**PErineal Assessment Repair Longitudinal Study (PEARLS):**
Can we improve perineal assessment and repair?

**Professor Christine Kettle**
University Hospital of North Staffordshire
Overview

• Background
• Informing study outcomes
  • National survey of current midwifery practice
  • Delphi study – what’s important to women
• PEARLS cluster RCT
• Study progress to date
Background

• Currently >350,000 women in UK experience perineal suturing after spontaneous vaginal delivery & millions more worldwide

• Consequences of perineal trauma have long lasting and devastating effect on women's physical and emotional wellbeing

• Large variation in practice relating to assessment, management and documentation of perineal trauma
Training Issues

- Sultan and colleagues (1995) highlighted dissatisfaction with training in perineal anatomy and repair
- Similarly – audit carried out (1995) at the University Hospital of North Staffs (UHNS) highlighted deficiencies with training and lack of supervision
- Locally & nationally – variations in practice
- UHNS structured training programmes: -
  - Episiotomy & 2nd degree tears
  - 3rd & 4th degree tears
Have you been trained to do that?

Well I've seen it done once!
Appropriate training

• Practitioners – appropriately trained – more likely to provide consistent high standard of perineal repair – reduce associated morbidity

• Need experienced practitioner to facilitate training & provide support & supervision
What is PEARLS?

- **PErineal Assessment and Repair Longitudinal Study (PEARLS)**
- National clinical quality improvement initiative
- Aim – to enhance assessment and management of perineal trauma
- Funded by the Health Foundation
- Undertaken by a multi-disciplinary team: -
  - Sue Macdonald (RCM); Debra Bick (KCL); Christine Kettle (Staffs University/UHNS); Khaled Ismail (Keele University/UHNS); Peter Thomas (Poole/Bournemouth); Sue Tohill (Project Midwife); Kenda Crozier (RCM); Judith Ockenden (NCT)
- Trial Steering Group
Aims & Objective

• Improve clinical care in line with evidence based guidance (RCOG Green-Top Guideline) – using appropriate suture technique & material
• Enhance the assessment and management of perineal trauma – short & long-term
• Improve clinician’s knowledge, skills & confidence in providing high quality evidence based perineal care
• Reduce immediate & long-term maternal postnatal morbidity
• Improve women’s experience of maternity care
Details of Study

• National UK survey of midwives – to review current practice and training

• Survey medical schools, leads for midwifery education, deaneries – content of existing training programmes

• Delphi study – identify outcomes important to women

• Matched pair cluster RCT – evaluation of standardised evidence based training package for the immediate and long-term management of perineal trauma
National Survey

• Aim:
  • To assess current practice and provision of training for clinicians undertaking perineal management
  • To review current practice in relation to knowledge of evidence-based management of perineal trauma

• Design:
  • Survey – structured questionnaire
  • Participants – random sample qualified midwives that were members of the RCM
  • Sample size – 1000
  • Inclusion criteria – midwives currently involved in the assessment, repair & supervision of perineal trauma
Findings

- 405 (40.5%) midwives returned questionnaires
- 322 (80%) met the inclusion criteria
- 83 (20%) were not eligible to take part

<table>
<thead>
<tr>
<th>Years Qualified</th>
<th>N = 322</th>
</tr>
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<tbody>
<tr>
<td>&gt; 20 years</td>
<td>113 (35%)</td>
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<tr>
<td>16 – 20 years</td>
<td>85 (26%)</td>
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<tr>
<td>11 – 15 years</td>
<td>34 (11%)</td>
</tr>
<tr>
<td>6 – 10 years</td>
<td>39 (12%)</td>
</tr>
<tr>
<td>1 – 5 years</td>
<td>39 (12%)</td>
</tr>
<tr>
<td>&lt; 1 year</td>
<td>4 (1%)</td>
</tr>
<tr>
<td>Missing data</td>
<td>8 (2%)</td>
</tr>
</tbody>
</table>
Findings – Assessment

Q – Confident to assess perineal trauma (n = 320)
  - All of the time - 117 (36%)
  - Most of time - 175 (55%)
  - Some of time - 28 (9%)

Q – PR as part of initial assessment (n = 319)
  - All of time - 133 (42%)
  - Most of time - 49 (15%)
  - Some of time - 87 (27%)
  - Never - 50 (16%)
Findings – Perineal Repair

