King's College Hospital NHS
NHS Trust

THREE VENEPUNCTURE TECHNIQUES IN BABIES: A COMPARATIVE STUDY

Report to the Medical Devices Agency, Department of Health

February 2001

Jane Hunt
Senior Nurse for Research & Development

Nora Donaldson
Biomedical Statistician

Sarah Tizzard
Research Nurse

Janet Rennie
Consultant in Neonatology

Table of Contents

Acknowledgements 4

List of Abbreviations 5

Chapter One – Background to the Study 6-7
- 1.1. Introduction 6
- 1.2. Aim of the Study 7

Chapter Two – The Study 8-14
- 2.1. The Setting 8
- 2.2. The Hypothesis 9
- 2.3. Methodology 9
- 2.3.1 Randomisation 10
- 2.3.2 The Sample 10
- 2.4. Ethical Considerations 11
- 2.5. Peer Review 11
- 2.6. Piloting 12
- 2.7. Data Collection 12
- 2.8. Data Analysis 13

Chapter Three – The Findings 15-16
- 3.1. Introduction 15
- 3.2. Results 15
- 3.2.1 Number of attempts 15
- 3.2.2. The extent of bruising 16
- 3.2.3 The presence of clotting 16
- 3.3 Conclusions 16

Chapter Four – Discussion 17-19
- 4.1. Introduction 17
- 4.2. The difficulties 17
- 4.2.1 External impediments to recruitment 18
- 4.2.2. Internal impediments to recruitment 18
- 4.3. Conclusion 19

Appendices

Tables

Table 1	Number of attempts	15
Table 2	Extent of bruising	16
Table 3	Presence of clotting	16

Acknowledgements

This study has been funded by the Medical Devices Agency (MDA), Department of Health. The Research Team are grateful to staff within the MDA for their advice and support in planning this project. In particular we are grateful to Carol Williams, Acting Nurse Director, Medical Devices Agency, Department of Health for initiating this study and to Dr Helen Glenister, Nurse Director who has continued to act as our link and guide us throughout the project.

Special thanks are given to all the staff within the neonatal and paediatric units in which this research was undertaken. Particular thanks are given to the Senior House Officer's without whose active participation would have made this study impossible.

We are particularly grateful to the parents who graciously assented the participation of their babies in this study.

The Research Team

Dr Jane Hunt, Senior Nurse for Research and Development, King's College Hospital NHS Trust

Sarah Tizzard, Research Nurse, Child Health, King's College Hospital NHS Trust

Dr Roy Philip, Specialist Registrar, ECMO Project, Great Ormond Street Hospital for Children NHS Trust

Dr Nora Donaldson, Biostatistician, King's College Hospital NHS Trust

Dr Janet Rennie, Consultant Neonatologist, Children Nationwide Neonatal Unit, King's College Hospital NHS Trust

Imelda Nolan, Neonatal Nurse Practitioner, Children Nationwide Neonatal Unit, King's College Hospital NHS Trust

Dr Alastair Baker, Consultant Paediatric Hepatologist, King's College Hospital NHS Trust

List of abbreviations

HDU	High Dependency Unit
EU	European Union
RCT	Randomised Controlled Trial
MDA	Medical Devices Agency
NICU	Neonatal Intensive Care Unit
NHS	National Health Service
NHSE	National Health Service Executive (from 1994)
NHSME	National Health Service Management Executive (before 1993)
PICU	Paediatric Intensive Care Unit
SCBU	Special Care Baby Unit
SHO	Senior House Officer
UK	United Kingdom

Chapter One – Background to the Study

1.1. Introduction

It has long been recognised in paediatrics and in children's nursing that medical devices designed for use in adults, have been modified and/or adapted for use in young children, babies and neonates. This has been common practice amongst clinicians[i] in certain areas where no suitable child-specific device has been available. The modification and adaptation of a medical device means that it is not being used as intended by the manufacturer and liability would therefore lie with the user.

