Cleft Research Workshop
Bristol Marriott Royal Hotel
4th – 5th of March 2010
The second workshop, as previous, was organized under the aegis of the Craniofacial Society and the NIHR programme “Evidence based health care for major congenital and acquired problems of the head and neck”. Clinicians, researchers and user representatives participated in the workshop with a focus upon the objectives of the NIHR grant. These broadly are to host workshops and develop a formal research strategy; to conduct systematic reviews and to evaluate the current care of children with cleft lip and palate. The workshop generated a warm atmosphere and insightful discussions from all participants about cleft research and cleft care.

You will find in the proceedings; the attendees list, the program and the presentations and notes in the order they appeared in the program.

We would like to thank all those who attended for their contributions that made this workshop so successful.

Yours sincerely,

Jonathan Sandy
Professor in Orthodontics/
Head of Department of Oral & Dental Science.

Andy Ness
Professor of Epidemiology/
Co-Director the Avon Longitudinal Study of Parents and Children
Cleft Workshop Attendance List Bristol Royal Marriott 2010

Liz Albery
Charlotte Atkinson
Tricia Bannister
Amanda Bates
Diane Beaumont
Alyson Bessell
Sara Brookes
Susan Butcher
Sue Carroll
Raouf Chorbachi
Mechelle Collard
Julie Davies
Scott Deacon
Caroline Drugan
Brendan Eley
Terry Gregg
Alex Griffiths
Piet Haers
Per Hall
Daniella Hearst
Christopher Hill
Peter Hodgkinson
Will Hollingworth
Nichola Hudson
Melissa Ke
Karine Latter
Sam Leary
Cathy Marsh

Felicity Mehendale
Sue Mildinhall
Andy Ness
Jayne O'Connell
Tina Owen
Martin Persson
Ron Pigott
Rosanna Preston
Arup Ray
Sue Ring
Anne Roberts
Sue Roulstone
Nicky Rumsey
Joyce Russell
Jonathan Sandy
Julia Scott
Debbie Sell
Gunvor Semb
Bill Shaw
Rona Slator
Jackie Smallridge
Sarah Smithson
Henrietta Spalding
Adrian Sugar
Harriet Templeman
Andrea Waylen
Sue Ziebland
CLEFT RESEARCH WORKSHOP
Location – Bristol Marriott Royal Hotel
March 2010

Thursday 4th March – Cathedral Room 5

COFFEE/TEA  Registration  9.30 – 10.30

Session 1  Cleft Research and beyond (Chair Jonathan Sandy)
Jonathan Sandy  Welcome and introduction  10.30 – 10.40
Susan Roulstone  Speech and language therapy – challenges that face the wider discipline  10.50 – 11.20
Bill Shaw  Manchester Cleft Centre  11.20 – 11.40
Andy Ness  Generation Cleft  11.40 – 12.00
Discussion  12.00 – 12.30

LUNCH  12.30 – 1.30

Session 2  The NIHR programme (Chair Andy Ness)
Andy Ness  Introduction  1.30 – 1.40
Alyson Bessell  SLT review  1.40 – 2.00
Jules Scott  Cleft team questionnaire  2.00 – 2.20
Melissa Ke  Health Economics  2.20 – 2.40
Martin Persson  CSAG II – the story so far  2.40 – 3.00
Discussion  3.00 – 3.30

TEA/COFFEE  3.30 – 4.00

Session 3  Other perspectives (Chair Nichola Rumsey)
Nichola Rumsey  Introduction  4.00 – 4.10
Amanda Bates  User perspectives  4.10 – 4.30
Sue Ziebland  HealthTalkonline  4.30 – 5.00
Trisha Bannister  Nurse perspective  5.00 – 5.20
Discussion  5.20 – 5.45

DINNER  The River Station  7.30
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<thead>
<tr>
<th>Time</th>
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<tr>
<td>9.00 – 10.00</td>
<td>TEA/COFFEE</td>
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<td>10.00 – 11.00</td>
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<td><strong>Parallel sessions</strong></td>
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<td><strong>User involvement (Martin Persson, College room 1)</strong></td>
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<td><strong>Generation Cleft (Andy Ness, Cathedral room 5)</strong></td>
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<td><strong>Manchester Cleft Centre (Bill Shaw, Cathedral Room 1)</strong></td>
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<td>11.00 – 11.30</td>
<td>TEA/COFFEE</td>
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<td><strong>Feedback &amp; discussion (panel of session chairs, Cathedral room 5)</strong></td>
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<td>Jonathan Sandy Closing remarks</td>
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<td>11.50 – 12.00</td>
<td>LUNCH</td>
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**Friday 5th March**

*Andy Ness*

23rd February 2010
Speech and language therapy – challenges that face the wider discipline

Sue Roulstone
Classification

Speech Disorders
Articulation  Phonological

Classification

Speech Sound Disorders
Articulation  Phonological
Speech sound disorders

- Phonological delay
- Consistent deviant phonological disorder
- Inconsistent deviant phonological disorder
- Articulation disorder
- Childhood apraxia of speech

Shriberg (1994, 2006)
- Speech delay
  - Genetic
  - Otitis media
  - Developmental psychosocial involvement
  - Apraxia
  - Dysarthria
- Speech errors - residual

Stackhouse & Wells, 1997, 2001
- Psycholinguistic model

Semantic representation
  - Phonological representation
    - Phonological recognition
      - Phonetic discrimination
        - Speech/non-speech recognition
          - Peripheral auditory processing
  - Motor programme
    - Motor programming
      - Motor planning
        - Motor execution
## Intervention approaches for SSD

<table>
<thead>
<tr>
<th>Phonological</th>
<th>Motorically based interventions</th>
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<tr>
<td>Constraint based nonlinear</td>
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<td>Core vocabulary</td>
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<td>Empty set</td>
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<td>Imagery therapy</td>
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<td>Minimal oppositions</td>
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<td>Metaphon</td>
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<td>Metaphonological intervention</td>
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<td>Minimal opposition contrast</td>
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<td>Mnemonic</td>
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<td>Multiple opposition contrast</td>
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<td>Natural speech intelligibility training</td>
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<td>Parents and children together</td>
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<td>Phonotactic therapy</td>
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<td>Psycholinguistically based intervention</td>
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<td>SALS</td>
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<td>Enhancing stimulability</td>
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<td>Whole language therapy</td>
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Baker 2006

## Targets

### Traditional
- Developmental
- Socially important
- Stimulable
- Minimal contrasts

### Recent
- Later sounds first
- Nonstimulable
- Maximal contrasts
Techniques

**Phonological**
- Auditory input
- Phonological awareness
- Making meaningful contrasts
- Stimulability

**Articulatory**
- Auditory discrimination
- Feedback:
  - Electropalatography
  - Auditory masking
  - Self monitoring
- Imitative modelling
- Non-speech sound stimulation and shaping
- Phonetic placement techniques
- Nasal occlusion
- Use of imagery
- Drills

