A feasibility study to inform a randomised control trial of methods to minimise pain response during routine immunisation of infants.

Anne E McGowan
<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th>A feasibility study to inform a randomised control trial of methods to minimise pain response during routine immunisation of infants.</th>
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<tbody>
<tr>
<td><strong>Author</strong></td>
<td>Anne McGowan</td>
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<tr>
<td><strong>Date</strong></td>
<td>May 2011</td>
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<tr>
<td><strong>Research funding body</strong></td>
<td>RCBC (Research Capacity Building Collaboration) Wales</td>
</tr>
<tr>
<td><strong>Host organisation</strong></td>
<td>School of Nursing and Midwifery Studies, Cardiff University</td>
</tr>
<tr>
<td><strong>Supervisor:</strong></td>
<td>Dr Annette Lankshear</td>
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</table>
| **Contact details** | Anne McGowan  
Nurse Consultant  
Vaccine Preventable Disease Programme  
Public Health Wales  
Temple of Peace  
Cardiff CF10 3NW  
Tel: 02920402474  
email: anne.mcgowan@wales.nhs.uk |
| **Dates of research** | May 2009 to May 2011                                                                                                                |
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**Figure 1** MBPS score differences in simultaneous and sequential groups over time compared to baseline score

**Figure 2** Median MBPS score difference in simultaneous and sequential groups over time compared to baseline score with significant differences.

**Figure 3** Visual analogue scale response

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Acknowledgements

I would like to acknowledge the financial support for this study from Research Capacity Building Collaboration (RCBC) Wales. Sincere thanks go to the staff, parents and carers who very graciously agreed to take part in this study. Thanks also to my colleagues in the Vaccine Preventable Disease Programme (VPDP) and Dr Annette Lankshear for their support and help.

Agreement is given for the report to be published on the RCBC Wales website

Short lay summary of project

By the time a child reaches 13 months of age he or she should have received ten vaccinations which equates to an average of two per immunisation appointment. It is therefore important to look at interventions to decrease pain associated with receiving vaccines and to examine the evidence base for current clinical practice.

This study (sample 72 babies randomly allocated to one or other treatment) was a pilot study designed to test a methodology to determine whether, when immunising babies aged 2 – 6 months, there is any difference in the perceived level of pain and distress experienced by babies when given two injections at the same time (simultaneous technique) as compared to giving them one injection after the other (sequential technique). Both practices are currently widespread. The study design utilised is the randomised controlled trial (RCT). The study has shown that there is no difference in parents’ perceptions of the distress experienced by babies receiving either simultaneous or sequential vaccinations. Preliminary findings of the observed measure of pain behaviour in babies do not indicate a difference in pain overall. Further analysis of these scores is required. In this respect the study has been successful and the method could be used in a larger randomised controlled trial.

Introduction

The aim of the study was to test a methodology to compare pain response during routine immunisation of infants using sequential versus simultaneous administration techniques.

In the RCT, two research questions were investigated:

Is there a difference in behavioural manifestations of pain (as defined by standard measures of intensity and duration) when immunisation injections are given to 2 to 6 month olds infants simultaneously compared with sequentially?

Is there a difference in parental perceptions of levels of distress between parents of the infants who receive simultaneous injections as compared to the parents of infants who received sequential injection?
Literature Review

A review of the literature and observational experience indicates that there is limited evidence on optimal methods for reducing pain during infant immunisation. A belief held by nurses is that giving multiple injections at the same time (simultaneous technique) is less painful for infants than giving them one injection after the other (sequential technique).

Taddio and Nulman (1994) conducted a trial with EMLA (local anaesthetic cream) with infants who received diphtheria, tetanus and pertussis injections. In this study pain scale ratings and total crying time were reduced in the group treated with EMLA. As a practical intervention, the use of EMLA cream has two significant drawbacks: the cream needs to sit on the skin for at least one hour before the injection and it is expensive. Ipp et al (2007), in a randomised controlled trial of 113 infants found that immunisation using a pragmatic rapid injection technique is less painful than a slow standard of care technique and recommended that it should be used for routine intramuscular immunisations. Horn and McCarthy (1999) conducted an experimental study randomizing 50 children aged 4 – 6 year old into either a sequential or simultaneous group for preschool booster immunisations. This study did not identify differences in distress behaviours between the two groups although parents’ perceptions were that simultaneous injections were preferable. A recently published study by Ipp et al (2009) using a Modified Behaviour Pain Scale (MBPS) pain scale has shown that infant pain response during routine intramuscular vaccine injection was affected by the order of administration of the vaccine:

