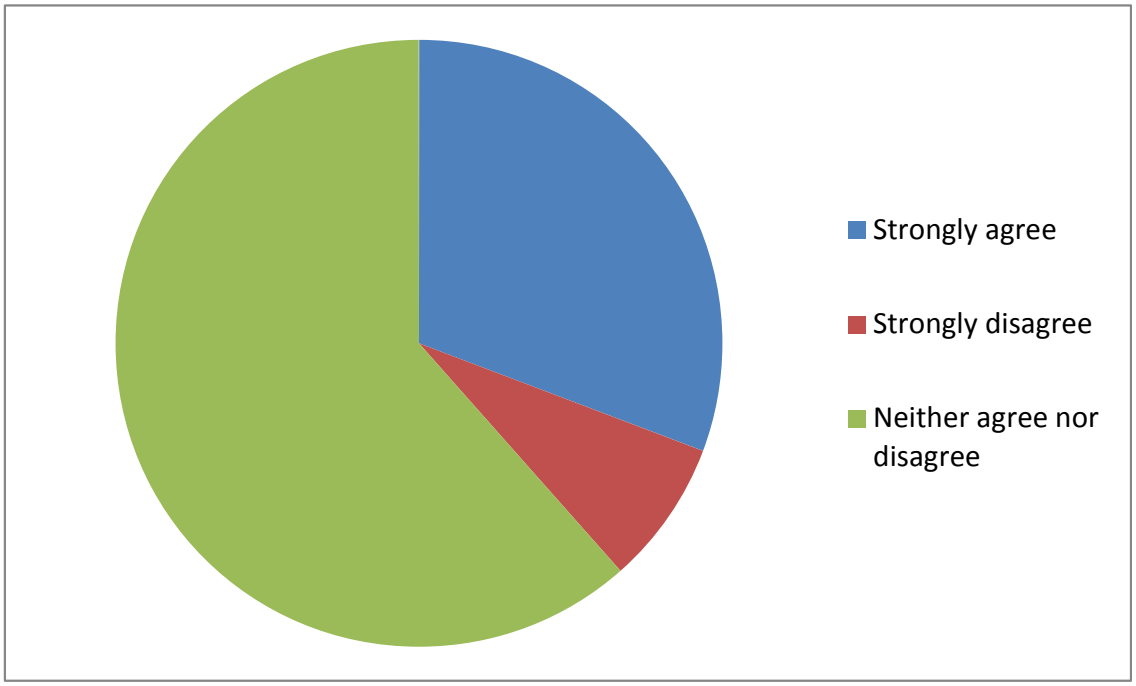
**3. Palate examination should be carried out by palpation alone**




Consensus achieved: 80% strongly disagree

| Response | Comments |
|---|---|
| Strongly disagree | All the published evidence shows that small soft palate clefts and bifid uvulas can be missed if this method is used |
| Strongly disagree | This method is unreliable. Incomplete cleft palates can be easily missed and even complete cleft palates undiagnosed by palpation as the nasal septum may be mistaken for an intact palate. There would be a consequent unsatisfactory and avoidable number of false negative and false positive diagnoses. |
| Strongly disagree | Clefts of the soft palate can be missed though this alone |
| Strongly disagree | Very difficult to feel a soft palate cleft. Person carrying out the palpation doesn't always know what they are feeling. A very wide cleft could mean the examiner feels the nasal septum and thinks they are feeling the palate. |
| Strongly disagree | You would not detect a small cleft of the posterior soft palate with this method and rarely diagnose an SMCP.<br>No, visualisation should be undertaken to identify cleft of the soft palate. However, palpation may be the only possibility if baby will not open mouth or doesn't 'gag' when palate palpated |
| Strongly disagree | Palpating the palate often misses a cleft of the soft palate |

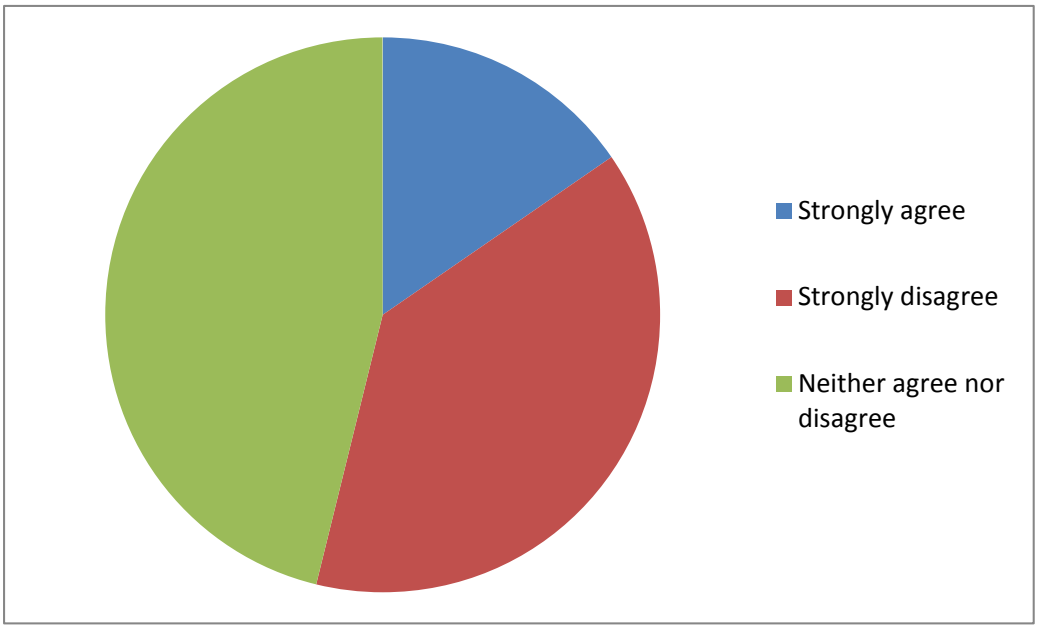
**4. Palate examination should be carried out by both palpation and visual inspection**




Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | Add: A tongue depressor should be utilised if the palate cannot be visualised. |
| Strongly agree | Only if carried out using a good pen torch and a tongue depressor, with assistance of a second person when necessary |
| Strongly agree | Ideally |
| Neither agree nor disagree | Palpation can be falsely reassuring since it cannot be relied upon to detect a soft palate cleft and a number of cases of clefts that extend into the hard palate have been missed on palpation. |
| Neither agree nor disagree | Visual remains the gold standard |
| Neither agree nor disagree | The issue here is not whether visual inspection is appropriate or not or a good diagnostic test or not but rather whether it l can be done with a single person examining the baby. To double up and have 2 individuals per newborn examination is not practical in majority of settings and it may not be possible safe to inspect the palate properly with single examiner |
| Neither agree nor disagree | Palpation may be unnecessary if there is a complete cleft of the lip and palate. |
| Neither agree nor disagree | Is palpation necessary when you can visualise the palate |
| Strongly disagree | I would disagree with this statement as appropriate visual inspection alone by a competent clinician will diagnose all cleft palates. Palpation adds nothing further to the diagnosis. However, if the visual inspection is inadequate in the presence of cleft palate then an inexperienced clinician may be falsely reassured by palpation that no cleft palate is present as the reliability of palpation is poor. |