**Intervention organisation**

**Focus**
- Group vs individual
- Adult personnel involved
- Child involved

**Purpose**
- Assessment
- Referral on
- Review
- Regular intervention

**Timing**
- Immediacy
- Length of episode
- Frequency
- Pathway
Complex system

Meaningful classification

Non-distinct and overlapping approaches

Emerging targets

Techniques with many theories

Infinite variety

So plenty to be done then!

susan.roulstone@uwe.ac.uk

www.speech-therapy.org.uk
Bill Shaw
Application to Establish the Healing Foundation UK Centre for Cleft Research

Good Clinical Practice (GCP)

Developed by regulatory authorities of EU, Japan, USA: Tripartite International Conference on Harmonisation (ICH, 1996)

- Data/results of investigations credible and accurate
- Rights, safety, confidentiality protected
- Since 1997 effective as “best practice”
- Since 2004 EU Directive “legal obligation”
13 Principles of GCP

- Ethical, risks/benefit, well-being of subjects, available info to support trial, sound protocol, IRB/IEC approval, care by qualified physician, all qualified/trained for tasks, informed consent, process allows accurate recording reporting, confidentiality, product appropriately handled, systems assure quality of every aspect

‘Best Research for Best Health’
January 2006

- National Institute for Health Research
- 5 year R&D strategy in England (Cooksey)
  MRC/NHS R&D merged (£1b pa)
- New structures, programmes, reallocation
- NHS support costs and infrastructure
- Where would CLP fit?
  - Medicines for Children Research Network
    (Topic specific networks) MCRN
  - Non-medicines Paediatric Speciality Group
Clinical Studies Groups

- Anaesthesia, Intensive Care, Pain Control and Cardiology: Dr Rob Teaker
- Diabetes, Endocrinology & Metabolic Medicine: Prof David Dunger
- Gastroenterology, Hepatology & Nutrition: Dr Stephen Murphy
- General Paediatrics (including Dermatology): Dr Colin Powell
- Methodology: Dr Peter Brocklehurst
- Neonatal: Prof David Field
- Neurosciences: Dr William Whitehouse
- Pharmacy & Pharmacology: Prof Ian Wong
- RAN1 (Rheumatology, Allergy, Nephrology, Infection, & Immunology): Dr Mike Sharland
- Respiratory & Cystic Fibrosis: Prof Jonathan Grigg

Medicines for Children Research Network

Specialty Group Chairs

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<th>Specialty Group</th>
<th>Chair</th>
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What the investment would buy:

- A lasting UK-wide resource dedicated to applied cleft clinical research
- Assembly of a core team under the same roof with the expertise required for world class research
- Immediate benefits of alignment within the UK’s new NHS research structures
- Research priorities set by a national “Clinical Studies Group” including users
- Entry to a top class network of research partners locally, nationally, internationally
- A portfolio of externally funded research with defined short, medium, and long-term deliverables

Project Types

- High priority clinical trials
- Other well-designed outcome studies
- Improvements in diagnosis and in understanding causality and risk of occurrence
- Evaluations of burden-of-care versus gain-in-outcome (patient preferences)
- Economic analysis
- Refinement of outcome measures
- Dissemination and implementation
- Patient choice in information and management plans
Clinical Studies Groups

- Allergy, Infection & Immunity
- Anaesthesia, Pain, Intensive Care, Cardiology (APICC)
- Diabetes, Endocrinology & Metabolic Medicine
- Gastroenterology, Hepatology & Nutrition
- General Paediatrics (including Dermatology)
- Methodology
- Neonatal
- Neurosciences
- Pharmacy & Pharmacology
- Respiratory & Cystic Fibrosis
- Rheumatology
- Nephrology
- Inherited Metabolic Disorders
- ? Cleft and Craniofacial Anomalies

PROACTIVE ROLES
- To identify research priorities within specialty area
- To propose and develop trial ideas and proposals
- Representatives sit on MCRN Operational Group

REACTIVE ROLES
- To work with investigators to develop study ideas to successful funding application
- To provide subject specific and methodological advice to investigators
- Representatives sit on MCRN Trial Adoption Committee

CLEFT AND CRANIOFACIAL ANOMALIES CSG
- User representative
- Professional representatives from CFSGBI and UK Cleft Genetics Group
- CLAPA representative
- International representative
- Appointed chair
MCRN Clinical Trials Unit

- Successfully argued need for CTU dedicated to paediatric research
- Core staff in post September 2005
- Sixteen studies funded, four submitted/in development
- Eight open, five in set-up, three closed

TOPS Trial
(Timing Of Primary Surgery for cleft palate)

650 infants with non-syndromic cleft palate

Randomise

Surgery at age 6 months
Surgery at age 12 months

6 Months

Surgery at 6 months

12 Months

12 month Assessment
Surgery at 12 months

3 Years (36 months)

3 Year Assessment

5 Years (60 months)

5 Year Assessment of Final Study Outcome

Shaw Semb Williamson Clayton-Smith
Funded: NIH
International Trial Sites

Scandcleft RCTs of primary surgery

Recruitment completed all three trials
150 babies with UCLP per trial

Sem et al., 2005
Funded: EU
World Health Organisation Trials Priorities

- Surgical methods for the repair of different orofacial cleft subtypes, not just unilateral clefts;
- Surgical methods for the correction of velopharyngeal insufficiency;
- Use of prophylactic ventilation tubes (grommets) for middle-ear disease in patients with cleft palate;
- Procedures in cleft care that place an increased burden on the patient, family or medical services, such as presurgical orthopaedics, primary dentition orthodontics and maxillary protraction;
- Methods for management of peri-operative pain, swelling and infection; and nursing;
- Methods to optimize feeding before and after surgery;
- Addressing the special circumstances of care in the developing world in respect of surgical, anaesthetic and nursing care;
- Different modalities of speech therapy, orthodontic treatment and counselling.

Patients’ Perspectives

- Measurement of patient empowerment as a primary patient benefit (McAllister, J Health Psy 2008)
- Studying children and young people with complex needs (Callery, Childcare Health Dev 2008)
- What are the health economic implications of different models of care? (Payne, Genetic Med 2008)

Core Outcome Measures in Trials
...will be launched in Liverpool, January 2010

Funded: MRC, NIHR
Why do we study syndromic clefting?