"Infants given the less painful DPTaP-Hib vaccine first followed by the more painful PCV experienced less pain overall when compared with those given the vaccines in the reverse order." (Ipp et al, 2009: P 471)

Breastfeeding is considered a combined analgesic intervention because several aspects of breastfeeding (e.g. holding the child, skin to skin contact, the sweet – tasting milk and the act of sucking) may attenuate pain responses. Four studies including a total of 478 infants up to 12 months of age reported less pain for infants breastfed during immunisation. (Dilli et al 2009, Efe et al 2007, Moddares et al 2006, Abdul Razek et al 2009.) However, some mothers may not wish to breastfeed during the vaccination and some infants may refuse to breastfeed.

A systematic review conducted by Taddio et al 2010 concluded that sucrose solutions are an effective analgesic intervention for infants up to 12 months of age and recommends sweet tasting solutions only for infants who are not breastfed during vaccinations. The risk of dental caries is considered negligible but does concern some parents.

Finally, a 2006 Cochrane review of psychological interventions for needle – related procedural pain in children and adolescents published by Uman et al concluded that further randomised controlled trials need to be conducted to explore this topic, particularly for the many interventions for which they could not locate any trials.

We conclude that there is a need for more systematic evidence to evaluate guidelines for vaccine administration techniques.
Method

This was a pragmatic randomised controlled trial (RCT) in a primary care setting in Gwent, S E Wales. It involved healthy children aged between 2 - 6 months attending routine immunisation clinics, receiving their primary immunisations of Diphtheria, Tetanus, acellular Pertussis, Polio, Haemophilus influenzae (DTaP/IPV/Hib) and either pneumococcal conjugate vaccine (PCV) or Meningococcal C (Men C) immunisations.

Sample

A convenience sample of 72 children aged between 2 and 6 months scheduled for routine primary immunisation was assessed to be statistically adequate to give indicative results. The age group was chosen because previous researchers have demonstrated that behavioural responses are relatively consistent in infants of that age (Johnson et al, 1993; Izard, et al, 1983). Other criteria for inclusion in addition to age required that the infant should be fit and well on the day, due to have two immunisations of either DTaP/IPV/Hib and PCV or DTaP/IPV/Hib and Men C; and that parental consent was obtained. Exclusion criteria applied to infants with known physical or psychological conditions; infants who had been hospitalised and infants whose parents were needle phobic. Parents were sent a letter and patient information sheet in advance along with their routine immunisation appointment from the Child Health Department at Aneurin Bevan Health Board (Appendix 2).

No attempt was made to control for parental behaviour as it was assumed that the sampling process randomised parental skill in comforting their infants after the procedure. Infant randomisation was achieved by computer generated block random allocation using Stata v10. (Stata Corp 1999) to achieve equal numbers in each group.

In advance of the clinic session coloured opaque envelopes were prepared independently. One colour used for the DTaP/IPV/Hib and PCV group and a different colour for DTaP/IPV/Hib and Men C group, each set being numbered sequentially. Inside the envelope was a randomly assigned allocation to either sequential or simultaneous administration. (Diagram 1) The nurse giving the envelope was blinded to the process. The data was collected in clinics between June and December 2010.
The non intervention group received sequential immunisations where immunisations are given by one after another by the clinic nurse. The intervention group received simultaneous immunisations where two clinic nurses administer immunisations at the same time. The clinic nurses were trained in standard clinical procedures (appendix 5) to avoid systematic bias.

The data were coded in January – February and analysed between March and May 2011. The coders recorded a baseline score before the first injection/s. Once the injection/s had been given, observations were made every 5 to 15 seconds for a period of 120 seconds after the injections. The coder’s tool for recording is available at Appendix 3. The baseline pain score is defined as the average reaction observed in the infant prior to vaccination. The post vaccination pain score is defined as the maximum reaction observed in the infant during the 120 second observation period. The minimum score that can be obtained on the MBSC is 0 and the maximum is 10. Scores were averaged between observers for each phase before and after and the mean pre and post scores for each infant were used. Pain scores were compared between the two groups using the t-test for continuous variables. The data from the Visual Analogue Scale and the MBPS coding from the video tapes was analysed by two researchers. There was double entry of the information using Epidata to improve reliability. An epidemiological scientist then further analysed the findings using Stata v 10.