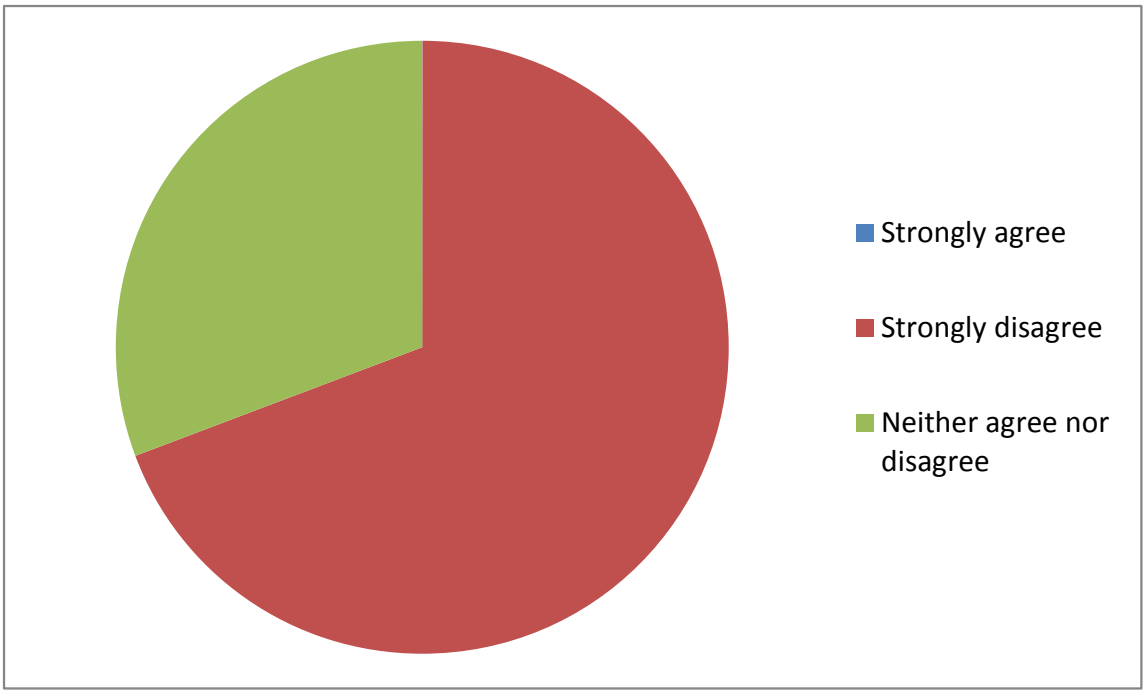
**5. In cases where visual inspection is incomplete (so the whole of the palate is not seen) palpation should be carried out.**




Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | ideally, palpation may be necessary to facilitate this |
| Strongly agree | Yes I have a baby that fits and grinds jaw palpation is the only way I could diagnose this |
| Neither agree nor disagree | If the entire palate (hard and soft) could not be visualised, this should be documented along with a record of the findings and reason for inability to visualise the palate. |
| Neither agree nor disagree | Additionally, a further full examination should be performed prior to discharge home |
| Neither agree nor disagree | The part the examiner may not see is the complete soft palate including the uvula. You will not be able to gain any more information by palpating the palate. Always better to be patient and visualise |
| Neither agree nor disagree | Palpation should be performed, but the palate should be fully examined visually before a cleft can be ruled out. If necessary, the palate should be re- examined on another occasion or by another examiner. If these attempts still fail to yield a complete examination, the patient should be referred to the local cleft team. |
| | If sucking and feeding is poor and there is nasal regurgitation of milk then a further attempt to visualise the whole palate is necessary |
| Strongly disagree | In cases where visual inspection is incomplete, a tongue depressor should be used |
| Strongly disagree | Need to ensure staff are trained to ensure visualisation |
| Strongly disagree | A complete visual inspection is imperative as you cannot feel to the very back of the palate |
| Strongly disagree | See comments under item 4. Palpation is unreliable. Under these circumstances it must be recorded in the notes by the examining clinician that visual inspection of the whole of the palate was incomplete and that this is relayed to a more senior member of staff who should visually examine the whole palate. |

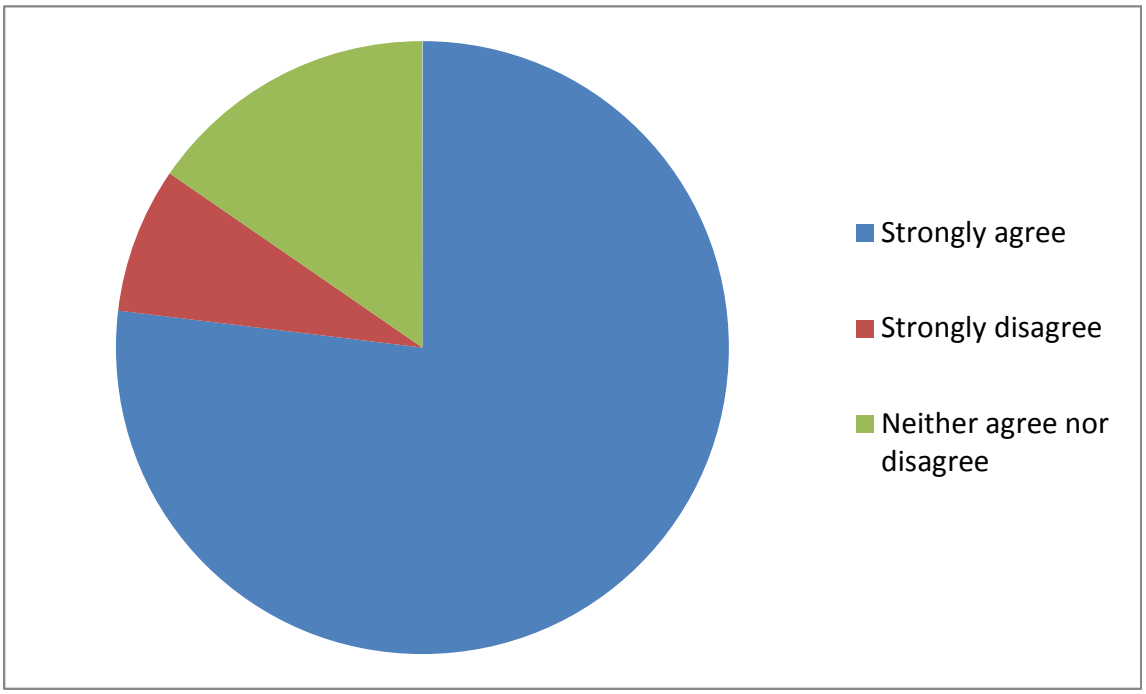
**6. Palpation is of equal value to visual inspection in detecting a cleft**