- 40% clefts are syndromic
- Individually rare, collectively important
- Families seek a diagnosis, explanation and advice for future pregnancies
- Implications for broader management of the child
- Implications for research
- Can provide clues to the causes of non-syndromic clefting

Van der Woude Syndrome

- Cleft lip/palate and lip pits
- Autosomal dominant
- Mutations in IRF6 (Murray, Dixon et al. Nature Genetics 2002)
- Sequence changes in IRF6 contribute 18% of susceptibility to non-syndromic clefting

Funded: Wellcome Trust
Genetic testing for Treacher Collins Syndrome introduced into clinical practice

- EU Diagnostic network
- Facilitates free and secure access to expert opinions on rare disorders
- Incorporates management guidelines

*Funded: EU DG Sanco 2007-10*
Patient management - Velocardiofacial Syndrome

Cleft, cardiac defects, hypocalcaemia, learning disability, impaired immunity

Delivering better genetic services

- Qualitative research study using modified grounded theory approach
- When, how and where do families want to receive genetic information and from whom
- Views of parents, cleft team and geneticists
- Aim to develop training resources and new models of providing genetic services
Key deliverables (infrastructure)  
Year 1

- Build teams and make appointments (CSG)
- Establish governance group and patient panel
- Develop strategy and KPIs (HF input)
- Appoint first NIHR trainees
- Website published
- First training conference

Key deliverables (infrastructure)  
Year 1

- Identify projects
- Apply NIHR research for patient benefit
- Initial steps NIHR programme grant
- Wellcome Trust programme for genetics analysis
bill.shaw@manchester.ac.uk
Generation cleft – a large prospective population based DNA backed resource

Andy Ness

Co-applicants (in alphabetical order)
Liz Albery                        George Davey Smith
Tony Ireland                     Susan Ring
Nicky Rumsey                     Jonathan Sandy
Steve Thomas

Structure of talk

• The potential contribution of the gene bank
• The value of prospective studies
• Proposals for generation cleft
Potential contribution of the gene bank

- Common variants of modest effect
- Cleft traits through familial phenotype
- Parent of origin effects – trios
- Draw causal inferences
- Identify families for detailed study
- Study of other traits (e.g. wound healing)
Type 2 diabetes
**FTO and obesity**

*Does my bum look big in these genes? Absolutely, say scientists*

**Homozygote ~3kg**
Per allele association with overweight
OR 1.18 (95% CI 1.14, 1.23)

Per allele association with obesity
OR 1.32 (95% CI 1.26, 1.39)

Association with fat but not lean mass


DXA scan data (analysis performed in ALSPAC)

Maternal FTO and fat mass

The value of prospective studies
Case control study

PAST  PRESENT  FUTURE

RETROSPECTIVE CASE CONTROL

STUDY

Exposure recalled

Cases and controls identified

Cheap and quick
Prone to bias

Cohort study

PAST  PRESENT  FUTURE

PROSPECTIVE COHORT STUDY

Exposed measured

Outcome recorded

Avoids bias
Doesn’t remove confounding
Strengths (and limitations) of cohort studies

• Natural history of conditions
• Temporal nature of associations
• Multiple common outcomes
• Minimise bias

BUT
• Expense and time (clinical cohorts)
• Rare diseases (unless traits)
• Trapped in time (unless sequential)
• Adequate records and loss to follow up

The Avon Longitudinal Study of Parents and Children (ALSPAC)

- A.k.a. Children of the nineties
- Cohort study
- Pregnant with a due date 1.4.91-31.12.92
- Resident in Avon (South West England)
- Enrolled pregnancies 14,541
- Following 13,801 mothers, 13,971 children
The Avon Longitudinal Study
ALSPAC
of Parents and Children

£3.5 million per year
120+ staff

Close up of Actigraph uni-axial movement sensor
An example of the graphical output from the Actigraph (1 day’s recording)

Serial DXA scans every two years from age 9+

Child having total body DXA scan on a Lunar Prodigy

Total Body Scan output showing different sub-regions
ALSPAC resource – current status

• Before birth to age 15+ (n~5,500)*
• DNA bank on children (n~11,000)
• DNA bank on mothers (n~10,000)
• Blood for cell lines on children (n~6,900)
• Blood for cell lines on mothers (n~5,800)
• Blood for cell lines on fathers (n~1,300)

* At recent data collection points

Activity, body composition and CVD

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<th>Late puberty</th>
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<td>9 10 11 12 13 14 15</td>
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<td>FM</td>
<td>FM FM FM FM</td>
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<td>PA</td>
<td>PA PA PA</td>
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<td>FM</td>
<td>CVD CVD CVD</td>
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* = fasting

Associations between MVPA and fat mass ages 12-14y

Change in fat mass with increased MVPA

-14.6%  -12.4%  -11.9%  -9.3%  -5.2%  -2.4%  -2.3%

+15 mins/day MVPA at 12yrs, fat mass at 12yrs
+15 mins/day MVPA at 12yrs, fat mass at 14yrs
+15 mins/day MVPA at 14yrs, fat mass at 14yrs
+15 mins/day change in MVPA 12-14yrs, change in fat mass 12-14yrs

boys   girls (with 95% confidence interval)

% change in fat mass

Riddoch et al, *BMJ* 2009; 339:b4544

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Proposals for Generation Cleft
Generation cleft – illustrative questions

• What factors influence adaptation and resilience?
• Is educational attainment lower? And if so why?
• What are the determinants of speech outcome?

Generation cleft – the cohort

• 3,500 families
• Recruited over 4 years
• Flexible time of recruitment
• Informed consent (genetics, linkage and follow up)
**Generation cleft – baseline**

**Data**
- Information from notes
- Health and lifestyle questionnaire
- Family history
- 3D face shape

**Biosamples**
- DNA on parents and cell lines on children
- Other samples – e.g. cord, hair, milk teeth (requires funding)
Generation cleft – follow up

3yr
• Child behaviour and parent-child relationship
• Growth and development
• Speech and language

5yr
• CSAIII, cognition and blood sample

7yr
• Educational attainment

Generation cleft – timelines

Year 1
• Appoint Bristol staff January 2011
• First 6mths prepare protocols and submit to ethics
• 2nd 6mths appoint and train staff and pilot measures

Years 2-5
• Years 2-5 recruit families to the study
• Year 5 collect 3yr follow up data on first ¼ of cohort

Later years
• Future follow up depends on further funding
Any questions?

The New Yorker, November 2001

"And it was so typically brilliant of you to have invited an epidemiologist."
Andy Ness
Evidence based health care for major congenital and acquired problems of the head and neck

Ness AR  Birchall M
Burton M  Fisher S
Nutting C  Peters T
Rogers S  Rumsey N
Sandy J  Thomas S
Thompson C  Worthington H

Aims of the programme

- Identify **KEY RESEARCH QUESTIONS** in partnership with users and clinicians and incorporate these into **FORMAL RESEARCH STRATEGIES**

- **SYSTEMATICALY REVIEW & SYNTHESISE** quantitative and qualitative evidence and translate this into **EVIDENCE-BASED PRACTICE GUIDELINES**

- **EVALUATE & DISSEMINATE THE OUTCOME** of centralisation in CLP and H&N
New staff appointed

Dr Alyson Bessell
Systematic reviewer

Dr Melissa Ke
Health Economics

Workshops and strategy

• February 26th-27th 2009
• Current workshop – 4th-5th March 2010
• Future workshops – timing, format and content?
• Strategy development?
Systematic reviews and guidelines

- Completed - Grommets review and NICE guidance
- Current - Speech and language, others
- Findings of Cochrane wound healing group
- Future I - ?psychological interventions ?other ideas
- Future II - qualitative synthesis
- Guidelines?