**Outcome measures**

Three measures were identified to document the infant’s degree of distress.

1. Observer measure of pain

A Modified Behaviour Pain Scale (MBPS) measure based on crying, facial grimacing and body movements (Ipp et al, 2007) was used. Behaviours are weighted to indicate the intensity of the distress e.g. a scream is accorded greater weight than a cry (Appendix 1). The immunisations were video-recorded and the tapes were reviewed and coded.
independently by paediatric nurses. Paediatric nurses were chosen as reviewers because they are familiar with pain assessment in infants and use a range of pain scales in their clinical work (Ho, et al 1996). To increase reliability they were briefed in the use of the MBPS and scoring was conducted independently. The coders reviewed the videotapes for the presence or absence of designated facial expressions in four areas: brow, nose, eyes and mouth. Facial expressions have been extensively investigated as a measure of pain (Izard, 1982). Cry characteristics have been used by Grunau and Johnson (1990) and others to describe pain. The reviewers coded for not crying, moaning (quiet, vocalising gentle or whimpering cry) and full lunged cry or sobbing. Observations of body movements have also been used by investigators to determine pain (Craig et al, 1993). Infants react to pain by thrashing, jerking, wiggling, withdrawing, and kicking. The coders reviewed the tapes and recorded whether movements were resting and relaxed, partial (squirming, arching, limb tensing or clenching), or whether there is an attempt to avoid pain by withdrawing the limb being injected. Alternatively they may note agitation with complex/generalised movements including head, torso or other limbs, and rigidity. The MBPS has been designed to include these three dimensions as this is said to improve both the reliability and validity of the assessment (Ipp et al, 2001).

2. Parent’s rating of pain

The parent’s perception of the infant’s distress was assessed before and after the injections using a Visual Analogue Scale (VAS) (Weivers & Lowe, 1990). A VAS is a straight line with markers that are labelled at each end of the scale of sensation, feeling or response to be measured. The scale comprises a 10 cm line with descriptive phrases at either end ranging from ‘not upset’ to ‘very upset’. Parents were asked to put a mark on the line at the position that best represented their perception of the child’s level of distress immediately before the consultation and after the immunisation and the distance of that mark from the left hand extremity was measured.

3. Duration of distress behaviour

Each infant’s pre vaccination observed score was noted on the data analysis form. It was intended to analyse the time taken for each infant to return to their pre vaccine mean score using the time recorded on the video tape by the independent coders.

Results

Ninety nine infants fulfilled the inclusion criteria. Of these 27 refused consent (response rate 73%). The most common reason for refusal of consent was a parental reluctance to be video recorded. Of the 72 infants who consented 40 were girls and 32 boys. Age ranged from 8 weeks to 14 weeks and 5 days, mean age 11 weeks and 2 days. For the sequential group the second immunisation was administered between a range of 11 to 53 seconds, the mean was 23.30 seconds.

Baseline scores before the injections as measured by the MBPS for both groups were not significantly different as shown in figure 1.
Figure 1 MBPS score differences in simultaneous and sequential groups over time compared to baseline score.

Median MBPS scores in Treatment groups 1 and 2 over time

<table>
<thead>
<tr>
<th>Time (s)</th>
<th>Sequential</th>
<th>Simultaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.5</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>7.75</td>
<td>8</td>
</tr>
<tr>
<td>30</td>
<td>6.75</td>
<td>8</td>
</tr>
<tr>
<td>60</td>
<td>7.25</td>
<td>7.25</td>
</tr>
<tr>
<td>90</td>
<td>6.5</td>
<td>6.5</td>
</tr>
<tr>
<td>105</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>120</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

T0s=time 1st (sequential) or both (simultaneous) vaccines administered.
**Figure 2** Median MBPS score difference in simultaneous and sequential groups over time compared to baseline score with significant differences.

Statistically significant differences in increase in MBPS scores between the two groups at the 95% level are marked with circles.