Consensus not achieved

| Response | Comments |
|---|---|
| Neither agree nor disagree | both important but visualisation in addition is best practice, especially in babies with a family history, exposure to teratogenic agents, suspected syndrome and/or feeding difficulties |
| Neither agree nor disagree | I do not know any objective data on these aspects of examination as diagnostic "tests" |
| Disagree strongly | Palpation is not a substitute for visualisation of the palate. Both should be completed as part of the full examination of the newborn. |
| Disagree strongly | Visual inspection has a high reliability even by relatively inexperienced clinicians and can achieve 100% reliability when performed by experienced clinicians. Palpation methods have a low reliability and would be associated with an unacceptably high number of missed diagnoses. They are definitely not of equal value. Palpation either alone or in addition to visual inspection should be considered inappropriate and unnecessary for the diagnosis of cleft palate. |
| Disagree strongly | All the published evidence shows that small soft palate clefts and bifid uvulas can be missed if this method is used |

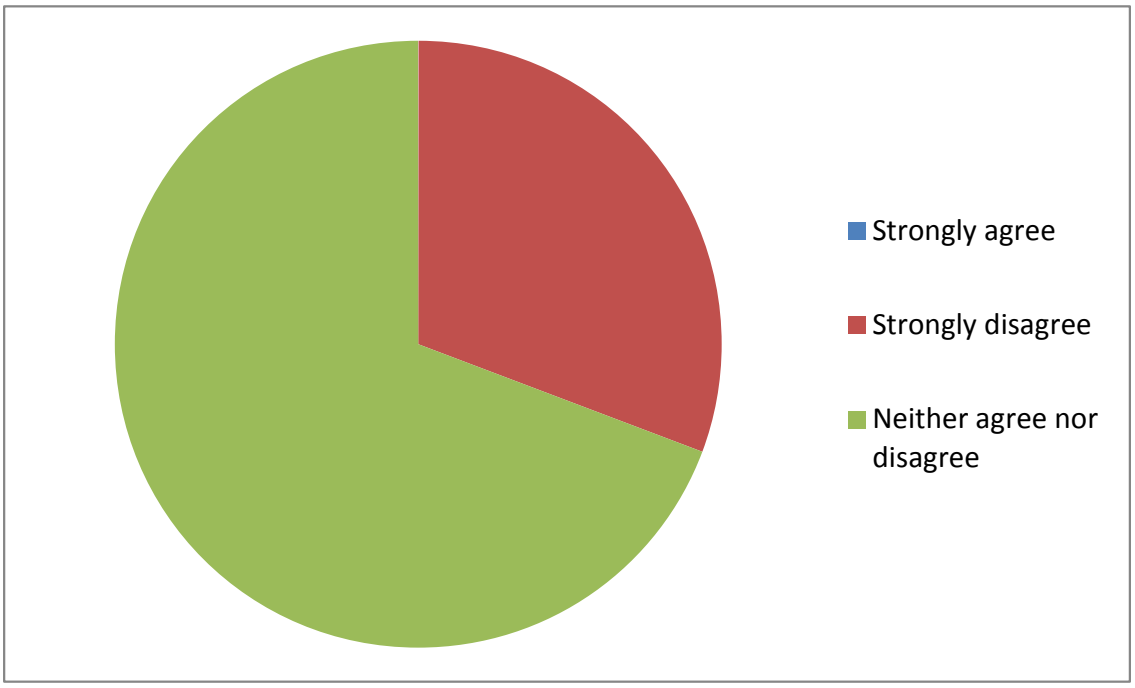
**7. A torch and method of depressing the tongue are required to consistently visualise the whole palate**




Consensus achieved: 80% strongly agree

| Response | Comments |
|---|---|
| Strongly agree | A torch and method of depressing the tongue should be utilised to provide consistency to the examination of the hard and soft palate |
| Strongly agree | In addition, the clinician examining the palate needs assistance from a colleague to hold the neonates head and ideally extend the neck, which makes visualisation of the palate easier. |
| Strongly agree | Yes it is a simple way to examine |
| Strongly agree | Have surveyed the various methods and this is the only one that consistently works An appropriate light source providing good illumination (such as a quality pen-torch, hand torch or head torch) and method of depressing the base of the tongue are required to consistently visualise the whole palate. |
| Strongly disagree | a good yawn is perfect |

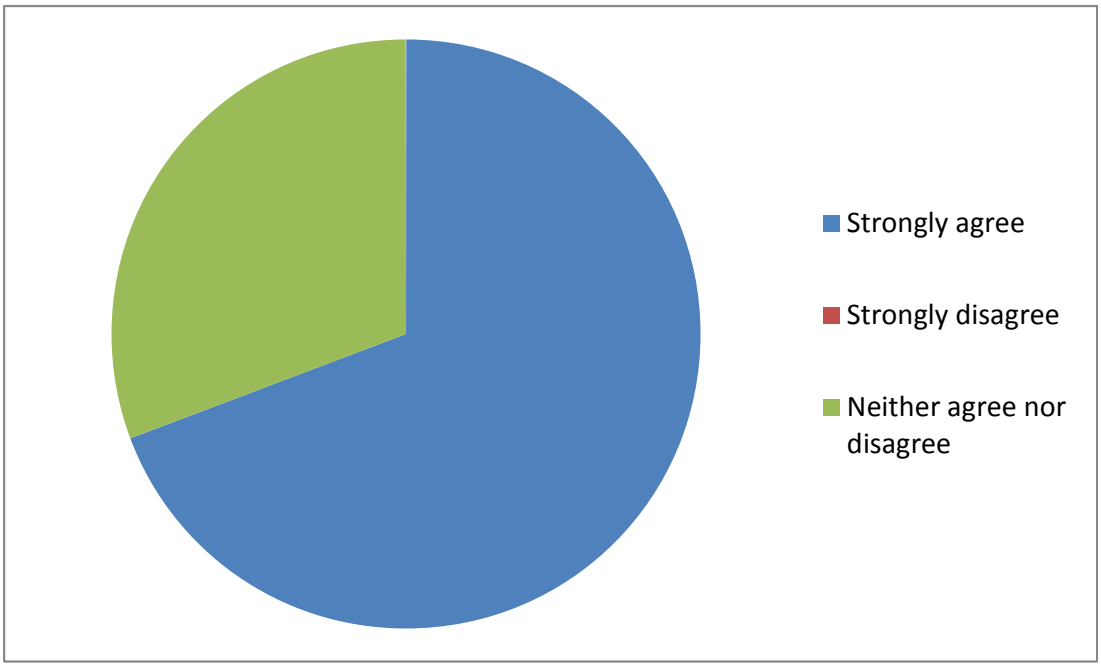
**8. Digital examination should be carried out once a cleft palate has been detected**