Evaluation of centralisation of cleft care

- Cleft team survey
- Economic evaluation
- CSAGII+ or CSAGIIR
- Additional ABG audit?
- Dissemination
NIHR head and neck programme

• Workshops 29th-30th April 2009
  20th-21st May 2010
• Systematic reviews Alysson just appointed
• Clinical cohort Draft protocol March 2009

Clinical cohort head and neck cancer

• 5,000 cases of head and neck cancer
• Centre survey – network, oncology and MDT
• Clinical details and care provided
• Blood sample and consent
• Individual characteristics and health and lifestyle
• Outcome – quality of life, morbidity and mortality
• Recruitment to start September 2010
Clinical cohort head and neck cancer

The New Yorker, November 2001

“And it was so typically brilliant of you to have invited an epidemiologist.”
Or maybe you just invited the wrong epidemiologist?

Thankyou
Speech and Language Therapy Review

Alyson Bessell, Liz Albery, Andy Ness, Martin Persson, Sue Roulstone & Debbie Sell

Objectives

- To present best available evidence related to the value of Speech and Language Therapy (SLT) in children with clefts across all age ranges:
  - Assess evidence to support efficacy of SLT compared to no intervention.
  - Assess which types of intervention appear more effective.
  - Assess whether timing of SLT affects speech outcomes.
  - Assess whether SLT impacts on other aspects of communication and psychosocial wellbeing.
Background

- Analysis of 212 pre-school children with repaired clefts - 68% enrolled in speech therapy\(^1\).
- The majority of children require direct SLT intervention\(^1\).
- No systematic reviews to summarise evidence for SLT interventions for children with clefts.
- Enderby & Emerson (1995\(^2\)) - research to investigate the effectiveness of SLT interventions ‘somewhat sparse’ and poor quality.

Approaches to Speech Therapy

- Babble workshops
- Input modelling
- Psycholinguistics processing
- Phonological Approach
- Traditional articulation therapy
Search Strategy

- **Population**: Children with non-syndromic cleft lip and/or cleft palate with/without cleft alveolus or children with syndromes with no known developmental delay.
- **Intervention**: Any SLT approach for children with clefts at any age, period of time, setting, or facilitator.
- **Comparators**: No intervention, different SLT approaches, facilitators, settings, or time points.
- **Outcome measures**: Any related to speech and any secondary outcomes related to psychosocial adjustment.
- **Study Design**: All except case studies (<5 participants).

Exclusions

- Syndromes with known developmental delay.
- Studies consisting of <90% children with cleft lip and/or palate.
- Case studies (<5 children).
- Studies that do not report a speech outcome.
Search Findings

• Total References: 1946
• Total without duplicates: 1241
• Title and abstract search conducted by 3 independent reviewers: short-list of 67 references
• Papers received: 34
• Papers ordered: 33
• Inclusion assessment (1st reviewer): 11 met inclusion (to be verified by 2nd reviewer)
• Data extraction: 6 to date (to be checked by 2nd reviewer)

Data Extraction

• Focused on mainly RCTs/Controlled trials.
• Specific focus on papers from Gonzalez Hospital Gea cleft centre studies (Pamplona et al).
• Information extracted from studies: Intervention info, surgical and speech therapy history, participant characteristics, study design, outcome measures, results.
Included Papers – Gonzalez Hospital

- **Participants**: UCLP, width grade I or II, surgical repair of lip and primary palate 1-3 months, secondary palate 12-18 months.
- **Interventions**: Phonological approach for Compensatory Articulation Disorder (CAD) = 2, Parental involvement in SLT = 2, Summer camp for CAD = 1, visual feedback = 1.
- **Comparators**: Articulation therapy for CAD = 1, no parental involvement in SLT = 2, whole language approach for CAD = 1, phonological approach for CAD = 1, No visual feedback = 1.
- **Outcomes**: Time taken to correct CAD, linguistic level, level of play, parental interaction style, level of CAD, correction of CAD at 12-weeks.
- **Study types**: 5 RCTs 1 Cohort.

Study 1: ID 3 (1999)

- Phonological approach to CAD (Intervention A, 14 participants) versus traditional articulation therapy (Intervention B, 15 participants)
- Time taken to correct CAD
- Intervention A: Total time for correction = 6-22 months. Mean = 14.5 (sd = 4.27), median = 13.50.
- Intervention B: Total time for correction = 14-46 months. Mean = 30.07 (sd = 10.22), median = 29.
- Student’s t-test = Intervention A significantly reduced time to correct CAD (p < 0.001).
Study 2: ID 46 (2000)

- Naturalistic intervention including mothers (A, 21 participants) versus naturalistic intervention excluding mothers (B, 20 participants).
- Linguistic level and level of play
  - Linguistic level: Intervention A: Mean gain @ 12 months = 2.38 (sd = 0.50). Intervention B: M = 1.2 (sd = 0.70). Intervention A significantly greater increase in level (Fisher exact test (p<0.05)).
  - Level of play: Intervention A: Mean gain = 0.81 (sd = 0.51). Intervention B: M = 0.8 (sd = 0.41). No significant difference (Fisher's exact test (p>0.05)).

Study 3: ID 278 (1996)

- Whole language therapy without mothers (A, 10 participants) versus whole language therapy with mothers (B, 11 participants)
- Linguistic level and level of play
  - Linguistic level: Intervention A: Mean level at 8 months = 3.4 (sd = 0.70). Intervention B: M = 4.09 (sd = 0.83). Intervention B significantly higher levels at follow up than Intervention A (Fisher exact test, p<0.05)
  - Level of play: Intervention A: M = 2.5 (sd = 0.53). Intervention B: M = 2.72 (sd = 0.47). No significant difference p>0.05 (Fisher exact test)

- Phonological approach (A, 15 participants) versus whole language approach (B, 15 participants)
- Time taken to correct CAD
  Intervention B: $M = 16.2$ (sd = 5.23), median = 16. No significant differences between groups (Student's t-test $p = 0.33$, $t = 0.98$).