Figure 2 shows the median difference in MBPS score at time intervals compared to the MBPS baseline score for both treatment groups:

- Babies who received sequential vaccination had higher median MBPS scores at more time points in the recordings.
- Pain scores for babies in the sequential group decline earlier than the simultaneous group but then increase again at the time point that corresponds to the second immunisation being administered.
- Differences in increase in MBPS scores between the two groups that are statistically significant at the 95% level occurred at 15, 30, 45 and 120 seconds.
- Pain scores were statistically higher at 120 seconds for the sequential group.
- When comparing the profile of median MBPS score increase from baseline between the two groups, increases are statistically significantly lower for the simultaneous vaccination group at more time points.
- From time point 30s, which corresponds to delivery of the second vaccination in the sequential group, onward, median increase in MBPS score was consistently higher in the sequential group than in the simultaneous group.
The box plot in figure 3 demonstrates the findings from the visual analogue scale (VAS) completed by parents/carers.

- Analysis shows that distributions overlap in both groups.
- Not surprisingly parents and carers perceived that their babies without exception were more upset after injections than before.
- When comparing changes in VAS mark positions before and after immunisations, the median change was greater in the sequential treatment group (5.6cm) compared to the simultaneous treatment group (4.7cm) although this difference was not statistically significant ($p=0.7$)

Figure 3 Visual analogue scale responses
Challenges Faced

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The lengthy ethical approval process involved scrutiny committees in Aneurin</td>
<td>Whilst this was time consuming (12 months), at each committee I was given constructive advice and support which improved the protocol.</td>
</tr>
<tr>
<td>Bevan and PHW Health Board’s, Cardiff University and SE Wales REC from May</td>
<td></td>
</tr>
<tr>
<td>2009 to 2010</td>
<td>Using a medical photographer and pilot testing video recording proved satisfactory but the use of CCTV would improve the data collection.</td>
</tr>
<tr>
<td>Video-recording babies</td>
<td>Use a 5 second interval for 45 seconds to ensure the immediate 2nd injection in the seq technique is recorded.</td>
</tr>
<tr>
<td>Coding the videotapes, the coding tool used did not have enough time</td>
<td>Areas not identified for training at start of study, resulted in time consuming tasks. Attempt at learning produced satisfactory results, and help sought from experienced others. Used Epi data for first time.</td>
</tr>
<tr>
<td>points on.</td>
<td></td>
</tr>
<tr>
<td>Time consumed in areas where skill is lacking (i.e. designing coding tools, diagrams and charts)</td>
<td></td>
</tr>
<tr>
<td>Endeavouring to interrogate, analyse and interpret the data</td>
<td>An epidemiologist colleague was available to analyse the data and offer advice.</td>
</tr>
</tbody>
</table>

Discussion

Results from this study show that there is no difference in the parent’s perception of distress between simultaneous and sequential vaccination techniques. The observed MBPS median scores show a different pattern of pain response but suggest no difference in pain overall and it is therefore difficult to conclude that one treatment was more painful than the other. Initial findings suggest that babies receiving sequential immunisation may exhibit slightly increased levels of discomfort for longer when compared to simultaneous immunisation, although this difference was not evident when evaluating parent and carer perception of their baby’s pain. Discriminatory power could be increased by increasing the frequency of the coded observations and video recording from this study could be re-assessed in this way. As a feasibility study the primary aim of this study was to assess the use of the MBPS, video recording, independent coders and the visual analogue scale to answer the research questions, in this regard it has been successful. The study has provided a rich dataset which can be interrogated further it has highlighted important questions to guide future larger trials.

This study did not set out to look at resource implications of the two treatments; however this should be built in to any future study to determine whether the requirement for an extra nurse in delivering simultaneous vaccinations is significant or whether it is outweighed by the time savings offered by sequential immunisation? In addition, there are other evidence based interventions as discussed in the literature review such as breast feeding, distraction and sucrose solutions which could be used in these clinical settings to minimise the distress to babies, which may prove more effective and be practically more desirable.
Initial findings from this study support the consensus from the Horn and McCarthy study in 1999; which did not identify different distress behaviours in the babies between the two groups.

**Strengths and limitations of research study**

The limitations of this study need to be considered when considering the transferability of the findings. As stated the discriminatory power could be enhanced by increasing the frequency of the coded observations. Further work will be carried out to rectify this by re-analysing the video tapes using more frequent time points. The number of variables could be reduced for example to limit the sample to two vaccinations i.e. Pediacel and Men C (exclude PCV). Future research should attempt to address these issues. However it’s strength as a RCT is that all extraneous variables are controlled for by randomisation.

