NCCPC

The National Collaborating Centre for Primary Care

Postnatal care

Routine postnatal care of women and their babies

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Preface

The postnatal period marks the establishment of a new phase of family life for women and their partners and the beginning of the lifelong health record for newborn babies. As a practicing GP I know just how important this period is and the vital role of the primary health care team. But I also know that it is essential to define clear standards of health care for this area as there is uncertainty about best practice. So I welcome this document which places the woman and her infant at the centre of care. Patient centred care is a value espoused by the Royal College of General Practitioners. In our document, Valuing General Practice, we outlined the core values of British general practice.[1] The guiding principles of practice identified by the College includes the concepts that health care must be a partnership with patients and involve a team approach in which professionals work in an integrated, co-ordinated manner. The Postnatal Care Guideline, developed by the National Collaborating Centre for Primary Care, based at the RCGP, reflects these precepts of contemporary general practice.

'Core' care for all women is defined with consideration for the context of care as well as the specific needs and preferences of the individual woman. In addition to providing clinical guidance about particular topics, the recommendations cover the importance of offering appropriate, responsive and timely information and of promoting health. Team working is a key feature of current general practice. The Postnatal Care Guideline recognizes the necessary flexibility of healthcare professionals' roles in evolving health care systems and highlights the need for coordination of care throughout the postnatal period. Effective communication between health care professionals is therefore identified as a necessary element in the delivery of high quality and cost effective care.

I commend this guidance to health communities including commissioners and urge them to implement it. The guidelines will ensure that the primary care focus during the puerperium is maintained and that it meets the needs of women, their families and the community, and ensures the appropriate use of health care resources.

Professor Mayur Lakhani ,

Chairman of Council, Royal College of General Practitioners,

London SW7 1PU

[1] http://www.rcgp.org.uk/Docs/Corp_valuing_gp.doc

1 Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

- A documented, individualised postnatal care plan should be developed with the woman, ideally in the antenatal period or as soon as possible after birth to include:
    - relevant factors from the antenatal, intrapartum and immediate postnatal period
    - details of the healthcare professionals involved in her care and that of her baby including roles and contact details
    - plans for the postnatal period.

This should be reviewed at each postnatal contact.

- There should be local protocols about written communication, in particular about the transfer of care between clinical sectors and healthcare professionals. These protocols should be audited.
- Women should be offered relevant and timely information to enable them to promote their own and their babies' health and well-being and to recognise and respond to problems.
- At the first postnatal contact, women should be advised of the signs and symptoms of potentially life-threatening conditions (given in Table 5-1) and to contact their healthcare professional immediately or call for emergency help if any signs and symptoms occur.
- All maternity care providers (whether working in hospital or in primary care) should implement an externally evaluated structured programme that encourages breastfeeding, using the Baby Friendly Initiative (www.babyfriendly.org.uk) as a minimum standard.

- At each postnatal contact, women should be asked about their emotional well-being, what family and social support they have and their usual coping strategies for dealing with day-to-day matters. Women and their families/partners should be encouraged to tell their healthcare professional about any changes in mood, emotional state and behaviour that are outside of the woman's normal pattern.

- At each postnatal contact parents should be offered information and advice to enable them to:

    - assess their baby's general condition

    - identify signs and symptoms of common health problems seen in babies

    - contact a healthcare professional or emergency service if required.

2 Introduction

Postnatal care is pre-eminently about the provision of a supportive environment in which a woman, her baby and the wider family can begin their new life together. It is not the management of a condition or an acute situation.

This guideline has been written within a conceptual framework which places the woman and her baby at the centre of care, appreciating that all postnatal care should be delivered in partnership with the woman and should be individualised to meet the needs of each mother-infant dyad. The guideline aims to identify the essential 'core care' which every woman and her baby should receive, as appropriate to their needs, during the first 6-8 weeks after birth, based upon the best evidence available.