One such device designed for use in adults, which has been modified for use in young children and babies, has been the hypodermic needle. The 'broken needle' technique, whilst noted for its 'obvious drawbacks' (Roberton & Rennie 1999:1372), is perceived to facilitate blood sampling from neonates (Roberton & Rennie 1999:930). Consultation with clinical experts in the fields of neonatology and paediatrics suggest that such techniques are widely practised amongst clinicians. The 'modified butterfly' technique is also practised in a number of organisations where babies and young children are cared for and where it is perceived to be a 'safer' technique. This practice involves removing the plastic tubing from the end of 'butterfly' needles and dripping blood through the end into specimen bottles. Our enquiries lead us to conclude that this practice is also considered by some clinicians to have its drawbacks. Nonetheless, these practices have existed to date because no alternative product has hitherto been available on the market.

Through modifying needles designed for sampling blood from adults, the potential for adverse incidents arises. The incidence of an 18 months old girl who was found to have an hypodermic needle embedded in her kidney was highlighted in the press (Brooks 1999, Lakeman 1999, Daily Telegraph Correspondent 1999) at the outset of this study. The child concerned had reportedly undergone a 'routine' test when aged nine months. This incident is similar to another reported three years previously. In both incidents, investigations identified the likely cause of infiltration to be due to inadequate clearing up procedures following blood sampling. Anecdotal evidence also leads the researchers to

surmise that these two reported cases are not isolated and that routine X rays undertaken in a number of organisations have identified neonates and young children both lying on broken needles and having broken needles embedded in tissues and organs. In both of the reported cases the needle was found to be French Gauge (FG) 21, commonly used for venous sampling from adults, which had been modified by removal of the hubcap.

In recognition of the 'obvious drawbacks' associated with these 'modifying' practices and the reported 'adverse incidents' allied to the 'broken needle' technique, a variety of new butterfly-type needles, specific to blood sampling from neonates and young children, have recently been designed and manufactured by a number of companies. Given the adverse publicity concerning the use of the 'broken needle' technique and the obvious safety issues concerning its use, it would seem pertinent to implement these new devices. However, whether one device is any more efficient in aiding health care professionals to extract blood samples from infants than another remains unknown.

Our review of the literature suggested that there is an absence of research in this area. To support our review, it has recently been suggested that the vast majority of literature concerning neonatal blood collection is related to examinations of heel puncture (Logan 1999). Given the dearth of research in this area, this project set out to examine the safety and efficacy of three venepuncture techniques in babies.

1.2 Aim of the Study

The main aim of the study was to compare three venepuncture techniques in babies: (1) the 'broken needle' technique, (2) the 'modified butterfly' technique and (3) a new 'single winged' needle designed specifically for venepuncture in neonates, infants and babies.

Chapter Two – The Study

2.1. The Setting

Anecdotally, the 'broken needle' and 'modified butterfly' techniques of blood sampling are commonly employed across a variety of neonatal and paediatric settings in the United Kingdom (UK). Reflecting their diverse use, the research team deemed it pertinent to undertake this research in both paediatric and neonatal environments.

Members of the research team work at a large London teaching hospital which provides both specialist tertiary and more general secondary paediatric and neonatal services. The neonatal unit comprises: a neonatal intensive care unit (NICU), a high dependency unit (HDU) and a special care baby unit (SCBU). It works closely with a specialist fetal medicine department and admits babies of very early gestation and low birth weight. Particular specialties offered within the unit include care of neonates with respiratory disorders, gastrointestinal and nutritional problems or neurological disorders. Approximately 500 newborn babies are admitted each year.

The children's unit provides specialist tertiary services in paediatric intensive care, liver and neurological disorders and for children with haematological disorders such as Sickle Cell disease. However, it also provides secondary care in medical and surgical children's wards for children with acute and chronic illnesses. Preliminary investigations suggested that during the second quarter of 2000, the children's liver unit and paediatric intensive care unit (PICU) jointly admitted around 30 babies under one year of age. Other wards, particularly the day care unit, also admitted infants for repeated investigations. The neonatal and paediatric units between them where deemed sufficiently sizeable with sufficient admissions to answer the research hypothesis.

Given the nature of both the paediatric and neonatal units in the hospital where the research was undertaken, many infants are subjected to investigations requiring multiple blood sampling. Although some babies who are admitted across either of the two units requiring frequent blood sampling have central venous access devices implanted, there are many babies who have blood sampled peripherally. A phlebotomist is employed to

take blood from older children in the children's unit and to take heel prick samples and a variety of staff including a neonatal nurse practitioner perform venepuncture in babies on the neonatal unit. However, within both units, it is predominantly Senior House Officers (SHOs) who undertake this task. It was this group of health care professionals therefore, who participated in the research.

