Learning from the PEARLS trial

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PEARL Study

PErineal Assessment and Repair Longitudinal Study

Funded by Health Foundation (National Clinical Quality Improvement Programme)

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Trial Steering Group

Background

Around 400,000 women sustain perineal injury in UK each year

Second degree tear most common

Assessment and management of trauma - core aspect of midwifery and obstetric care

Widespread and persistent morbidity

Implications for future mode of delivery

A quality improvement issue

Divergence between practice and evidence based guidance

Divergence in assessment, management and documentation of perineal trauma

Clinicians may not have received adequate basic or updated training to recognise or repair trauma (Sultan et al 1995, Kettle 1996)

Little guidance on postnatal management (Bick et al 2002)

Low priority for clinicians and managers

PEARLS

Aims and objectives

Improve clinical care in line with evidence-based guidance

Reduce immediate and longer-term maternal morbidity

Improve women's experiences of maternity care and perceptions of health & well-being

To achieve this through:

Development, implementation and evaluation of a training package to enhance assessment and immediate/longer-term management of perineal trauma to comply with 'best practice'

Study design

Mixed methods to capture elements of care to inform a quality improvement project

Surveys of current practice and training

Delphi survey and consensus conference to identify outcomes of importance to women

Matched pair cluster RCT of training intervention

(audit of clinical practice)

The intervention

Training

Assessment of trauma, principles of surgical repair & surgical skills to manage perineal trauma

Interactive CD Rom

Reading material; self-directed learning; postnatal care guidelines (NICE 2006, Bick et al 2002/2008)

Assessment of clinical skills (OSAT) within 3 months of training

The intervention

Local facilitator/cascaded training

Facilitators attended a two day ‘hands on’ training programme with project team (led by Chris Kettle and Khaled Ismail)

Each unit provided with Keele/Staffs Episiotomy Trainer and accompanying materials, equipment

Keele/Staffs Episiotomy Trainer

The intervention

Postnatal management

Pain relief protocol

Care planned according to individual need

Postnatal leaflet for women: Information on taking care of health (diet, nutrition, signs & symptoms of infection, where to seek help)

Primary outcome	Secondary outcomes
Any pain whilst walking or sitting down during the past 24 hours as reported at 10 – 12 days	**10 – 12 days** Breast feeding Use of analgesia Wound dehiscence / infection Sutures requiring removal **3 months** EPDS score Resumption of intercourse Women's satisfaction with the repair

Inclusion criteria

Women who sustain episiotomy or second degree tear

Spontaneous or instrumental vaginal delivery

Exclusion criteria: ≤16years: unable to read/speak English: stillbirth or neonatal death

Sample size

Need to account for cluster design and intra-cluster correlation coefficient (ICC)

Factors pertaining to the cluster (maternity unit) and the individual which could affect outcome

To detect reduction in primary outcome of 20% (*from 75% to 55%, Kettle et al 2002*) at 1% significance required sample size of 635

Needed minimum of 16 clusters (assuming 40 women in each)

Recruitment of sites

Open call

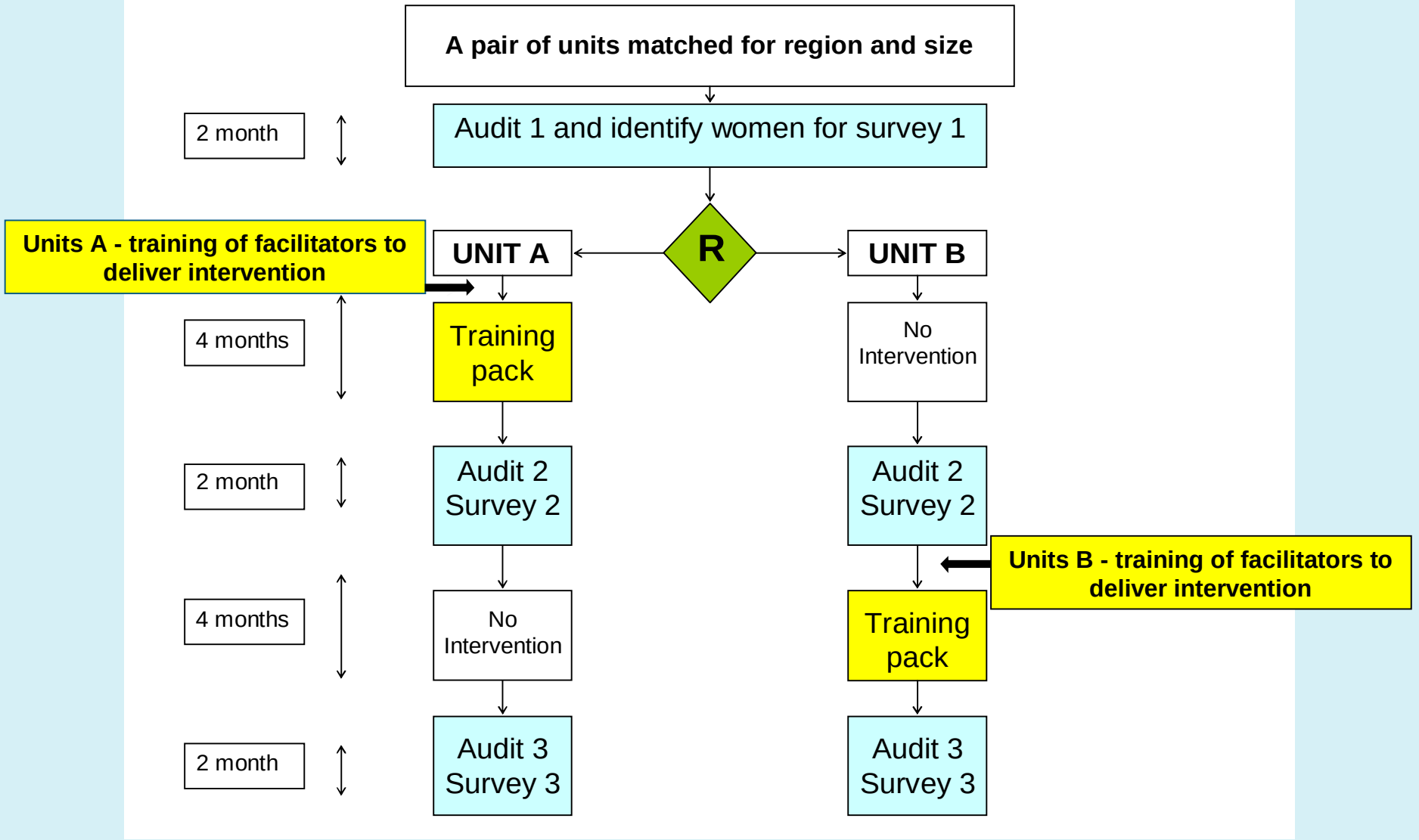
24 originally recruited, two sites dropped out