Q – Confidence in performing perineal repair (n=317)

- All of time - 67 (21%)
- Most of time - 185 (58%)
- Some of time - 53 (17%)
- Never - 12 (4%)

Midwives qualified for > 20 years were more likely to be confident ‘all’ or ‘most’ of the time to undertake perineal repairs
Findings – Suturing Technique

- Only 17 (5%) out of 322 midwives used the recommended evidence-based suturing technique (continuous non-locking to close vagina and perineal muscles and subcutaneous sutures to close perineal skin).
- More likely to be used by midwives practicing for >20 years (n = 8)

1. Loose, continuous non-locking stitch to vaginal wall
2. Loose, continuous non-locking stitch to perineal muscles
3. Closure of skin using a loose subcutaneous stitch
Findings – Non suturing

Q – Do you leave some second degree tears to heal naturally (n = 308)

• Yes - 176 (57%)
• No - 132 (43%)

Comments:

• Against unit policy to leave second degree tears unsutured
• Would leave small tear with mothers consent
• As a community midwife I have observed that they heal better
• Our trust protocol requires that all second degree tears are sutured. However, if it is a small 2nd degree tear - it would be best left to heal by nature and it might be re-labelled as 1st degree
Findings - Training

Q – Does your unit provide structured training (n=317)
   Yes - 216 (67%)
   No - 87 (27%)
   Don’t know - 14 (4%)

Q – Does your unit provide a training update (n=317)
   Yes - 172 (53%)
   No - 131 (40%)
   Don’t know - 14 (4%)

• Only 10% had received training in the last 12 months
• A third had not received training for over 5 years
Comments

• Not heard of RCOG guideline

• Not really confident, need more training

• As an independent midwife not heard of RCOG guideline, had to do a ‘Google’ search – now will change practice

• Never had the opportunity to learn new technique

• Was a student in 1996-1998 when non suturing of second degree tears was practiced therefore I’m not confident
Final Comments

• Student in 1980’s – never felt prepared or confident – usually avoid suturing

• I need more extensive training, I know midwives that qualified with me who also lack confidence

• Many senior midwives do not have the confidence

• This questionnaire has highlighted the need for some personal updating

• Statement from one midwife currently using the continuous evidence-based technique:

  “I have been observing others using the interrupted method so I may start using that instead”
Delphi Study

Aim:
To obtain consensus from women who had experienced perineal trauma (experts) regarding outcomes, which they considered to be important up to 3 months following birth.
Participants & Methods

• All women who had experienced a vaginal birth and perineal suturing (up to six months prior to the study taking place) were invited to participate

• Two round Delphi study carried out (April 2006) n = 27 at the University Hospital of North Staffordshire, UK
  – Women were invited to a cheese and wine evening

• One round consensus survey (Nov 2006) n = 45 women at the Royal Berkshire Hospital, Reading, UK
  – Women were invited to a coffee morning

• Approval was gained through 'Patient Partnership' groups

• Also repeated in Brazil (Oct 2007) n = 17 women/midwives at a conference at the University of São Paulo, Brazil
Methods continued -

• Important outcomes identified from focus groups

• Used to generate a list of questions used for the first and second rounds (iterations) of the Delphi studies and consensus survey

• Generated 44 questions – subdivided into:
  • first week after delivery
  • 2 – 4 weeks postpartum
  • 3 months postpartum

• Women were asked to score the questions & rank them on a scale of 1 – 6 in order of importance

• ‘Who Wants to be a Millionaire’ style key pad were used for scoring
## Comparisons