2.2. The Hypothesis

This research set out to address the null hypothesis that there is no significant difference in outcome between the blood sampling methods incorporated into the study.

2.3. Methodology

Whilst the 'broken needle' and 'modified butterfly' techniques of blood sampling are employed in both babies and toddlers, it is sampling blood from neonates and infants which pose the greatest challenges to health care professionals routinely undertaking this task. Neonates and infants on a busy unit are also more likely to be exposed to undetected misplaced needles than older, more active toddlers. It is also in this age group that adverse incidents have hitherto predominantly been reported (Brooks 1999, Lakeman 1999, Daily Telegraph Correspondent 1999). Given these factors, this study set out to examine the safety and efficacy of three blood sampling techniques in babies under one year of age. The three blood sampling techniques examined were: (i) the 'broken needle' technique, (ii) the 'modified butterfly' technique and (iii) a technique incorporating a new device referred to as the 'single winged' technique.

To ensure validity, consistency of needle gauge of the devices incorporated in the study was considered of paramount importance by the research team. A recent limited review of the literature suggested that when sampling blood from babies and young children, recommendations about needle gauges are often made (Caws & Pfund 1999). These gauges vary in size from 27 – 21, depending on the size of the baby or young child. Acknowledging both the literature and preferences of staff from the participating units, a 23 gauge needle was selected as the size to be incorporated within this research, representing 'middle ground'.

2.3.1 Randomisation

The objectivity of randomised control trials (RCTs) has recently been called into question (McCormack & Greenhalgh 2000). However, it is generally recognised that within an 'Hierarchy of Evidence' RCTs epitomise the most reliable means of data collection on which to assess the validity of research findings (NHS Centre for Reviews and Dissemination 1996, Torgeson & Roberts 1999). To this end a RCT was deemed the most appropriate method to adopt to address the research hypothesis.

Babies recruited into the study were randomised with the assistance of computer-generated sequences. The randomised sequencing elicited the order in which the three techniques of blood sampling were used and a 'concealment' method of randomisation (Torgeson & Roberts 1999) was adopted with randomised sequences placed into envelopes and sealed.

2.3.2 The Sample

Babies and their families who participated in this research were drawn from the NICU, the HDU, the SCBU and the children's unit at the participating hospital. To be eligible we required babies to weigh over 1500 grams and be under twelve months of age. These stipulations were made because staff felt that babies who weighed less than 1500 grams were particularly formidable to take blood from and toddlers over the age of twelve months posed different challenges when performing venepuncture. Other babies who were perceived to pose particular difficulties in performing venepuncture were those who had been asphyxiated and so these too were excluded from the study. In addition, to be eligible all babies needed to require at least three routine blood samples via venepuncture so that the three techniques could be assessed. A resting period between consecutive blood samples of at least six hours was also set to allow for sufficient time to observe for any bruising. Babies were excluded if a vein was not available or if s/he had an indwelling catheter *in situ*, in which case an alternative procedure (heel prick, central line access etc.) was used. Additional exclusion criteria included babies from non-English speaking families for whom translation could not be provided.

A parallel study comparing heel prick and venepuncture in the newborn (Logan 1999) found a significant difference in terms of the number of repeat punctures with 17% of babies in the venepuncture group having more than one skin puncture. Based on this we assumed an expected probability of discordant pairs of the order of 0.20 and set out to detect a change in the risk of repeat skin punctures given by an odds ratio of 2.5. To guarantee a power of 80%, at the 5% significant level, 38 discordant pairs were needed for which we anticipated recruiting 180 babies (Julious & Campbell 1998).