A key component of the guideline is information to empower the woman to care for her baby and herself so as to promote their longer-term physiological and emotional well-being. The guidance on the information which the healthcare professional should offer women and their partners/families is listed, for convenience, in Tables 5-1, 6-1 and 7-2. These cover information about maternal health, infant feeding and infant health, respectively. The guideline also cross refers to the Department of Health publication *Birth to Five* (Department of Health. 2005) which has a wealth of information for the woman on the postnatal period and baby care which has not been duplicated in this guideline.

Although for most women and babies, the postnatal period is uncomplicated, core postnatal care is also about recognising any deviation from expected recovery after birth and then about evaluating and intervening appropriately. The guideline gives advice on when additional care may be required. These recommendations have been given an appropriate 'status level' indicating the degree of urgency in dealing with the problem. The status levels are defined in Table 2-1. If additional care is required it should be offered so as to minimise, as much as possible, any impact on the relationship between the woman and her baby.

2.1 Background

Current models of postnatal care originate from the beginning of the 20th century, when they were established in response to concerns about the contemporary high maternal mortality rate. The timing and content of care have altered little since then, despite a dramatic reduction in mortality rates which occurred around the middle of the 20th century. Postnatal care provision crosses acute and primary healthcare sectors, with the majority of care taking place in the woman's home. Care is likely to include routine clinical examination and observation of the woman and her baby, routine infant screening to detect potential disorders, support for infant feeding and ongoing provision of information and support. Postnatal care is usually concluded by a 6 – 8 week postnatal examination, which marks the end of the woman's maternity care

There has been limited research into provision and content of postnatal care, and the number and range of postnatal contacts women have with their midwife, health visitor and GP are not well documented. Although midwives were required to visit postnatal women every day for 10 days until 1986 when a policy of selective visiting was introduced, in many locations the traditional daily visit pattern persisted, as highlighted in a report by the Audit Commission published in 1997 (Audit Commission 1997). (*See Chapter 4 Planning Content and Delivery of Care)*. However, the schedule of routine daily visits is no longer prevalent.

There has been little evaluation of whether current models of care meet individual women's and babies' physical and emotional health needs, or make most appropriate use of the skills and time of the relevant healthcare professionals (MacArthur et al. 2002). The needs of fathers/partners have not been rigorously evaluated, nor have the concerns of women from diverse cultures been adequately explored. Neither have the requirements of women with specific needs such as physical disabilities been comprehensively studied. (Singh & Newburn 2000)

2.2 Need for the guideline

2.2.1 Epidemiology

There were 639,721 live births registered in England and Wales in 2004. (Office for National Statistics. 2005). Although postnatal care is routinely provided for all women and their infants, several important indicators and a number of recent studies raise concern about its quality and effectiveness. These have highlighted widespread and persistent health problems experienced by women after childbirth, many of which are unreported by women and not identified by healthcare professionals. Common health problems include physical morbidity such as backache, breast feeding problems, perineal pain, stress incontinence, and mental health problems, such as postnatal depression. One of the first studies to document the substantial level of morbidity was published by MacArthur and colleagues (MacArthur, Lewis, & Knox 1991) who found that 47% of 11,701 women who gave birth at one maternity unit in the West Midlands reported one or more new health problems since giving birth, which lasted for over 6 weeks. Many of the health problems lasted for much longer than this. Researchers from Scotland found that 76% of over 1200 women questioned experienced at least one health problem with onset at some time between discharge from the postnatal ward and 8 weeks postpartum (Glazener et al. 1995). This level of childbirth-related morbidity has been confirmed in studies from other developed countries (Brown & Lumley 1998;Saurel-Cubizolles et al. 2000).