Consensus not achieved

| Response | Comments |
|---|---|
| Neither agree nor disagree | Digital examination may be carried out once a cleft palate has been detected to locate breadth and depth of the cleft |
| Neither agree nor disagree | May feel a notch in the hard palate where only a soft palate cleft is detected visually |
| Neither agree nor disagree | Could be useful to assess for a tongue tie, movement of the tongue and assess strength of suck as part of a feeding assessment. |
| Strongly disagree | Once a cleft palate has been detected then digital examination provides no additional value to the diagnosis and is redundant and of low reliability. |
| Strongly disagree | There is no need if you can see it |
| Strongly disagree | digital examination may facilitate visualisation of soft palate cleft, but once this seen, no need to use digital means |

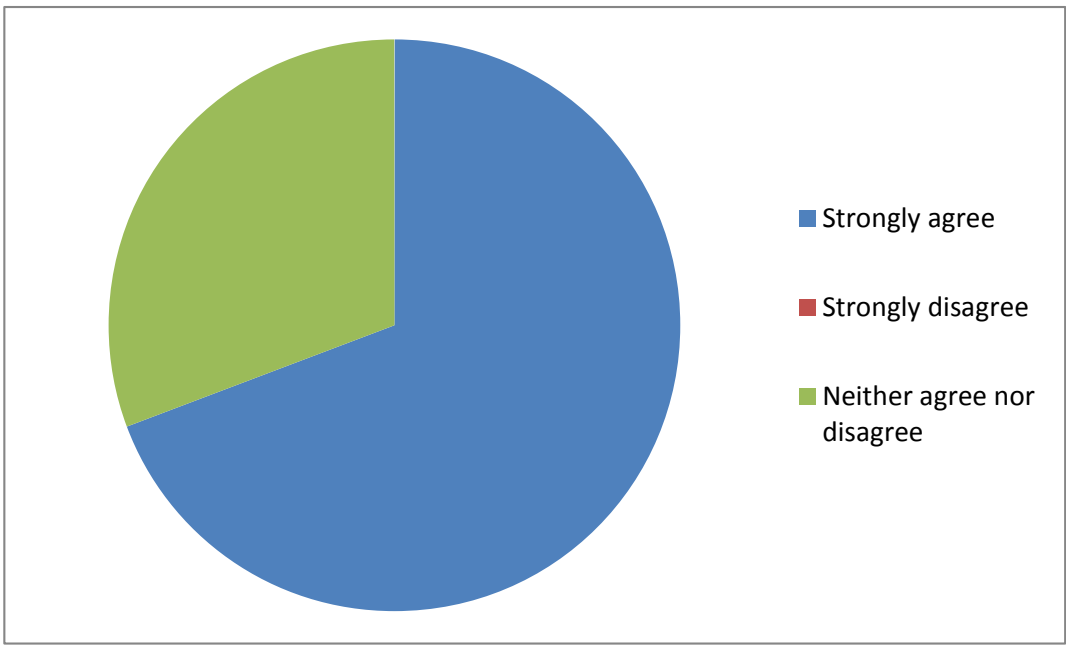
**9. Visual inspection of the palate correctly performed is more likely to detect all clefts of the palate than palpation/digital examination alone**




Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | Palpating a cleft accurately relies on a good knowledge of the anatomy of varying types of cleft and would be challenging for a non-cleft specialist |
| Strongly agree | Absolutely. Incontestable. |
| Strongly agree | I do not know any data that can support/refute this. |
| Neither agree nor disagree | To allow for a smcp where it may not be possible to see the translucent layer of membrane but maybe possible feel for a hard palate notch. |

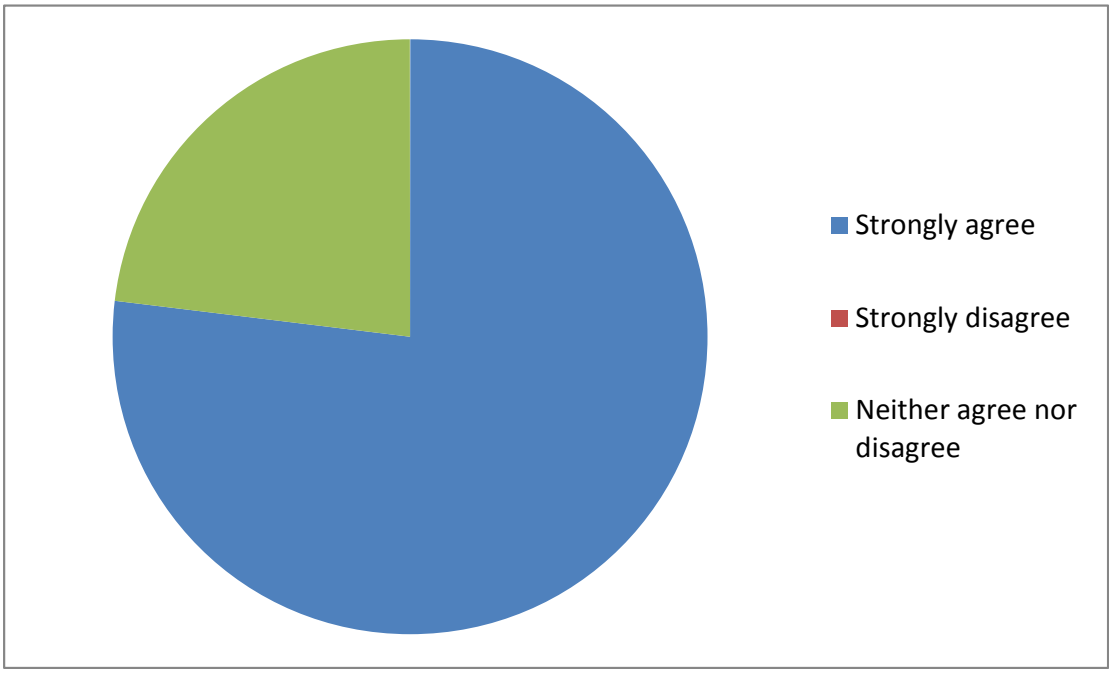
**10. Parents should be informed if the whole palate (including the uvula) is not inspected**