2.4. Ethical Considerations

Babies participating in this study were not subject to blood sampling outside routine monitoring of their condition and each device examined in this study is registered for use within the European Union and is CE marked. Furthermore, the 'broken needle' and 'modified butterfly' techniques are commonly employed in neonatal and paediatric units in the UK and elsewhere in the world. However, this study necessitated randomisation and written consent was therefore sought and obtained from babies' parents. Prior to consent being gained written information was given to parents (Appendix 1) and time given to them prior to gaining signatures on written consent forms (Appendix 2). Verbal consent was sought from each of the participating SHOs and approval to undertake this study was sought from consultants. Ethical approval was gained from the Local Research Ethics Committee. Towards the latter stages of the study the consent form was modified to accommodate more recent recommendations (see Appendix 3).

2.5. Peer Review

In an era of 'Research Governance' (DoH 2000a, NHSE 2000) external peer reviewing of all research undertaken within NHS settings may be considered 'best practice'. In accordance with this 'best practice', the proposal outlining this research was subjected to both internal and external peer review. The internal peer review comprised numerous discussions amongst the research team and clinicians involved with the project and academic staff within the MDA. The proposal was scrutinised externally by a nursing professor with a wealth of experience in evaluating nursing and/or clinical interventions.

2.6. Piloting

A nurse researcher was appointed and assigned to co-ordinate the study. She familiarised herself with the methodology and was then trained in the use of the devices examined within the study. In particular she was trained in the use of the 'single wing' device. In turn, she then trained all SHOs in the use of the three techniques. This training was then followed by a practising period of one week before the data collection began.

A data collection form was designed and piloted. During this period a literature search revealed an absence of tools appropriate for use in babies for measuring bruising. Therefore it was decided to record the extent of any bruising in millimetres, using disposable tape measures. Pilot work resulted in minor modifications being made to the data collection form (Appendix 4). Patients recruited into the early stages of the research were therefore included in the final analysis.

2.7. Data Collection

Each baby whose parent agreed their baby's participation had three consecutive blood samples taken by each of the three randomly assigned venepuncture techniques. Each technique and the corresponding device were colour-coded for ease of identification; red for 'broken needle', blue for 'modified butterfly' and yellow for the 'single wing'. The assigned colour was printed onto the data collection form by each technique title and a sticker of the corresponding colour was attached to the packaging of every physical device.

The nurse researcher entered the randomised sequence and study number of each baby onto its data collection form (Appendix 4). The forms, in turn, were attached to the babies' cots or incubators, for the duration of the data collection period. In addition, a clear plastic specimen bag was attached to the cot which contained the colour-coded devices and a disposable paper tape measure. This allowed for the forms and devices to be immediately accessible to the staff when they were due to take blood and also helped act as a constant reminder that the baby had been consented into the project.

Four A4 sized posters were designed. The first reminded staff of the entry criteria for the study. The other three each displayed one of the devices, with the device's study name and colour-coding. This series of four posters, were then displayed in the units' treatment rooms and social gathering points (such as coffee rooms). Both written and verbal reminders were also issued by the nurse researcher to the paediatric SHOs responsible for taking the blood by the designated venepuncture technique. This attempted to ensure that the correct randomised sequence was followed and that the data were entered on to the data collection form promptly and accurately. As blood samples were collected, data were entered on to the data collection form by either the paediatric SHO who had undertaken the venepuncture technique or by the nurse researcher. On completion of the three randomly assigned venepuncture techniques, or on the baby's discharge, if sooner, the nurse researcher collected the data collection forms.

2.8. Data Analysis

Statistical analysis aimed to compare the three venepuncture techniques in terms of three main end-point variables. These were indicators of: (1) whether the blood sample had been obtained after one, two or greater than two attempts; (2) whether there was clotting in the sample and (3) whether there was bruising and the extent of bruising measured at the largest diameter of the bruise.

Data were coded and variables entered into Microsoft Excel™ '97. Nineteen variables were created. These comprised: each baby's personal study number, gestational age at birth, age in days and weight in grams at the time of their inclusion into the study. In addition, the randomised sequence order, time elapsed, in hours, between the first and second device being used and then the time elapsed between the second and third device being used were also inputted. The number of attempts made with each device was then entered, along with the baby's venepuncture site used for each attempt. Clotting problems were also entered with two variables being created – a distinction was made between any immediate clotting at the time of taking the sample and any clotting that occurred later in the laboratory. The presence/absence of bruising to the baby from each technique was then recorded, and the measurement of any bruising, was inputted in millimetres.