Study 5: ID 502 (2005)

- Summer camp using phonological approach (A, 45 participants) versus standard phonological SLT (B, 45 participants)
- Level of CAD
- Intervention A: 22% no CAD, 51% mild, 22% moderate, 5% severe. Pre-post $(p<0.05 \text{ chi square})$
  Intervention B: 15% no CAD, 31% mild, 45% moderate, 9% severe. Pre-post $(p<0.05 \text{ chi sq})$. No differences between groups $(\text{chi sq } p>0.10)$.
- Costs: Intervention A $100 for 60 hours over 3 weeks. Intervention B: $412 for 104 hours over 12 months
Study 6: ID 957 (1997)

- Videonasopharyngoscopy without visual feedback (A, 9 participants) versus videonasopharyngoscopy with visual feedback (B, 8 participants)
- Modification or persistence of CAD measured at end of therapy (12 weeks)
- Intervention A: 1 modified, 8 persistent, M = 0.125 (sd = 0.35). Intervention B: 8 modified, 0 persistent. Intervention B significantly better at modifying CAD (Fisher exact test p<0.05)

Summary

- Mothers involvement in SLT: naturalistic therapy no effect, whole language therapy more effective but only for linguistic performance
- Videonasopharyngoscopy with visual feedback more effective
- Summer camp and normal phonological SLT similar but summer camp cheaper and shorter
- Phonological approach to CAD: More effective than articulation therapy, similar to whole language
Risk of Bias

- RCTs:
  - Method of sequence allocation: 1 reported (adequate)
  - Method of allocation concealment: unclear
  - Blinding: Sufficient blinding of outcome assessment (4/5)
  - Incomplete outcome data: None
  - Selective reporting of outcome measures: None

Thank you!

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References


Rationale

- CSAG study of cleft services, 1998

- Recommendations
  - Service centralisation
  - Multidisciplinary team working
Aims

- To describe the following at each of the cleft centres
  - Cleft team facilities
  - Cleft team members
  - Cleft team organisation

- To assess team members’ perceptions of team work within their current cleft team setting

Cleft Team Questionnaires

- Cleft Service
- Cleft Surgery
- Hearing
- Orthodontics
- Paediatric Dental Care
- Psychology
- Restorative Dentistry
- SALT
- Specialist Cleft Nursing
- Team Coordination
Semi-structured interview

- Clinical directors
- Interview schedule posted
- Recorded
- Transcribed
- Verification of transcript

Team Work Assessment

- Team foundation
- Team functioning
- Team performance
- Team skills
- Team leadership
- Team climate and atmosphere
- Team identity
Study Sample

- Hub site team members
  - Inclusions
  - Exclusions

Team Contact

- Initial contact with clinical director
  - Confirm participation
  - Identify specialty team members
  - Arrange date for site visit
Data collection

- Post questionnaire to clinical director
- Site visits
  - Meet with clinical director
  - Semi-structured interview
- Distribute specialty questionnaires

Timeline

March 2010  Contact clinical directors
April – Sept 2010  Data collection
Sept 2010 - Feb 2011  Data analysis and write up
March 2011  Submit dissertation
Thank you for listening
Melissa Ke
Cleft Care in the UK: A Health Economics Perspective

Presented by
Dr. Melissa Ke
Lecturer in Health Economics
Department of Oral and Dental Science
University of Bristol

Presentation Outline

• What is health economics?
• What is the current literature on the health economics of cleft care?
• What is the proposed health economics work package in CSAG II?
• What are the plans for future health economics research in cleft care?
What is Health Economics?

Health economics is the discipline of economics applied to the topic of health

- Scarcity of resources
- Choices: Maximise benefits + Minimise resources
- Unlimited ‘wants’
- Efficiency

What is Health Economics?

One IVF course = £2,700. What is the opportunity cost?
One-third of a cochlear implant
- 11 cataract removals
- 1 heart bypass operation
- 150 vaccinations for Measles, Mumps and Rubella
What is Health Economics?

- Demand for health care
- Supply of health care
- Economic evaluation
- Health insurance
- Healthcare systems
- Health policy

Health Economics of Cleft Care

Current literature

- Cost study
  - One in China (2006)
  - One in the Netherlands (2002)
  - One in India (1996)

Economic Evaluation
Summary of results from cost-studies:
- difficult to make comparisons as studies were in different settings, different time periods, different age groups, varying sample sizes
- No published data for the UK
- No published data on personal costs

Summary of results from economic evaluation:
- Three different studies:
  a) effect of presurgical orthopedic treatment (PSOT) vs non-PSOT on time taken for surgical lip closure
  b) effect of infant orthopedic treatment (IO) vs non-IO on speech development at 2.5 years
  c) effect of breast feeding vs spoon-feeding on lip repair
Health Economics in CSAG II

1) Economic impact of centralisation of cleft services
2) Personal costs to parents of children with UCLP
3) Assessing the relative value of the different attributes of cleft services from the perspective of parents of children with UCLP

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Economic impact of centralisation of cleft services
- Cleft team questionnaire
- Budget/Income
- Expenditure = staff, pharmaceutical, laboratory tests, radiology, photography, overheads, capital
- Service levels/Outputs, e.g. number of new cases, number of outpatients/inpatients
Health Economics in CSAG II

Personal costs to parents of children with UCLP
- Parent questionnaire
- Direct non-medical costs, e.g. educational assessments, special education, outside child care, equipment or aids, travel expenses
- Indirect costs i.e. productivity loss, loss of earnings

Assessing the relative value of the different attributes of cleft services
- Discrete Choice Experiment (DCE)
- 2 parts = preliminary semi-structured qualitative interviews with parents; questionnaire
Future Research

• Cost of cleft care in the UK for different phenotypes
• Economic evaluation of an intervention (clinical procedure, multi-disciplinary care) in cleft care

Thank you!
Martin Persson
CSAG II
The story so far
The main story is that

We have had phone conferences with each cleft centre.
We all have agreed upon that
  • Cleft centres will set up special 5 year audit clinics days
  • Children born 1st April 2005 to 31st March 2007 will be included in the study
The story so far

- We all have agreed upon that
  - Cleft centres will set up special 5 year audit clinics days
  - Children born 1st April 2005 to 31st March 2007 will be included in the study
The story so far

- Centres are providing us with dates for the clinics for the time period 1st July 2010 and end 31st December 2012
  - If not done, please provide
The story so far

- We are visiting and informing all sites
  - Our progress so far
The story so far

- We have circulated the CSAG II protocol and the appendices for comments.
  - Thank you so much for the valuable feedback provided!
The future story

- Observe a clinical audit, if possible
- Ensure that all data collection is possible
- Ensure that equipment (researchers brought)/function
- Ensure that duplication of records will be possible
- Provide paper and electronic copies of the proforma documents

Stage 3 - Training with each Cleff Centre

- If possible, arrange so research team can observe a clinic
- If possible, arrange a meeting with R&D
- Ensure that all data that can be collected
• **Height and weight**
• **Speech and language** (duplicate tapes)
• **Audiology**
• **Dental arch relationship** (duplicate models)
• **Dental health**
• **2-D facial aesthetics** (duplicate photographs)
• **Psychological status and Health & Lifestyle**
• **Parent satisfaction** (to take away at the end)

---

**R&D**

- **Site contracts**
  - Related to support costs
- **Possible honorary contracts**
The future story

We look forward to collaborate with all of you!