Consensus not achieved

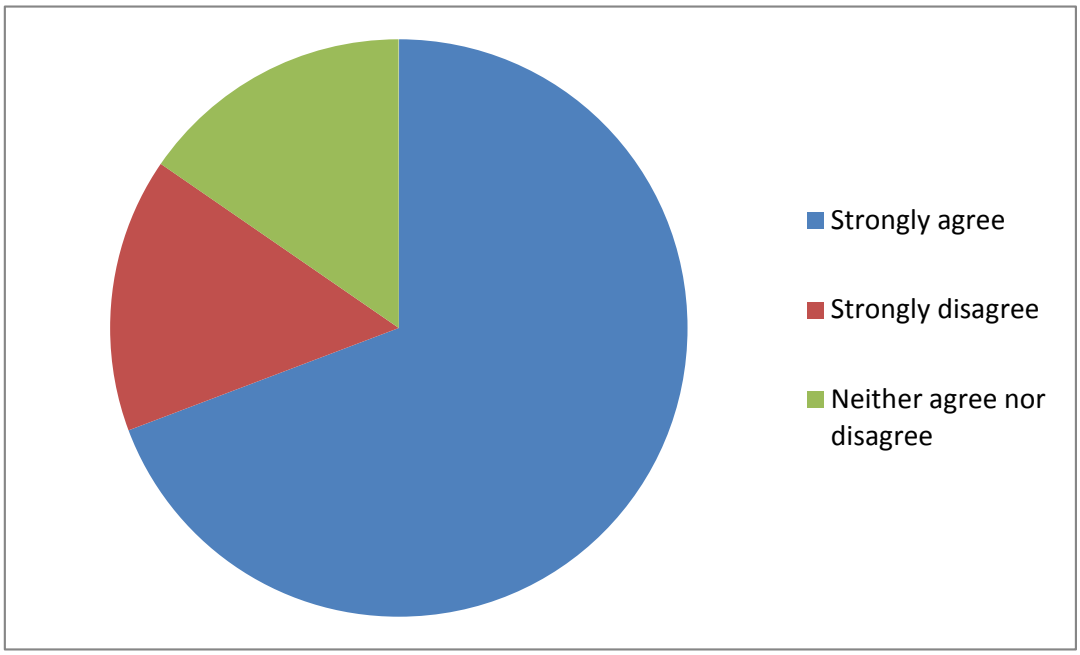
| Response | Comments |
|---|---|
| Strongly agree | yes because they are aware of the need to check hearts, eyes etc but unless have knowledge of calf palate wouldn't even consider the value. Parents are upset when they see in the red book (PHCR) that palate is not circled as checked or at worse assessed as normal only weeks down the line to find out was a cleft palate and misdiagnosis has been made. |
| Strongly agree | they need to know this and why it is important |
| Neither agree nor disagree | Parents should be informed if the whole palate (including the soft palate) is not inspected. Partial or complete separation of the uvula alone without other separation of the soft palate is unlikely to represent a diagnosis of overt cleft palate. Bifidity of the uvula alone without cleft palate is reported to affect up to 10% of the population. Visual inspection of the uvula can also be difficult for experienced clinicians using the appropriate method of visual examination. It would therefore be reasonable to conclude that if the hard and soft palate are intact on visual examination that no cleft palate is present even if the whole of the uvula is not visualised, despite repeated attempts. It would be reasonable and recommended to record in the patient records that the uvula was not visualised. |

**11. If the whole palate is not inspected at first attempt then a further attempt at visual inspection should be made within 24 hours**




Consensus achieved: 77% strongly agree

**12. If the whole palate (including the uvula) is not inspected, healthcare professionals should recommend to parents that their baby is reviewed if there are feeding difficulties or nasal regurgitation during feeding occurs.**



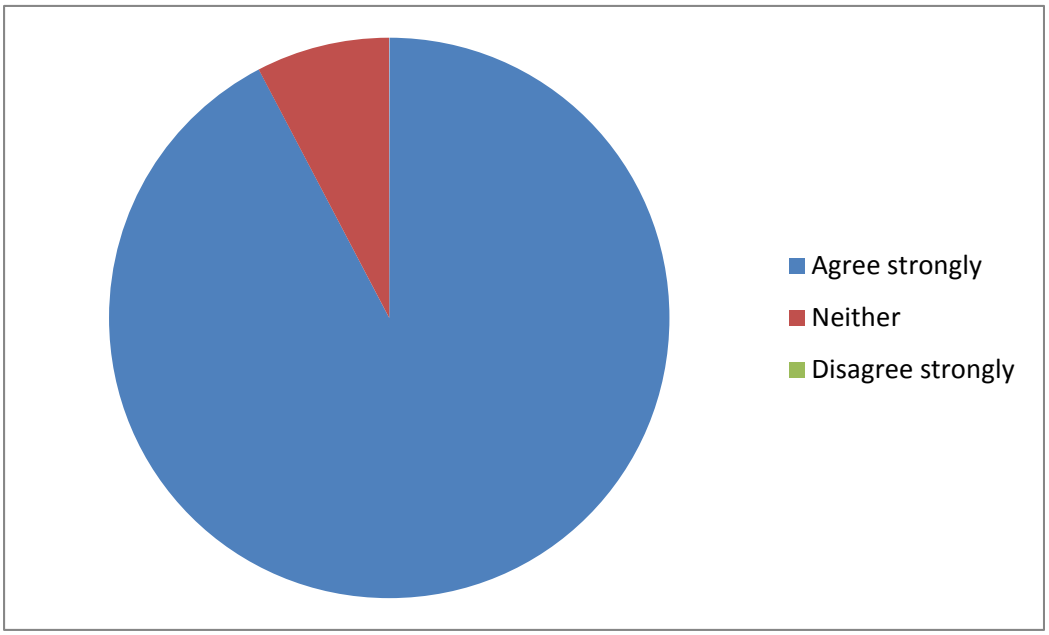

Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | preferably with somebody senior who understands the importance of a complete visualisation |
| Strongly agree | Definitely but some parents might not feel able to ask for help or speak to a healthcare professional. I have had parents who have tried only to be told that the symptoms are 'normal' I even had one GP who refused to check the baby's mouth when the mother thought he had a cleft palate so I don't think this would help unless the health professional had reasonable knowledge of cleft palates |
| Strongly agree | yes, this would be an indication for further inspection |
| Neither agree nor disagree | The parents should be alerted to these potential signs but further attempts to visualise the palate should be made |
| Neither agree nor disagree | Again depends on the perceived added value of inspection vs palpation. |
| Strongly disagree | This approach could lead to an unnecessarily high number of parents seeking review as feeding difficulties and/or nasal regurgitation in the absence of cleft palate are not uncommon. This would cause inappropriate anxiety for parents due to unfounded concerns of cleft palate. Furthermore this recommendation could be used as a 'get-out clause' when visual examination of the palate has been clinically inadequate or indeed not even attempted. |
| Strongly disagree | Agree with statement 11. |

## 5. Round two statements and results

The statements from round two are presented below along with a pie chart of participants responses any comments made by the panel.