Variable comparison was proposed using Anova with repeated measures, assessing the effect of age, gestational age and weight of the baby.

Chapter Three – The Findings

3.1. Introduction

Seventeen babies were recruited into the study. Fourteen of these babies completed the study, having blood taken and documented for all three devices. The three remaining babies were discharged home before completion; one having two of the techniques completed, a second after having one technique and a third had no samples taken. A first interim analysis has therefore been undertaken. These results are documented in this section of the report.

3.2. Results

Data were analysed in terms of: (1) number of attempts at venepuncture with each of the devices, (2) extent of bruising and (3) the presence of any clotting either during the procedure or later, in the in the laboratory.

3.2.1. Number of attempts

In a first interim analysis with 14 babies recruited, no significant difference was found between the three techniques in terms of mean number of attempts (P=0.6). In particular, the Wilcoxon signed-rank test found no significant difference between the modified butterfly and the single-wing technique (P=0.16) or between the broken needle and single-wing (P=0.25). Findings regarding the number of attempts at venepuncture are summarised in Table 1.

Table 1: Number of attempts

Comparison	**N**	**Number of attempts Mean (95%c.i.)**	**Median**
Broken Needle	14	1.5 (1.1, 1.9)	1.0
Modified Butterfly	14	1.5 (1.1, 2.0)	1.0
Single Wing	13	1.2 (0.9, 1.6)	1.0

3.2.2. The extent of bruising

Likewise, no significant difference between the means of the three techniques was found (P=0.6) when analysing the extent of bruising (Table 2). In particular, the pairwise comparisons of modified butterfly with broken needle (P=0.19) and single wing (P=34) yielded non-significant results.

Table 2: Extent of bruising

Comparison	**N**	**No. of attempts Mean (95%c.i.)**	**Maximum**
Broken Needle	14	0.55 (0.3, 1.3)	4.0
Modified Butterfly	14	0.07 (-0.09, 0.25)	1.0
Single Wing	13	0.3 (-0.21, 0.8)	4.0

3.2.3. The presence of clotting

Similar results were obtained for the outcome signalling presence of clotting (Table 3).

Table 3: Presence of clotting.

Comparison	**N**	**No. of babies**
Broken Needle	13	0
Modified Butterfly	13	1
Single Wing	13	0

3.3. Conclusions

The trial was severely underpowered and the analyses presented are by no means final analyses. These analyses constitute a first interim analysis of the data, as it was originally envisaged in the protocol. The result of this first interim analysis is inconclusive and calls for continuation of recruitment in order to achieve the intended power of the study.

Chapter Four – Discussion

4.1. Introduction

It was not by co-incidence that this research adopted a collaborative approach between differing professional groups, in particular between medicine and nursing. In an era when professional partnerships exist between hospital doctors and nurses (Hunt 1998) and the boundaries between the two professions become increasingly blurred (e.g. Walby *et al*. 1994, Dowling, Barrell & West 1995, Beattie 1995, Mackay *et al.* 1995, Dowling 1997), doctoring and nursing roles are becoming increasingly ill-defined. Since the reduction in junior doctors hours brought about through the 'New Deal' Policy' (NHSME 1991) and more recently through *Improving Junior Doctors' Working Lives Action Teams* (DoH 2000b), and greater moves towards extending nursing roles, nurses are increasingly taking on the roles traditionally undertaken by doctors. Venepuncture is one such area and Fulbrook and Caws (1999) have recently reported that over 8% of nursing time in one children's out-patient department is spent taking blood. Furthermore, recent research suggests that venepuncture is a superior technique for extracting blood compared to heel prick (Larson *et al.* 1998, Logan 1999) as it is less painful (Larson *et al.* 1998), reduces the length of time a baby cries after the procedure (Logan 1999) and has a shorter sample collection time (Logan 1999). These findings have implications for potentially increasing the numbers of venepunctures performed by both nursing and medical staff.

Given the extent to which venepuncture is undertaken by both nurses and doctors, it was anticipated at the outset of the study that results from the research would have multidisciplinary implications for practice and a concluding chapter in a research report would usually be dedicated to discussing such implications. However, given the poor recruitment to this study, this chapter instead will discuss the difficulties encountered along the way and propose a route forward.