**Conclusion**

This feasibility study has provided the basis for future research by testing the intervention for significant impact and testing the methodology for a future larger randomised controlled trial. With some slight modifications the methods are found to be acceptable. The findings from the coded pain scores showed an interesting pattern with some significant differences in the level of pain but do not give a firm basis for recommending one approach over another. From a public health point of view any effective measures that will reduce anticipated pain and improve patient satisfaction both from the parents’ and infants’ point of view is valuable.

**Dissemination plans**

Oral presentation at the Welsh Immunisation Conference 13th April 2011, The Riverfront Newport. Poster submission at HPA Conference Warwick Sept 2011. Journal articles will be written disseminating the study to a wider audience. Requested to present at RCN conference by Martin Semple (to follow up). National dissemination through VPDP in Wales.

**Cost of project**

Supervision - £3500
Primary care - £1000
Medical Photographer - £1500
Independent coders - £750
Travel admin costs to PHW Trust - £500
Epidemilogical support - £1750
Total = £9000
## Timeline

<table>
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<tr>
<th>Period</th>
<th>Activity Description</th>
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<tbody>
<tr>
<td>May 2009 to May 2010</td>
<td>Ethical approval, pre test video recording</td>
</tr>
<tr>
<td>April – June 2010</td>
<td>Plan clinics, Train Nurses, Inform primary care staff</td>
</tr>
<tr>
<td>June – Dec 2010</td>
<td>Data collection</td>
</tr>
<tr>
<td>Jan – Feb 2011</td>
<td>Coding and data input</td>
</tr>
<tr>
<td>March to May 2011</td>
<td>Analysis and write up study</td>
</tr>
</tbody>
</table>

## Research project - positive/ negative experiences

<table>
<thead>
<tr>
<th>Positive experiences</th>
<th>Negative experiences</th>
</tr>
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<tbody>
<tr>
<td>Learning about literature searching, and the need to think widely about terms, sources and databases</td>
<td>The ethical approval took longer than anticipated</td>
</tr>
<tr>
<td>Attending supervision on a regular basis</td>
<td>The need to have excellent organisational skills for reference management. I have used ref manager but it has taken a long time to master.</td>
</tr>
<tr>
<td>Networking with primary care colleagues, medical photographer and paediatric nurses.</td>
<td>Data collection took longer than anticipated.</td>
</tr>
<tr>
<td>Support from my colleagues in the programme</td>
<td>Analysis and writing up stage- lack of available time due to extension already expired</td>
</tr>
<tr>
<td>Talking directly to parents about immunisations, data collection phase</td>
<td></td>
</tr>
<tr>
<td>Learning and developing skills about randomised controlled trials which aided reflection and actions</td>
<td></td>
</tr>
<tr>
<td>Reflecting on research programme to assist learning. Planning tasks and meeting with team and manager to increase knowledge of research process</td>
<td></td>
</tr>
<tr>
<td>Importance of maintaining a journal and collaborative work with team members as data collection progressed</td>
<td></td>
</tr>
<tr>
<td>Importance of having effective systems for organising, managing and retrieving data</td>
<td></td>
</tr>
</tbody>
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## Plans to continue this work/other research

To build on this research by further analysis of the videotapes and dataset.
Reference:


Appendix 1: Modified Behaviour Pain Scale (MBPS) in infants

The infant is assessed prior to the procedure to give a baseline for comparison during and after the procedure.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Finding</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facial expression</strong></td>
<td>Definite positive expression (smiling)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Neutral expression</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Slightly negative expression (grimace)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Definite negative expression (furrowed brow eyes closed tightly)</td>
<td>3</td>
</tr>
<tr>
<td><strong>Cry</strong></td>
<td>Laughing or giggling</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Not crying</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Moaning quiet vocalizing gentle or whimpering</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Full lunged cry or sobbing</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Full lunged cry, more than baseline cry (scored only if child crying at baseline)</td>
<td>4</td>
</tr>
<tr>
<td><strong>Movements</strong></td>
<td>Usual movements and activity</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Resting and relaxed</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Partial movement (squirming, arching, limb, tensing, clenching)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Attempt to avoid pain by withdrawing the limb where puncture is done</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Agitation with complex/generalized movements involving the head, torso or other limbs.</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Rigidity</td>
<td>3</td>
</tr>
</tbody>
</table>

Where:

- Slightly negative expressions include brow bulging and naso-labial furrow.
- Definitely negative expressions include brow bulging, naso labial furrow eyes closed tight, open lips with or without a reddened face.