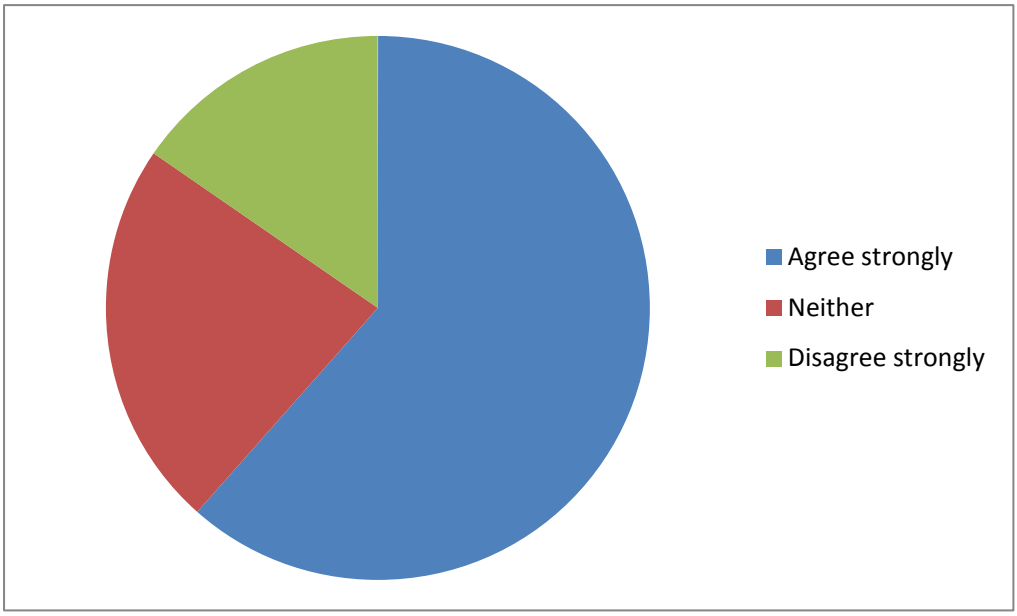
**1. The inspection of the hard and soft palate by visualisation is an integral part of the neonatal full physical examination and should be recorded as part of the child health record; training in palatal inspection should be provided alongside training in the conduct of the examination.**




Consensus achieved: 92% strongly agree

| Response | Comments |
|---|---|
| Strongly agree | Training is currently provided as part of our NIPE module |
| Strongly agree | To avoid cross infection to the baby is important to state that the wooden spatulas are sterilized in individual packs |
| Neither agree nor disagree | It is the practicality of doing this as a sole practitioner that causes difficulty. If is often impossible to visualise palate without two people contributing to examination and there are rarely two clinicians doing this together in most settings. It is not appropriate to ask mother to hold a baby firmly in the way required in first few hours/day or so after birth |

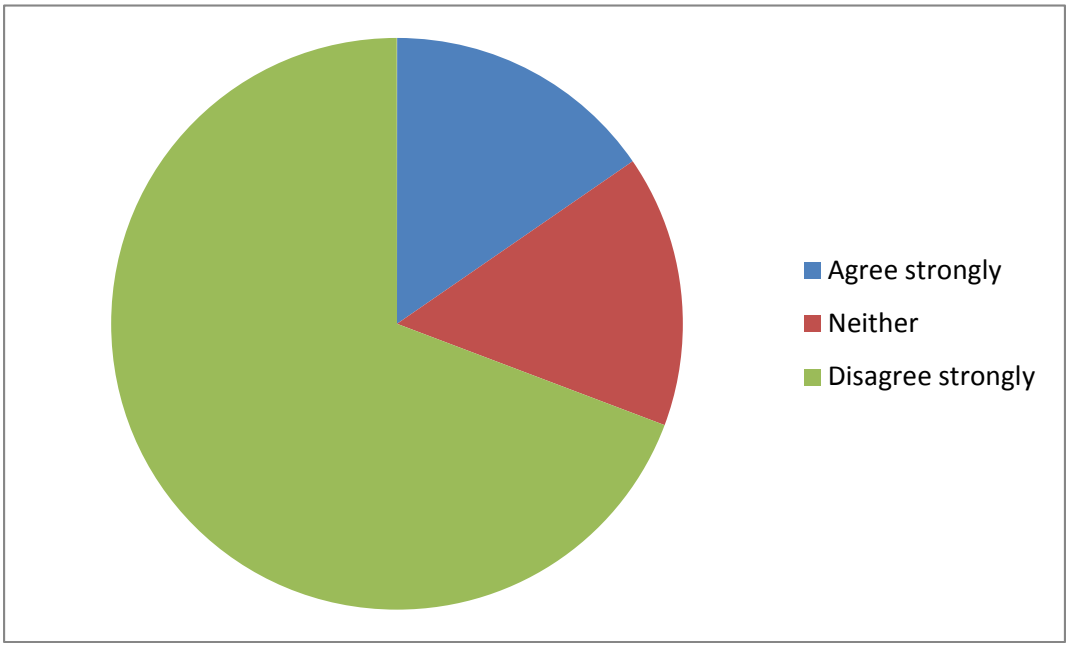
**2. Palate examination should be carried out by both palpation and visual inspection**




Consensus not achieved

| Response | Comments |
|---|---|
| Strongly agree | This is what is currently recommended and taught |
| Strongly agree | To ascertain the shape and other deviations of the gums and palate it is important to undertake both palpation and visualization. It is also important to ascertain the strength of the sucking and swallowing reflex and to ascertain whether or not the baby has a gag reflex which are also very important factors to ascertain prior to assessing the soft palate. |
| Strongly agree | visual inspection is the most important aspect however and should be carried out with an appropriate light source the tongue should be depressed and the uvula should be visualised |
| Neither disagree nor agree | it is the practicality of doing this as a sole practitioner that causes difficulty. If is often impossible to visualise palate without two people contributing to examination and there are rarely two clinicians doing this together in most settings. It is not appropriated to ask mother to hold a baby firmly in the way required in first few hours/day or so after birth |
| Neither disagree nor agree | Visual inspection is key |
| Neither disagree nor agree | visual exam is more important |
| Strongly disagree | only visual examination is needed |
| Strongly disagree | Visual inspection of the whole palate is the gold standard. Change wording to 'Examination of the hard and soft palate must be carried out by visual inspection. Palpation of the palate adds nothing further to the diagnosis of cleft palate under these circumstances. |