4.2. The difficulties

Given the annual admission rates to both the paediatric and neonatal units (see Chapter Two), it was anticipated at the outset of the study that sufficient numbers of babies would be admitted across the neonatal and paediatric units to address the hypothesis. However, from the outset of the data collection period, a number of difficulties arose which affected recruitment to the study. These primarily evolved from external influences. However, there were also some internal factors affecting recruitment and both of these are discussed in the following sections of the report.

4.2.1 External impediments to recruitment

During the planning and execution of this research several adverse incidents pertaining to both research and clinical practice in neonates and children were reported in the press. These incidents have not only impinged on the data collection process of our study, but have also, anecdotally, impeded research involving babies and young children elsewhere. Following publication of the Redfern Inquiry (DoH 2001), some of these reported incidents are still ongoing (e.g. see Boseley 2001) which may continue to hamper the efforts of researchers during 2001.

The first incident concerns research undertaken some years ago at a hospital in North Staffordshire, without ethical approval. This research examined novel incubators and findings from the subsequent enquiry, made headline news earlier in the year the data collection was undertaken (Boseley 2000a, Wainwright 1999). Secondly, a community children's nurse accused of the premature death of terminally ill children in Essex hit the national press at the outset of data collection (The Guardian, staff and agencies 2000). This report, whilst not related to research, heightened already existing anxiety amongst concerned parents. Thirdly, the removal of children's organs at post mortum and the subsequent retention of organs by hospitals without the parents' consent, continues to make headline news (Boseley 2000b, Carter 2000, Boseley 2001). Lastly, reports of problems with central catheters in babies made the news towards the latter stages of data collection process.

These reports all made headline news as families were about to be recruited into the study and each in turn, were cited by parents as reasons for not wishing to allow their baby to participate in the study. Despite highlighting the need to give consent to participate in the study, we found many parents remained extremely cautious about the health care system in which their child was being treated and declined participation. These concerns significantly hampered the data collection as more parents from the neonatal unit declined consent for their child's participation in the study than gave it.

4.2.2. Internal impediments to recruitment

Recently, a young patient with liver disease exsanguinated when complications arose following routine investigations. It was perceived that inadequate venous access contributed to the child's death. As a consequence, at the outset of the study a change in clinical practice within the paediatric unit arose, resulting in an increase in the numbers of children having central lines inserted. An outcome of this measure, which impacted on this research, was that far fewer children met the eligibility criteria for the study, than were previously available.

An additional obstacle to the research concerns a dearth of eligible babies admitted to the paediatric unit during the period of data collection. Although prior to the data collection period, there had been approximately 10 babies a month admitted to the unit, this number decreased during the period in which the data collection occurred. Furthermore, of those who were admitted who were otherwise eligible, many were non-English speaking for whom translators could not be found. This further hampered our efforts at recruitment.

A further setback to data collection lay in covering periods of absence (e.g. holidays, evenings, weekends etc.). Despite making contingency plans with a number of nursing and junior medical staff to recruit babies in the absence of the research nurse, the pressures of work in extremely busy, acute understaffed paediatric and neonatal units (e.g. see Parmanum *et al*. 2000), rendered these plans impossible. This resulted in no new additional babies being recruited during these times.

4.3. Conclusion

A number of adverse events both internally and externally hampered our best efforts to recruit babies into the study in the given time. This has resulted in an interim analysis being undertaken. Despite the difficulties outlined in this report, the research team would propose continuation to achieve the intended power of the study.

References

Beattie A (1995) War and peace among the health tribes **in** Soothill K, Mackay L & Webb (eds.) *Interprofessional relations in health care*. Edward Arnold. pp.11-26.

Boseley S (2000a) NHS on trial over secret baby tests: Doctors criticised for using children without proper safeguards. *The Guardian*. 9th May.