Interpretation: Minimum score= 0 and maximum score= 10.

Appendix 2 Letters to parents/carers

Date

Dear ……………………………

Re: Gray Hill Surgery baby clinic, Caldicot

………………………….. is due to attend Grayhill Surgery on Tuesday ………………………………. for their routine immunisations. I will be co-ordinating a small research study in the clinic that day and would welcome your participation. An information sheet is enclosed which explains the study in detail.

Taking part in the study is entirely voluntary and requires your informed consent. You are free to withdraw your consent at any time and your daughter/son’s treatment will not be affected.

The study has been approved by South East Wales Ethics Committee.

Please take your time to read the enclosed information. If you have further questions please contact me on 02920 402471 or I will be available on the day to answer them.

Yours sincerely,

Anne McGowan

Nurse Consultant

Vaccine Preventable Disease Programme, Public Health Wales
Appendix 3

Patient Information Sheet ~ a study to look at methods to minimise pain and distress following routine immunisation of infants.

We would like to invite you to take part in our research study. Your involvement is entirely voluntary. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. We suggest this should take about 10 minutes.

What is the purpose of this study?

We want to compare the amount of distress (if any) experienced by infants receiving their routine immunisations. It is a small study where one group of infants will receive their injections at the same time from 2 nurses and the other group will receive their injections one after another from 1 nurse. Sometimes we don't know which way of treating patients is best, so to find out, we need to make comparisons between the different treatments. To do this, we put people into groups and give each group a different treatment; comparing the results to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly) so your baby has an equal chance of receiving the immunisations at the same time compared to one after another. This is called a randomised controlled trial.

The study is important to see if infants who receive their immunisations at the same time experience less pain or distress compared to the other group. The study will take place in your usual immunisation clinic and the immunisations will be given by the same staff as usual. Around 70 babies will take part; half will be randomly selected for 2 injections at once and the other half for one injection after another. If the findings from this study are useful they will help in the planning of a large scale study.

Why have I been chosen?

You have been chosen because your baby is due their first or second immunisations and is between 2 and 6 months old.

Do I have to take part?

You do not have to take part; agreeing to be a part of this study is voluntary and requires your informed consent. You are free to withdraw at any time without giving a reason and your child’s care will continue as normal, receiving one injection at a time.

What will happen to me if I take part?

The nurse will ask you a few simple questions about the immunisations and also discuss your babies’ previous medical and immunisation history as usual. Once you and the nurse are ready to go ahead with the immunisations you will be given an envelope that contains a number that will randomly (by chance) allocate you to either the one at a time or the 2 at once immunisation procedure. The immunisation process will be video recorded. The tapes will be stored and viewed by trained paediatric nurses in secure premises, according to Health Board policies and the Data Protection Act (1998). Your child will receive the same immunisations as routine.

What do I have to do?

When the immunisations are given; it will be video taped so that independent researchers can then record how the babies respond. You will be asked to consent to this recording process in line with Aneurin Bevin Health Board NHS Trust’s policy.
You will be asked some questions after the immunisations about your understanding of the distress experienced by your baby.
What are the side effects of taking part?

There should not be any extra side effects by taking part in this study. Your baby may experience the anticipated side effects of routine immunisations to DTaP/IPV/ Hib, Men C and PCV that the nurse will advise you about and give you contact details if you have concerns.

What are the possible risks and disadvantages of taking part?

There are no foreseen possible risks or disadvantages to taking part in this study.

What are the possible benefits in taking part?

It is hoped that the findings from this study will lead to a larger trial to best see which way of giving immunisations causes least pain and distress for babies.

What if there is problem?