Thank you!
Amanda Bates
User Involvement in Research
Amanda Bates, University of Kent

Public Involvement Officer – Research Design Service South East (RDS SE)

PhD student – Tizard Centre

Introduction

• What is Patient and Public Involvement (PPI)?
• Benefits and challenges of PPI
• How to ‘do’ PPI well
• PhD “Cleft care and learning disability: Promoting the voice of service users”
What is Patient and Public Involvement?

- People who use services are active in the research process rather than ‘subjects’ of research

- Research with or by the public (service users) rather than to, about or for the public (service users)

(INVOLVE 2004 Involving the public in NHS, public health and social care research)

- Not about representation – eliciting multiple perspectives

Why involve service users/patients?

- PPI gives researchers access to privileged knowledge

- PPI embodies principles of citizenship

- PPI can help the research process practically
Examples of user involvement

• INVOLVE (national advisory body on PPI) continuum;
• Consultation
• Collaboration
• User control

Challenges and issues …

For clinicians:

• Giving over control to ‘non-experts’ can feel threatening
• Service users can be seen as too engaged and/or too emotional
• Lack of consensus amongst service users might be seen as a problem
• ‘Colliding worlds’
Challenges and issues …

For service users/patients:

• May have no real power/influence
• Intimidating
• Raising expectations - not fulfilled
• Roles unclear

Further concerns

• Will being involved (or not) affect the service or treatment I receive?
• Who else will be involved? (professionals and service users)
• Time, commitment, expenses, not understanding cleft related terms/research
• What if I disagree with researcher/clinician?
• Will I receive support/training?
• Who do I contact with questions? Suitable contact methods?
• Personal and wider benefits?
Challenges and issues …

For the research process:

• Added research support costs

• Adds to complexity, time, and bureaucracy

• Lack of relevant training/mentoring provision

• Clarity of roles/responsibilities

Good practice - PPI

• Engaging people who can represent the ‘end-users’ of any study

• Ensure at least 2 lay people engaged in any collaborative work

• Offer reimbursement of costs and payment (see INVOLVE literature)

• Roles and responsibilities, job description

• Allow time for positive working relationships to develop

• Accessible/inclusive environment

• Provide a glossary and avoid jargon

• Clear expectations from the start
Views on good PPI from service users

- Mutual respect
- Support/training
- Communication
- Resources
- Respect for the knowledge and insights of service users/families
- A strong personal commitment from everybody to use involvement to improve both research and service delivery
- Feedback

Views on PPI from researchers

- Made the research relevant to user concerns
- Methodologically helpful
- Access to expert/insider knowledge
- Improved dissemination
What next?

- Engage with INVOLVE resources early in the process and attend INVOLVE events - [www.invo.org.uk](http://www.invo.org.uk)

Key publications:

1. Involving the public in NHS, public health, and social care research: Briefing Notes for Researchers  
   [http://www.invo.org.uk/pdfs/Briefing%20Note%20Final.dat.pdf](http://www.invo.org.uk/pdfs/Briefing%20Note%20Final.dat.pdf)

2. National Institute for Health Research: Payment rates for public involvement  

3. Exploring Impact Summary: Public involvement in NHS, public health and social care research  

Useful reading


Acknowledgements

• Thanks to Raksha Pandya, Kate Winridge and Liz Ockleford in East Midlands RDS and Kay Aranda in South East Coast RDS.

Cleft care and learning disability:
Promoting the voice of service users.
Background

- Potential mismatch between service user and health professional beliefs
- Importance of self perceptions
- Language/communication/access
- Empowerment issues
- Decision making (choice and control).

Review of the literature (1)

- Surgery and treatment aimed at improving function and facial appearance (McDade et al 1991)
- Absence of a link between severity of a facial difference and adjustment to it (Rumsey & Harcourt 2004)
- Lack of qualitative research (Nelson 2009)
- Cleft research - neglect of additional diagnoses (Billaud Feragen et al 2009).
Review of the literature (2)

- Half of those with a cleft have a language or learning disability (Ceponiene et al 2000)
- Neglect of PwLDs in the NHS - staff training needs (Valuing People 2001)
- Paucity of research – PwLD and appearance (McCarthy 1998)
- Assumption of disinterest?
- Cosmetic surgery and children with Down’s Syndrome (Jones 2000).

Social experiences

Self perceptions

Service delivery

Staff training (PwLD)

Decision making

Access/information needs

QoL

Child vs parental views
Challenges and opportunities

- Service user researcher or ... ?
- Reflexive account
- Research steering group
- Promoting voice of service users – shift in culture
- Dissemination/feedback to user groups as well as to professionals.

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Many thanks.
Sue Ziebland
Qualitative research on experiences of health and illness disseminated via
www.healthtalkonline.org

Sue Ziebland
Reader in Qualitative Health Research & Research Director, Health Experiences Research Group, Department of Primary Health Care, University of Oxford

What is Health Talk Online?

- Formerly known as DIPEX www.dipex.org
- Award winning multimedia websites www.healthtalkonline.org and www.youthhealthtalk.org
- Qualitative research studies of health experiences
- A resource for patients and the public, carers, policy makers, professionals in practice and training
- Collaboration between DIPEX charity, the research group in University of Oxford dept Primary health care and other academic collaborators ....
The beginnings

- 1998-9 Ann and Andrew, the kitchen table and ethics
- 2001 July [www.dipex.org](http://www.dipex.org) launched prostate cancer and hypertension; 40 sites added next 7 years
- 2008 re-design and new name, T&L section
- 2010 over 50 conditions on site, 14 senior qualitative researchers in Oxford group including first PhD student
- Parents and young people’s experiences of long term conditions, congenital heart disease, autism, aspergers, clinical trials...
What health information and support do people say they need?

- Information about the condition and treatments
- Perspectives of those with experiential knowledge (especially if resonate with their own)
- Reassurance that others have been through similar positive and negative experiences
- How to deal with school, work, social life, other people...
- The roles of the various health and social care professionals involved
- What to ask (and tell) health & social care staff
- For other people (including HPs and family) to understand what it is like

How might Healthtalkonline help?