22 sites across UK (including 2 birth centres)

Matched by no. of births, location, type of unit, qualifications of facilitator (11 pairs)

Additional 6 clusters will give the study protection should up to 3 clusters drop out

Plan of investigation for pair of matched units (n = 22 units)



Randomisation and roll-out

Randomisation to Unit A or Unit B (clinical trials unit)

Baseline Audit (A1) and Women's Survey (S1)

Unit A commences training intervention

Primary outcome measured at Audit 2 and S2 (when Unit A has implemented intervention, Unit B has not started)

Following Audit 2 and S2, package implemented in Unit B

Outcomes in Units A & B compared in Audit 3 and S3

Sustainability ascertained. Comparison of change over time between and within units

Data Collection: Audit 1 & Survey 1

Audit 1: carried out over two month period during March to August 2008 (depending on commencement date for each paired cluster)

- Received total 1534 completed audit forms

Survey 1:

- 752 women recruited (over one month period)
- 464 returned 10 day questionnaire
- 366 returned three month questionnaire

Data Collection: Audit 2 & Survey 2

Audit 2: carried out over two 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
- 597 returned three month questionnaire

Data Collection: Audit 3 & Survey 3

Audit 3: carried out over two month period during February to October 2009 (depending on commencement date for each paired cluster)

- Received total 1634 completed audit forms

Survey 3:

- 1376 women recruited (over 2 month period)
- 782 returned 10 day questionnaire
- To date - 536 returned three month questionnaire

Data collection Audit 3 and Survey 3 ongoing in two units

Reflection on study processes

Considerable attention had to be given to the level of planning required for a large complex clinical intervention

Funding body request for additional study input had considerable implications for practice and for the trial team: the ‘funding to practice gap’

Expertise of trial team is crucial

Reflections on study processes

Obtaining ethical approval for a trial and a quality improvement project was difficult

Obtaining site specific R & D approval for all 22 units extremely time consuming. Level of information required, R & D offices failure to respond, time between meetings if changes to protocol made etc

Unit A often had R & D approval before its matched Unit B. Would pair units before seeking R & D approval

Huge pressures on NHS Trusts impacted on capacity to collect data. Trusts need to consider implications before agreeing to take part in research and ensure ‘buy-in’ from all stakeholders

Trial teams need to consider implications for Trusts when designing recruitment and data capture processes and expectations of contribution of clinical staff

Reflections on study processes

Greater lead in time with facilitators would have been beneficial (practice demands do not match research implementation demands)

Facilitators often needed additional support from trial team due to delays in starting main study

Involvement & support for PEARLS had to accommodate other priorities of the maternity unit

Reflections on study processes

Continuity: if a facilitator left, some units found them difficult to replace

Facilitators reported some difficulty engaging clinical colleagues in training, especially obstetric colleagues

Financial costs: PEARLS is registered with the UK CRN portfolio. Trust managers need advice and support to claim financial support for involvement in PEARLS (and support to 'ring-fence' the income generated)

Importance of regular communication between trial team and sites emphasised

Reflection on study processes

Involving women in identification of study outcomes was extremely important for PEARLS

Set the need for the study in context and demonstrated expertise & insight service users can bring to research

Informed priority outcomes of importance for women

Study milestones

- Despite issues, a fantastic trial thanks to support of all involved
- Delphi and consensus completed
- National survey completed
- Recruitment of units and women achieved
- Facilitator training completed
- Health Foundation leadership training scheme for facilitators
- Development of one of the largest databases of perineal trauma outcomes to date
- Papers prepared for publication: first results in 2010

Conclusion: Lessons from PEARLS

Funding obtained did not reflect work demands at practice or trial team level

Study teams would benefit from guidance from funding bodies, RDU's etc on level of funding required to fully support large scale clinical projects

Ideally, one dedicated F/T clinician would be funded for each study site (funding limits may prohibit this)

Difficult to identify barriers to roll-out at the outset

Conclusion: Lessons from PEARLS

Consideration needed with respect to level of funding available

On-going communication with all study sites (two way process) is essential

Complexity of data capture, data management and data analysis have to be considered at the outset

Trial teams must publish process as well as primary outcomes

For more information: www.rcm.org.uk. Current Controlled Trials Registry: ISRCTN28960026