<table>
<thead>
<tr>
<th>UK</th>
<th>Brazil</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Week 1</strong></td>
<td><strong>Week 1</strong></td>
</tr>
<tr>
<td>1. Fear of perineal infection</td>
<td>1. Fear of perineal infection</td>
</tr>
<tr>
<td>2. Able to open bowels without pain or fear of stitches bursting</td>
<td>2. Able to open bowels without pain or fear of stitches bursting</td>
</tr>
<tr>
<td>3. Wound breakdown</td>
<td>3. Provision of consistent information</td>
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<tr>
<td>4. Not being incontinent of urine and faeces</td>
<td>4. Not experiencing severe pain</td>
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<tr>
<td><strong>Weeks 2 – 4</strong></td>
<td><strong>Weeks 2 – 4</strong></td>
</tr>
<tr>
<td>1. Fear of perineal infection</td>
<td>1. Fear of perineal infection</td>
</tr>
<tr>
<td>2. Perineal comfort when walking, sitting and feeding baby</td>
<td>2. Perineal comfort when sitting</td>
</tr>
<tr>
<td>3. Wound healed quickly</td>
<td>3. Wound healed quickly</td>
</tr>
<tr>
<td>4. Not experiencing severe pain</td>
<td>4. Not experiencing severe pain</td>
</tr>
<tr>
<td><strong>3 months</strong></td>
<td><strong>3 months</strong></td>
</tr>
<tr>
<td>1. Wound healed quickly</td>
<td>1. Perineal comfort when sitting and walking</td>
</tr>
<tr>
<td>2. Feeling back to normal</td>
<td>2. Not experiencing severe pain</td>
</tr>
<tr>
<td>3. Perineal comfort when walking</td>
<td>3. Perineal area felt comfortable</td>
</tr>
<tr>
<td>4. Fear of perineal infection</td>
<td>4. Resume pain free intercourse</td>
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</tbody>
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Delphi study findings

• It is interesting that wherever childbirth takes place that women have similar concerns and fears

• The Delphi and consensus survey - established what outcomes were important to women

• Findings were used in the development of the questionnaires for the PEARLS Cluster RCT – quality improvement project
PEARLS Cluster RCT

Aims and objectives:

• To improve clinical care in line with evidence-based guidelines

• To evaluate if enhanced clinical training in perineal assessment and management can reduce short and long-term maternal morbidity

• To improve women’s experiences of maternity care relating to perineal trauma following childbirth and perceptions of health & well-being
Methods

Design: Multi-centered, matched pair randomised cluster trial
  • Matching criteria includes size and type of unit, number of births, type of perineal repair training and experience of facilitator

Setting: 22 maternity units in the UK

Participants eligibility criteria: All women who sustain a second degree tear or episiotomy in the participating units and give informed written consent

Exclusion criteria: Under 16 years of age; non-English speaking or suffered a pregnancy loss

All births during the pre-specified periods will contribute to the analysis

Ethical approval: Thames Valley Ethics Committee
<table>
<thead>
<tr>
<th>Primary outcome</th>
<th>Secondary outcomes</th>
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<tbody>
<tr>
<td>Experience of perineal pain when walking or sitting down during the previous 24 hours – reported at 10 to 12 days</td>
<td>10 – 12 days</td>
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<tr>
<td></td>
<td>Use of analgesia</td>
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<td></td>
<td>Wound dehiscence &amp; infection</td>
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<td></td>
<td>Sutures requiring removal</td>
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<tr>
<td></td>
<td>Breast feeding rates</td>
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<td></td>
<td>3 months</td>
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<td></td>
<td>EPDS score</td>
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<td></td>
<td>Resumption of intercourse</td>
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<td></td>
<td>Women’s satisfaction with the repair</td>
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**Intervention**

- Reading material for independent study and self-directed learning

- **The Second Degree & Episiotomy Workshop**

- **Interactive DVD**

- **OSAT**
  - Objective Structures Assessment of Training

- **Postnatal information leaflet for women to promote self management**
Facilitators Training

• Local facilitators attended a two day ‘hands on’ perineal management workshop with project team to help them to deliver the intervention:
  • Lectures – anatomy; basic surgical skills; recognition of perineal trauma; evidence based practice (suture materials and technique); postnatal management and leadership programme
  • Hands-on-workshop
  • Training materials (DVD, lectures, training equipment including Keele and Staffs Episiotomy Repair Trainer, Instruments etc)
  • Ongoing support
  • Site visits – to ensure standardisation of training
Training equipment

Keele & Staffs Episiotomy Repair Trainer – developed with Limbs & Things UK Ltd

DVD – anatomy, basic surgical skills, identification of trauma, suturing techniques & postnatal care
A pair of units matched for region and size