- HEALTH EXPERIENCES (video, audio, written) from carefully balanced samples of interviews
- Analysis of approx 25 issues important to people we interview, illustrated with video and audio clips from the interviews
- Questions that people raise -not the ones health professionals think they should ask
- Clips of professionals explaining condition, treatment options, issues
- Links to evidence based information, details of support groups & other resources
- Forum
Research methods

- Stand alone qualitative interview studies (40-50 interviews throughout UK per collection)
- Diverse/maximum variation sample
- Literature and field review
- Advisory panel (specialist advice and quality assurance)
- Interviews at home, experienced qualitative researcher
- Narrative method - unstructured and semi-structured sections
- Digital video and audio recorded

Parents (CHD and breastfeeding sites)
Analysis and selection of interview clips for website

- interviews collected until analytic categories are saturated
- transcripts from interviews read and annotated for coding
- themes include anticipated and emerging issues
- 25 summaries on website based on patient pathways / journey present themes in accessible language, illustrated with clips (200-250 each module)
  - Ziebland S, McPherson A. Making Sense of Qualitative Data Analysis with illustrations from the DIPEx project. Medical Education 2006; 405-414

Consent & Copyright procedures

- Ethical approval (original 1999; NRES 2009)
- Two stages
  - before interview - consent to video or audio taped interview
  - after interview - copyright form for deposit of interview with the researcher
  - Teaching, publications, research & broadcasting, secondary analysis
What’s new? Current HTO studies

- YP weight and health
- Leukaemia
- CIN3 & GCIN
- Young people’s experiences of clinical trials
- Pancreatic cancer
- Schizophrenia
- Screening for unrecognised disease of heart valve
- Young people, drugs and alcohol
- TIA
- Bio banking
- Infertility
- Conditions affecting people of Jewish ethnicity
- Near miss maternal morbidity (NPEU), Men with breast cancer (Glasgow), Penile cancer (Leeds)

HTO Teaching and learning area

- Videos, and analytic summaries available free on the website
- Widely used in teaching health and social care professionals about patients experiences
- Designated area of HTO site with teaching and learning materials
- Developing resource for HP training
- Links to other resources for teaching
Potential for HTO site on parents (and young people) experiences

- Interviews with parents, adults and young people, whole country
- Interviews for several purposes:
  - HTO site
  - Secondary analysis eg to identify issues important to families (eg questionnaire devt)
  - Papers for peer reviewed and media articles
  - Teaching and learning resources on parents and YP perspectives
  - NHS choices and NICE, policy makers

Ann McPherson, co-founder
More information

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Trisha Bannister
Contribution of Nursing Research to the Care of Children/Families Affected by Cleft Lip & Palate

Trisha Bannister MSc MBE

Nursing Research

- Build a scientific foundation for clinical practice
- Prevent disease & disability
- Manage & ameliorate symptoms caused by illness
- Enhance the end of life & palliative care
Sources of Nursing Knowledge

- Customs & traditions
- Intuition
- Role modelling
- Trial & error
- Careful observation & deduction
- Logical reasoning from existing knowledge
- Scientific research

History of Research

- 1800 Florence Nightingale recognised importance of clinical research
- This was scarce until 1980's
- Focused on educational & organizational issues
- Introduction of BSc in nursing
- Research integrated into the programmes
- Recognition of contribution by nursing departments
The Clinical Nurse Specialist

- Advanced Practitioner
- Educated to degree level
- Opportunity & encouragement to work towards a Masters degree
- 7 CNS have MSc qualifications

Role of Clinical Nurse Specialist

- Care giver
- Counsellor
- Agent of change
- Leader
- Case Manager
- Communicator/consultant
- Advocate for client
- Teacher
- Researcher/research user
Barriers to Research

- Research related
- Nurse related
- Organizational related

Participation

- Identify clinical problems
- Participate in data collection
- Share and diseminate research findings
- User of research
- Conducts research
Methods Related to Nursing

- **Quantitative**, focusing on outcomes for patients and dominated by randomized controlled trials

- **Qualitative**, depicts a patient’s journey & undertaken by interviews, case studies, and focus groups

Triangulation is stated to produce strongest findings in nursing

Studies Already Undertaken

- Assisted feeding is more reliable for infants with clefts: a randomized trial
- Exploring Parents’ reactions to the diagnosis of Cleft Lip and Palate
- A study into weight gain in infants with cleft lip and palate
- Parents’ experience of managing babies with a late diagnosis of cleft palate
- A pilot study comparing the impact of 2 postoperative feeding methods
- Parents’ views of 4D ultrasound scans following the diagnosis of a cleft condition
- Development of a Care Map for managing babies born with an isolated cleft of the palate
Current National Approach

- Establish the CNS role nationally as core member
- Formation of National audit/research group within nurses SIG
- Formation of standards of care
- National audit projects
  - Missed cleft palate, breast feeding, Pts satisfaction with CNS service
- Learning to work as national group
- Develop tools properly piloted
- Multi-centre approach
- Research culture

The Future

- Strategic investment into research training
- Manchester programme: 10 fully funded places for a Masters in Clinical Research
- Leaders in clinical research
Multidisciplinary approach

- Become part of a team undertaking research either locally or multicentre
- Include academic institutions as part of team
- Development of confidence to apply for NIHR and Research for patient benefit funding

Conclusion

- Need to overcome barriers
- Develop confidence
- Engage in training of research methods
- The role of next generation CNS
- Enhance level of research
- Develop both National and Local projects
User involvement
User involvement session

Issues around engaging users in research

- Need to consider the INVOLVE guidelines in ensuring that users are involved in the right way in research activities.
- Need to consider how users could be involved in clinical practice as well as research.
- Nurses were concerned that they do not have much time to involve users. They do try to feed back key issues to parents for discussion and about clinical practice.
- Some felt that the focus should be on user involvement in research not clinical practice. It was felt that it was important to ensure that users understood about audit and research and were given feedback about the findings of such studies.
- Users need to be trained in what research is so they are better informed and supported.
- Need to consider possibilities for training and support for users involved in research and CLAPA, INVOLVE and Changing Faces could support this in conjunction with the Healing Foundation.
- Suggested offering leaflets to parents through units about research to ensure all families are accessed. It was suggested that the psychologist would be key in this process.
- It was suggested that there could be local networks of interested parents and adult users that could form user involvement panels. This would look similar to the young people’s research council at Changing Faces where the group is actively involved in discussing and guiding research within appearance.

For Generation cleft and the Healing Foundation centre it was felt that we needed at least 2 adult users and 2 parents working on each programme right from the very early stages guiding and influencing the research process not just reading consent and information forms.

We need to be very clear about their role upfront and how much time they are going to have to commit and what monetary compensation may be available. There needs to be real roles and involvement not tokenistic gestures.

We also need a mediator to work with users to ensure that they are supported and understand what is going on, and to act as a go-between if they have any issues with the research that they feel too intimidated to address with the wider research team. The mediator needs to be someone with a strong understanding of user involvement.