If you have any concerns about this study, you should ask to speak to the researcher who will do her best to answer your questions (02920402471). If you would like to speak to someone independently please contact Christina Overs, Chief Nurse, Aneurin Bevan, Health Board NHS Trust 01633 628905. If you remain unhappy you may wish to make a more formal complaint through Mamhilad House, Block A, Mamhilad Park Estate, Torfaen, NP4 0YP. Tel: 01873 732732.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential and any information about you which leaves the clinic will have your name and address removed.

What will happen to the results of this study?

The results from this study will be disseminated through publication, conferences and training. Significant findings will be developed in the form of guidelines for health care that can be used in immunisation sessions and will guide future research.

Who is organising and funding this study?

This study is funded by a research grant from RCBC Wales (Research Capacity Building Collaboration for nurses and allied health professionals in Wales) It is hosted by Cardiff University and the research is carried out by Public Health Wales. The sponsors of this study will pay Gray Hill Surgery for including you in this study.

Who has reviewed the study?

All research within the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interest. This study has been reviewed and given a favourable opinion by the South East Wales Research Ethics Committee. Further information about this is available at [http://www.nres.npsa.nhs.uk/](http://www.nres.npsa.nhs.uk/)

Contact for further information

Anne McGowan Nurse Consultant Vaccine Preventable Disease Programme/Public Health Wales 02920202471 or anne.mcgowan@nphs.wales.nhs.uk
Appendix 4: Information for Coders

Many thanks for agreeing to help with the coding of the video tapes. It would be helpful if you could please re read the clinical trial protocol version 9 16th March 2010 to give you the background on the study.

Please ensure you are viewing the tapes in private and care is taken to store and manage all tapes and data in line with the Data Protection Act and policies of Aneurin Bevan NHS trust and Public Health Wales policies.

A Modified Behaviour Pain Scale (MBPS) measure based on crying, facial grimacing and body movements (Ipp et al, 2007) have been used to code. Behaviours are weighted to indicate the intensity of the distress e.g. a scream is accorded greater weight than a cry. The MBPS has been designed to include these three dimensions as this is said to improve both the reliability and validity of the assessment (Ipp et al, 2001).

- You will review the videotapes for the presence or absence of designated behaviours in the following areas: facial expressions, cry characteristics and observations of body movements.
- You will record a baseline score immediately before the immunisation/s is given.
- Once the injection has been given, observations will be made every 5 seconds for 15 seconds and then every 15 seconds up to 2 minutes
- Please record the video time stated on tape at first immunisation/s on the form
- Record the time for each reading under the correct heading
- There is a 2 second + or - leeway allowed on each recording
- In the notes section
  - Mark P in the appropriate time column if a pacifier is introduced
  - Mark B in the appropriate time column if a bottle is used
  - Mark X in the appropriate time column if the film stops before the 2 minutes.
- Record any comments necessary, if more space is required maintain a log of comments according to random number and submit with coding form
- Keep a record of the time taken to complete the coding

If at any stage you want to discuss further please contact me on my mobile 07800641172.
Anne McGowan
Appendix 5 Information for clinic nurses; standard clinic procedures include.

1. Vaccines will be drawn up by the clinic nurses following manufacturers guidelines.
2. Infants will be held during the procedure by a parent or carer, with the infant in a sitting position facing outwards (away from the carer).
3. Infants will be immunised using a blue 23 gauge 25mm length needle.
4. Standardised intramuscular injection technique will be used, where the needle is inserted at a $90^\circ$ angle with steady pressure into the anterolateral aspect of the thigh.
5. DTaPHib/IPV will be given into the right thigh, either Men C or PCV will be given into the left thigh.
6. After the injection is given cotton wool should be applied to the site with direct gentle pressure for 10 seconds. The skin should not be stroked or massaged.
7. The simultaneous vaccines will be injected at the same time. The nurses will, following agreement from the parent /carer synchronise their administration by kneeling /crouching next to infant and counting down from , 3 ,2 ,1 to administer simultaneously.
8. The sequential vaccines will be injected onto alternate limbs within 60 to 90 seconds of each other. DTaPHib/IPV vaccine should be given first.
9. The nurses will alternate taking it in turns to give the sequential vaccines.
10. No aspiration will be performed.
11. Alcohol swabs will not be used.
12. The syringe contents will be rapidly injected for 1 – 2 seconds followed by rapid withdrawal of the needle and application of a cotton wool pad.
13. The nurses giving the vaccine will document batch numbers, sites, date, time signing and printing their name and designation as required for records.