- Audit 1 and identify women for survey 1

**Units A** - training of facilitators to deliver intervention

- Training pack

- Audit 2 Survey 2

- Audit 3 Survey 3

**Units B** - training of facilitators to deliver intervention

- No Intervention

- Training pack

- Audit 2 Survey 2

- Audit 3 Survey 3
Audit 1 & Survey 1

• **Audit 1** – prospective clinical audit over one a month period to collect baseline data from each pair of units (cluster)

• **Aim:** To assess practice prior to implementing the intervention against quality standards for perineal management

• **Survey 1** – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10-12 days & 3 months postpartum

• **Aim:** To assess impact on short and long term maternal morbidity prior to implementation of the intervention
Data Collection: Audit 1 & Survey 1

• **Audit 1:** carried out over one month period during March to August 2008 (depending on commencement date for each paired cluster)
  • Received total 1534 completed audit forms

• **Survey 1:**
  • 708 women recruited (over one month period)
  • 463 returned 10 day questionnaire
  • 366 returned three month questionnaire
Audit 2 & Survey 2

• The Intervention commenced in Units A

• Training period of 2 months - facilitators trained midwives and doctors during April – August 2008 (depending on commencement date for each paired cluster)

• Followed by 2 months consolidation period

• Audit 2 – second prospective clinical audit was undertaken in Units A & B following 4 month period

• Survey 2 – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10 - 12 days & 3 months postpartum

• Aim: To compare data from previous Audit 1 and Survey 1 – to assess the impact that the intervention may have on units that had receive the intervention (Units A)
Data Collection: Audit 2 & Survey 2

- **Audit 2:** carried out over 2 month period during August to November 2008 (depending on commencement date for each paired cluster)
  - Received total 1570 completed audit forms
- **Survey 2:**
  - 1428 women recruited (over 2 month period)
  - 772 returned 10 day questionnaire
  - 496 returned three month questionnaire
Audit 3 & Survey 3

- The Intervention commenced in Units B
- Training period of 2 months - facilitators trained midwives and doctors during October 2008 – June 2009 (depending on commencement date for each paired cluster)
- Followed by 2 months consolidation period

- Audit 3 – third prospective clinical audit was undertaken in Units A & B following 4 month period
- Survey 3 – women who sustained episiotomy or second degree tear were asked to complete questionnaire at 10 - 12 days & 3 months postpartum

- Aim: To compare data from previous audits and surveys – to assess the impact and sustainability of the intervention in Units A and B
Data Collection: Audit 3 & Survey 3

• **Audit 3:** carried out over 2 month period during February to October 2009 (depending on commencement date for each paired cluster – most units finished in May 2009)
  • Received total 1600 completed audit forms

• **Survey 3:**
  • 1236 women recruited (over 2 month period)
  • 800 returned 10 day questionnaire
  • To date - 300 returned three month questionnaire

• Data collection Audit 3 and Survey 3 ongoing – one unit still completing training period
Challenges

- Obtaining ethical approval – quality improvement project
- Site Specific R & D approval for each individual unit with own requirements – very time consuming
- Facilitators needed extra support due to delay in starting main study
- Huge pressures on NHS Trusts – reduced staffing levels, financial problems, deployment of facilitators which had major impact on capacity to deliver training and collect data
Study Milestones

- Delphi and consensus study completed
- National survey completed
- Recruitment of units
- Facilitator training completed
- Health Foundation leadership training scheme for facilitators
  - Data collection ongoing
  - Papers prepared for publication
  - Results should be available 2010
Conclusion

• First RCT to assess the impact of an ‘hands-on’ training package for the assessment and management of childbirth associated perineal trauma

• Findings may have implications for the development of national standards for pre and post-reg education

• Likely to produce the largest data set to date on aspects of clinical management and women’s health outcomes

• Implications for women’s health globally
Acknowledgements

• The Health Foundation for funding PEARLS
• The PEARLS Central Project Team:
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  • Professor Chris Kettle (UHNS & Staffordshire University)
  • Ms Sue McDonald (Royal College of Midwives)
  • Mrs Sue Tohill (Staffordshire University)
  • Professor Peter Thomas (Bournemouth University)

And finally
A big thank-you to all the women who kindly agreed to take part in the study
Thank-you

PEARLS - [www.rcm.org.uk](http://www.rcm.org.uk)
Current Controlled Trials Registry: International Standard Randomised Controlled Trial Number Register (ISRCTN) – 28960026