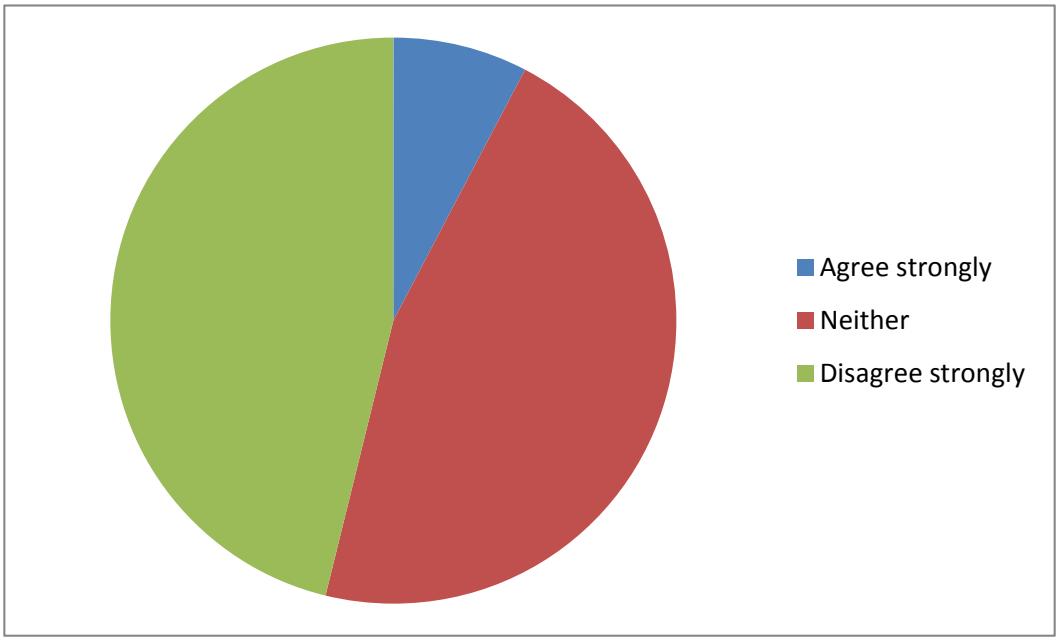
**3. In cases where visual inspection is incomplete (so the whole of the palate is not seen) palpation should be carried out and the result be relied upon to determine presence or absence of a cleft.**




Consensus not achieved

| Response | Comments |
|---|---|
| Disagree strongly | Palpation and visualisation together are essential |
| Disagree strongly | The visualization should be deemed vital to the assessment thus if not undertaken it is not complete assessment |
| Disagree strongly | A repeat visual inspection and history of poor feeding necessitate a repeat examination at a subsequent time and by a cleft team member |
| Disagree strongly | sub mucosal clefts may be missed |
| Disagree strongly | in such cases points 6 and 7 apply |
| Disagree strongly | This would be very unreliable and lead to missed diagnoses and inappropriate management. |
| Neither agree nor disagree | Babies that have other abnormalities may be difficult to examine and to open their mouth so I would tend to "keep on the books" until a cleft could be excluded. |

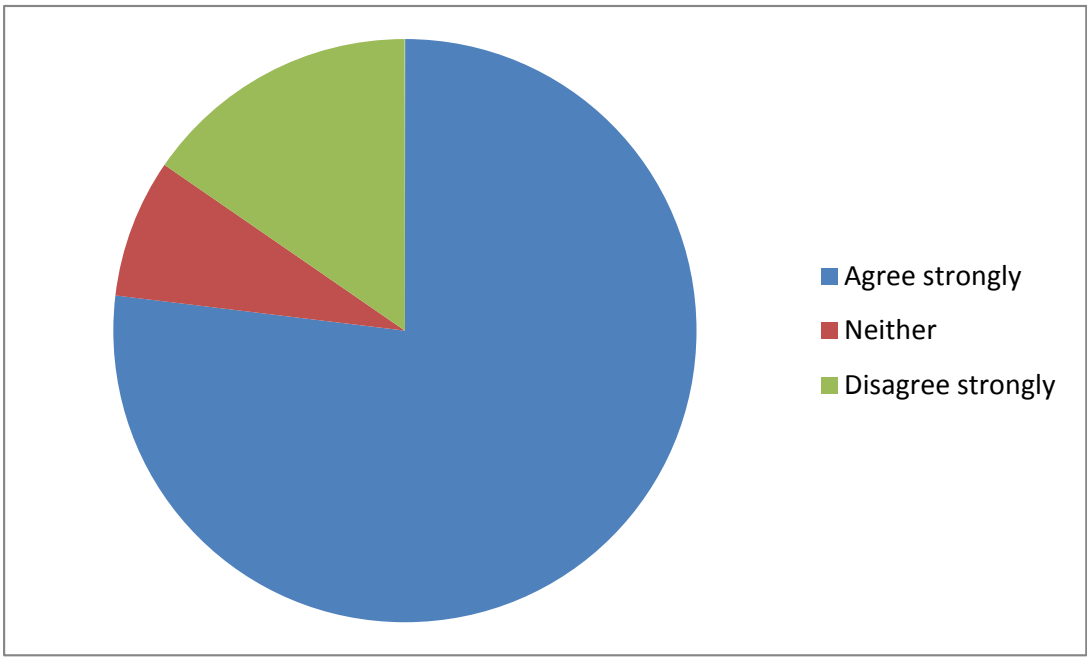
**4. Digital examination may improve diagnostic accuracy once a cleft has been detected visually**




Consensus not achieved

| Response | Comments |
|---|---|
| Agree strongly | Palpation should be undertaken first and then visualization 2nd. |
| Disagree strongly | The accuracy of diagnosis of 'cleft palate' is not improved by digital examination. Visual detection alone is sufficient for cleft palate. |
| Disagree strongly | Why palpate when you can see it. Primary practitioner would refer to cleft team on visualisation almost certainly. |
| Neither disagree not agree | I am not aware that this would be necessary if it has been diagnosed via visualisation although it is likely to have been carried out first anyway. It is best to refer to the cleft palate team straight away. |
| Neither disagree not agree | If there is a clear cleft then the management remains the same so the extent of the muscle defect is not necessarily relevant to the frontline staff but would obviously be documented by the surgeon following palate repair. However in the case of a SMCP where it is difficult to visualise the translucent area a palpation to identify a hard palate notch maybe helpful. |
| Neither disagree not agree | Once the cleft has been visualised there would be no need to palpate for a more accurate diagnosis |

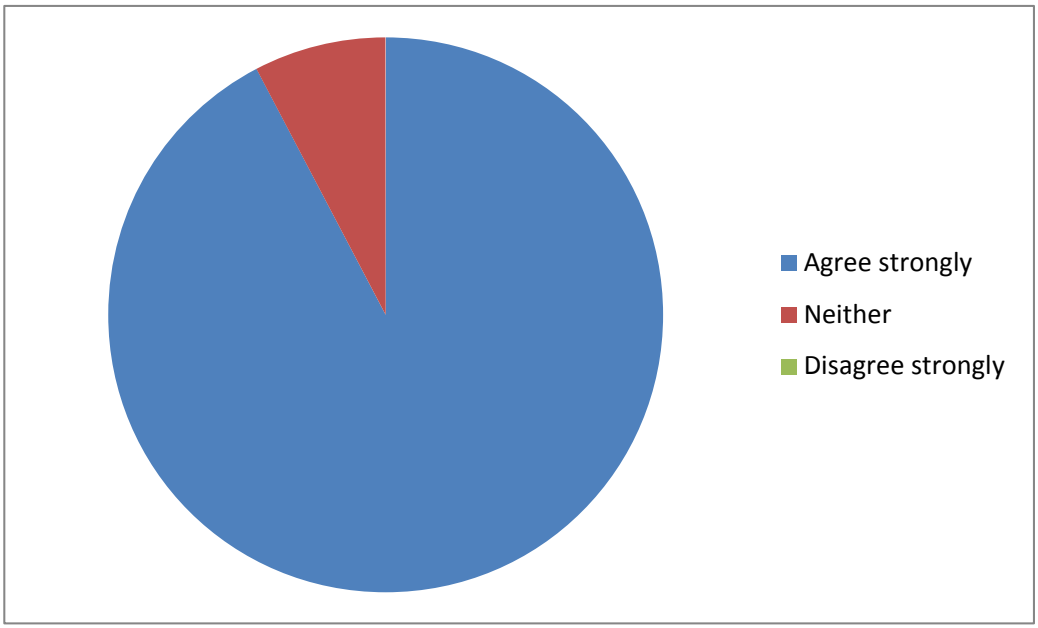
**5. Visual inspection of the palate correctly performed is more likely to detect clefts of the palate, excluding submucous clefts, than palpation/digital examination alone.**