Burden of Audit/research

- There is too much of a burden on users in relation to the amount of audit and research activities they are asked to be involved with.
- Need to think of new ways of collecting audit data that took some of the burden off of the parents and users.
- It was suggested that maybe we need to ration audit and target research more effectively.
- Need to consider how we might manage or vet projects
- It was suggested that the SIG groups and tri-audit groups need to co-ordinate their research efforts more effectively, and maybe have a national body involved in vetting projects and users could be involved in this process by deciding which studies they felt were particularly relevant, or by suggesting research ideas they felt were interesting.
- There were concerns that there are already too many bodies, we just need those that exist to work more closely with one another.
- Overall it was felt that we should start by utilising the facilities and groups we already have and then thinking about how to move forward a later date.

**Dissemination and sharing of research/audit findings**

The internet was discussed as a good possible way of getting users involved in research, either through advertising research projects, or through disseminating findings from research. It was felt that research findings should be freely available and shared between CRANE, CLAPA and the craniofacial society, as well as the individual centres. The other issue was around the use of internet-based questionnaires to help increased response rate and reduce burden on users and parents.

It was suggested that future Craniofacial society conferences could take place alongside CLAPA conferences, so that users get some time together and then are invited to the main craniofacial society conference where researchers and clinicians present to a lay audience at a level they are likely to understand.

It was considered important to have transparency and honesty around research data and what is collected rather than a sense of not wanting to show it to users which breeds mistrust.
Generation Cleft
Generation cleft session

Name

- What will the study be called? - Generation cleft? Generation C? Other? Need to discuss with users, possibility of 2 names – one for research and 1 for general public?

Users

- Need to establish a group of users early on and have them involved throughout the study.
- There is the possibility of engaging with healthtalkonline. Could look at user experiences as a qualitative project with Changing Faces and Craniofacial Society.

Logistics

- Need to consider how to target difficult to reach users.
- Possibility of having newsletters, maybe in different languages to ensure we do not exclude ethnic minority groups.
- Considerations are needed over how to conduct multiple studies and what these should be. Need to ensure users are not overburdened by having to take part in a lot of studies and audits, unless of course they want to.
- Need to consider how to address the nurse time needed at each centre. This would involve either a research nurse or buying some of the time of cleft nurse specialists.

Design:

- Contact parents at 18 months to 2 years.
- Collect clinical data at age 3 years.
- Don’t have special audits for this process – just standard practice ensuring universality of recording data.
- Losses to clinical follow-up – particularly in isolated cleft lip. This tells its own story but it is hoped that rates will be quite low.
- There will 18-20 months for consultation to allow for individual to give suggestions or ideas.
- After the formal announcement from the Healing Foundation the group will ensure everyone is informed about whom the Generation cleft team consists of.
- Look at toxicology data?
Manchester cleft centre

How should we run it? How do we engage the cleft teams?

- Need to control the amount of research taking place
- Get ideas from clinicians/teams and users
- Important to streamline current research
- It is important that cleft teams have a sense of ownership over their ideas by ensuring they are actively involved in the research.
- Need to consider whether cleft centres who have research ideas want to run those research projects
- It was felt it was fine for University of Manchester to run trials as they have the infrastructure, but that centres should participate and need fair representation of the contribution of individual centres in all publications.
- Clinicians would also be welcomed to become involved in research as it was useful for access to participants. There has to be a 2-way process between researchers and clinicians. Bill Shaw will organise a meeting to involve the cleft teams in the research process
- Discussed future of CRANE. Currently used to store data, but if it folds then this money will disappear.

National Institute for Health Research (NIHR)/Medicines for Children Research Network (MCRN) – Develop Clinical Studies Group (CSG) within the MCRN which represents users and clinicians. Members could be appointed by open application via Craniofacial Society of Great Britain and Ireland (GFSGBI) with an independent chair appointed by MCRN. The Healing Foundation would fund the maintenance of the cleft CSG. At CFSGBI discuss with MCRN about how CSG will be created based on a pre-existing policy based on previous experience of MCRN. There are 2 funding routes 1) Grant to University of Manchester 2) Research grant to cleft centre (Manchester?). It was suggested that the CSG need to have an audit lead, and SIG representation. It was felt that audit data needed to feed into the CSG and perhaps it could co-ordinate research and audit. Bill Shaw to keep negotiations open around CSG involvement in audit. The CSG would have an educational function and there would be individual involvement in specific projects. There is potential within this to create links with other research fellowships, such as those currently in existence in Birmingham.

It is important to co-ordinate efforts more effectively. We currently have the following organisations: Audit committee, CRANE, tri-centre audits, team audits, research committee (Jonathan Sandy – which has now been formally disbanded!) and now the CSG. It is important that there is central co-ordination as currently each group is pulling in different directions and it is important to share data where possible and clearly define ownership of data. We need to rationalise audit, and ensure we do not replicate data collection, and clearly identify who holds the data. Tri-centre audits were considered to be useful to allow comparison of outcomes. Additionally we need to reduce diversity in audit practice, which could be addressed through the CFSGBI council. As part of avoiding replication, there needs to be an ongoing dialogue with Bristol University to ensure replication does not take place.
Research Priorities List

- Need to look at the priorities list again with a view to having simple ideas which equal rapid outcomes
- Need to consider funding issues - pilot studies could be funded firstly through CSFGBI then through grant for trials.
- There is a need for objective outcome measures. The need for this indicates the clear importance for links between research and audit.
- Priorities for research:
  - Tisseal makes bone grafts take better? Could be done quickly
  - Toxicology in clefting
  - Qualitative study in missed cleft palates and their impact
  - Hearing loss – Feasibility study – current practice and health economics impact
  - Qualitative study of the experiences of families undergoing speech and language therapy
CLAPA CONFERENCE 2010

A CONFERENCE FOR PEOPLE WITH CLEFT LIP AND / OR PALATE, THEIR FAMILIES AND THE HEALTH PROFESSIONALS WHO SUPPORT THEM

For full conference details please visit
http://clapaconference2010.wordpress.com/

Saturday 15th May 2010, Jurys Inn Nottingham

Conference Fee £15 - Preferential Accommodation Rates

Creche Available

info@clapa.com 020 7833 4883
Sculpture for Surgeons 2010
31st Jul-3rd Aug

Aimed at consultants and trainees in reconstructive surgery. No previous artistic experience or ability is required. The course will teach observational skills in 3d assessment of the face to enable a better appreciation of the form being reconstructed.

A lifesize portrait head in clay will be achieved under the tuition of sculptor Luke Shepherd.
(www.abbronze.co.uk)

Cost:
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Venue: Hills Road Sixth Form College
Cambs. CB2 2PE

Application to organiser Per Hall by email
per.hall@addenbrookes.nhs.uk
Places limited to 16 delegates
24.5 CME points awarded by the Royal College of Surgeons