Boseley S (2000b) Arrogance of doctors led to organ scandal: Inquiry says removal of children's hearts ignored views of parents. *The Guardian*. 11th May.
http://www.guardianunlimited.co.uk/Archive/Article/0,4273,4016923,00.html

Boseley S (2001) 'Grotesque' breach of trust at Alder Hey. *The Guardian.* 29th January.
http://www.guardianunlimited.co.uk/uk_news/story/0,3604,43028,00.html

Brooks L (1999) Scan on baby reveals needle left in kidney. *The Guardian*. 8th June.
http://www.guardianunlimited.co.uk/Archive/Article/0,4273,3872851,00.html

Carter H (2000) Hospital suffers bitter legacy of organ scandal: Strain is telling on staff as they pick up the pieces at Alder Hey, its reputation shattered by retention of children's organs without consent. *The Guardian*. 3rd June.
http://www.guardianunlimited.co.uk/Archive/Article/0,4273,4025060,00.html

Caws L, Pfund R (1999) Venepuncture and cannulation on infants and children. *Journal of Child Health*. **3**(2):11-16.

Daily Telegraph Correspondent (1999) Hospital admits it 'probably' left needle in baby. *Daily Telegraph.* 26th July

DoH (2000a) *Research and Development for a first class service: R&D funding in the new NHS*. DoH. Leeds. March.

DoH (2000b) *Improving Junior Doctors' Working Lives Action Teams*. DoH. December. HSC 2000/36.

DoH (2001) *The Royal Liverpool Children's Inquiry*. Report chaired by M. Redfern QC. DoH. January.

Dowling S, Barrett S, West R (1994) With nurse practitioners, who needs house officers? *British Medical Journal*. **312**:1211-1214.

Dowling S (1997) Life can be tough for the in betweenies. *Nursing Times.* **93**(10):27-28.

Fulbrook P, Caws L (1999) The role of the nurse in the paediatric out-patient department. *Journal of Child Health Care*. **3**(1):13-22

Comment:

Comment:

Hunt JA (1998) *Mixed Funding Within The British Health Care System: An Examination of the Effects on Professional Relationships Between Paediatric Oncology Outreach Nurse Specialists and Other Health Care Professionals.* Unpublished PhD. University of Surrey. January.

Julious SA, Campbell MJ (1998) sample size calculations for paired or matched ordinal data. *Statistics in Medicine.* **17**:1635-1642

Lakeman G (1999) Needle in tot sparks blood jab safeguard. *The Mirror*. 26th July.

Larson BA,Tannfeldt G, Lagercrantz H, Olsson GL (1998) Venipuncture Is More Effective and Less Painful Than Heel Lancing for Blood Tests in Neonates. *Pediatrics*. **101**(5):882-886

Logan PW (1999) Venepuncture versus heel prick for the collection of the newborn screening test. *Australian Journal of Advanced Nursing.* **17**(1):30-36.

Mackay L, Soothill K, Webb C (1995) Troubled times: The context for interprofessional collaboration **in** Soothill K, Mackay L , Webb C (eds.) *Interprofessional relations in healthcare.* Edward Arnold. London. pp5-10.

McCormack J, Greenlagh T (2000) Seeing what you want to see I randomised controlled trials: versions and perversions of UKPDS data.
http://www.bmj.com/cgi/content/full/320/7251/1720

National Health Service Centre for Reviews and Dissemination (1996) *Understanding Systematic Reviews of Research on Effectiveness.* CRD Report 4. University of York.

NHSME (1991) *Junior Doctors: the new deal.* NHSME. London.

NHSE (2000) *Report of a review of the research framework in North Staffordshire Hospital NHS Trust.* NHSE West Midlands Regional Office.

Parmanum J, Field D, Rennie J, Steer P (2000) National census of availability of neonatal intensive care.
http://www.bmj.com/cgi/content/full/321/7263/727

Roberton NRC, Rennie JM (1999) *Textbook of Neonatology. 3rd Edition.* Churchill Livingstone.

The Guardian staff and agencies (2000) Nurse suspended over children's deaths. *The Guardian.* 22nd June.

Torgerson DJ, Roberts C (1999) Randomisation methods: concealment. *British Medical Journal.* **319**:375-376.

Wainwright M (1999) Inquiry into 'baby experiments'. *The Guardian*. 19th February. http://www.guardianunlimited.co.uk/Archive/Article/0,4273,3824224,00.html

Walby S, Greenhill J, Mackay L, Soothill K (1994) *Medicine and Nursing: Professional in a changing Health Service.* Sage. London.

[i] The term 'clinician' is used throughout to denote medical staff of all grades, nurse practitioners and other nurses.