Consensus achieved: 77% strongly agree

| Response | Comments |
|---|---|
| Agree strongly | also please note Visual inspection of the palate correctly performed is also more likely to detect sub mucous cleft palates, than palpation/ digital examination alone |
| Agree strongly | Fully agree as long as 'correctly performed' means inspection of the whole palate from the incisive papilla (just behind the upper front gum area) to the uvula at the back of the soft palate with a good light source. |

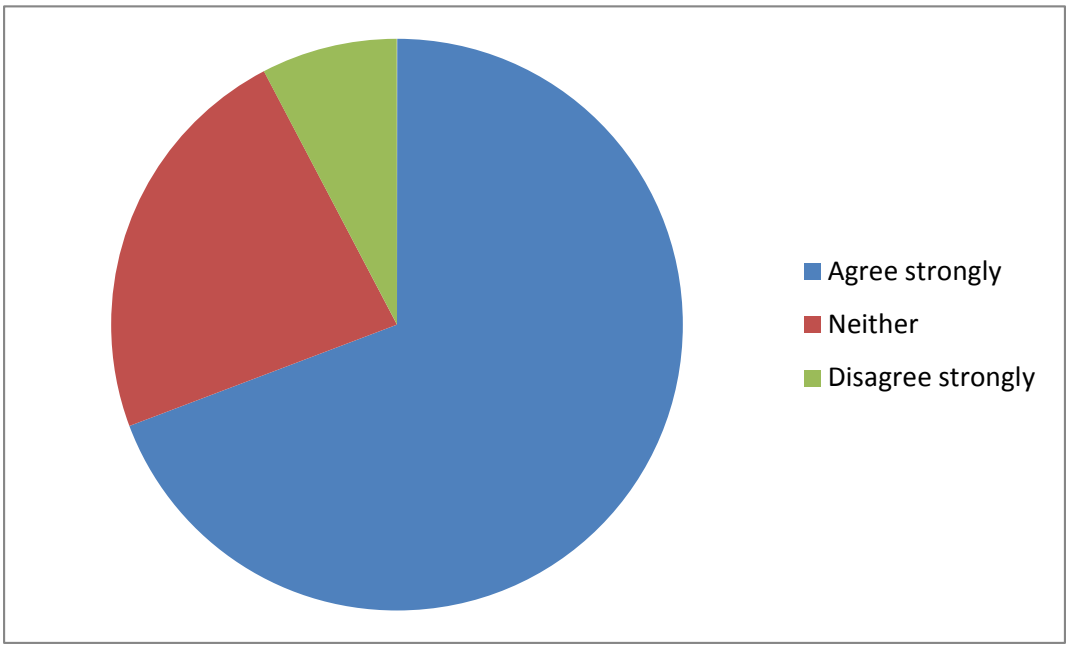
**6. Parents should be informed if the whole palate (including the full length of the soft palate) could not be seen**




Consensus achieved: 92% strongly agree

| Response | Comments |
|---|---|
| Agree strongly | Parents should always be informed of the outcome of the examination and if a referral is necessary to complete the examination |
| Agree strongly | The parents should be informed prior to the examination what it entails and what we are we examine and what will be deemed a full a examination If we informed them correctly they are proving informed consent to the procedure and if it's not complete with be encouraged to make sure that baby obtains the full examination. |
| Agree strongly | Yes but an experienced specialist will also be able to examine for other signs such as feeding, clicking sound that would support a confident diagnosis. |
| Agree strongly | Parents need to understand the accuracy of the screening examination. |
| Agree strongly | And recorded in records and arrangements made for repeat examination of the palate during the period of confinement either by the same individual or another healthcare professional competent in palate examination. |
| Neither agree nor disagree | Probably reasonable to make them aware of potential feeding issues etc that might prompt earlier review. |

**7. Healthcare professionals should delay discharging the baby home until the whole palate has been inspected, or arrange to return for review as soon as practicable**




Consensus not achieved

| Response | Comments |
|---|---|
| Neither disagree nor agree | Babies can be discharged but have the NIPE check in the community to include this examination |
| Neither agree nor disagree | Not practical. Babies are examined in the community by midwives who have received examination of the newborn training and education. Babies should not be kept in hospital if feeding well. Further attempt to visualise the palate should be made at a later date. |
| Neither agree nor disagree | I don't think discharge should be delayed but he parents should receive a full explanation of the concerns and be encouraged to see the midwife or GP in the community (or return to the hospital)as soon as possible. This should be documented in the notes and communication with the wider MDT must be a priority. |
| Agree strongly | This would be the best policy. Examination of the palate in a neonate is usually straightforward. If a child were discharged home without the whole palate being inspected, I would be concerned that this could then be overlooked and the opportunity missed. I would also be concerned that this could encourage a more 'relaxed' approach by some practitioners carrying out the neonatal check, in other words a cursory examination of the mouth and palate, tick 'whole palate not seen' discharge and arrange review. I would not encourage such an approach. |
| Agree strongly | I would not delay but arrange an early refer with a more senior paediatrician |
| Agree strongly | combined with an holistic assessment of feeding and other indicators of cleft palate |

| Response | Comments |
|---|---|
| Agree strongly | I don't think a baby should be brought back to the hospital for a palate examination as routine follow up. If theory are discharged it would be more prudent to have community practitioners who can perform a full newborn examination which excludes the palate. |
| Agree strongly | Discharge may not have to be delayed but a review must be arranged |
| Agree strongly | It is important to note that not all births are in hospital but are undertaken in standalone birth centres or home birth and some babies are sent home without the full assessment. It is important that this procedure is mandatory for midwives undertaking the examination following birth and that needs to be national directive to make sure that pre-registration midwives are taught to assess the soft and hard palate correctly. The process of assessment should be on a teaching video to support the appropriate assessment to make sure that the baby is swaddled and the head supported to avoid movement while the spatula is inserted in the baby's mouth to avoid damage to the mucosa. A teaching video will hopefully be provided to support any guideline which may be produced to support safe practice. Please feel free to let me know if you wish to have support to make this video to support all practitioners to undertake this part of the holistic assessment. |
| Agree strongly | A complete examination should always be finalised prior to parents going home to ensure a correct care plan is in place and relevant referrals |