Despite the many health advantages of breastfeeding for a woman and her baby, routinely collected data on infant feeding persistently describe low uptake and duration of breastfeeding (Dyson et al. 2006). In the most recent Infant Feeding Survey conducted by the Office for National Statistics in the year 2000, breastfeeding rates in England and Wales at one week postpartum were only 57% among the 71% of women who initially breastfed, despite this being the period of the most intense input from health professionals who provide postnatal care. At 6 weeks only 43% of all women were breastfeeding; and of the women who had initiated breastfeeding only 65% were still doing so. The WHO

recommend the minimum duration of exclusive breastfeeding should be 6 months (Dewey 2006), amongst women participating in this survey only were still giving any breast milk at 6 months. (Hamlyn, Brooker, & Oleinikova 2002).

2.2.2 Experience of those receiving care

Postnatal care for women has traditionally focussed on routine observation and examination of vaginal blood loss, uterine involution, blood pressure and temperature, with limited guidance for healthcare professionals on postnatal practice. The few studies which have examined women's views of their care, have found that their own perceived needs were not met by the attending healthcare professionals (Audit Commission 1997;Murphy & Atkinson 1989), and duplication of visits and conflicting advice were commonly reported, particularly in relation to breastfeeding (Rajan 1994). The content of midwifery visits was examined in a small study of postnatal care in two English health districts (Marchant & Garcia 1995). Thirty-three midwives were sent a questionnaire, 16 (48%) of whom responded. When asked which items from a given list should be checked on a daily basis, midwives reported they would check a woman's psychological state, uterus, lochia and breasts, perineum, urine function and legs. The small sample size means that results should be treated with caution, but highlighted that constraints of tradition and routine may have prevented midwives from performing individualised care.

Dissatisfaction with postnatal care, particularly care provided in hospital, was reported by the Audit Commission (Audit Commission 1997), when women made more negative comments about hospital postnatal services than any other aspect of their maternity care. A large survey undertaken by the National Childbirth Trust (National Childbirth Trust. 2003) which targeted members through their website and journal, asked women for their opinions on the postnatal care they received during the first month of the birth. Of the 960 women who responded, around half reported that they received all of the information, care and emotional support they needed. However one in ten women reported they received very little or no information and around a quarter of women reported they had received no emotional support.

Several randomised controlled trials of revisions to current postnatal care have been undertaken to assess if improvements in maternal health outcomes could be achieved (Gunn et al. 1998;MacArthur et al. 2002;Morrell et al. 2000b;Reid 2002). These studies were all conducted during the postnatal period, but differed substantially in the content of the intervention. There were no documented improvements in maternal physical health in any of the studies but maternal satisfaction scores were higher than controls in two of the studies and maternal mental health scores were significantly better than controls in one study (see full study reviews in narrative).

2.3 Woman and baby centred care

Please note that in the NICE short form this section has been abridged.

In keeping with aims and ethos of this guideline essential principles of care have been identified by the Guideline Development Group (GDG) which should characterise all services provided during the postnatal period.

Women and their families should be treated with kindness, respect and dignity at all times with consideration given to privacy and where care is provided in a maternity care unit, to creating a clean, warm and welcoming environment. The views, beliefs and values of the woman, her partner and her family in relation to her care and that of her baby should be sought and respected at all times. The woman should be fully involved in planning the timing and content of each postnatal care contact so that care is flexible and tailored to meet her social, clinical and emotional needs and those of her baby and family.

All actions and interventions carried out on the woman or her baby at any time in the postnatal period need to have been fully explained and consent obtained before they are enacted. Where the person from whom consent is being sought does not have the capacity to make decisions, healthcare professionals should follow the Department of Health guidelines (Department of Health. 2001).

Good communication between healthcare professionals and the woman and her family is essential. Women should be fully informed and understand the aims and process of postnatal care. This should be supported by provision of evidence-based information offered in a form tailored to the needs of the individual.

Both care and information provided should be culturally appropriate and the cultural practices of women from ethnic minority groups should be incorporated into their individual postnatal care plans. Care and information should also be provided in a form accessible to women, their partners and families with additional needs, such as people with physical, cognitive or sensory disabilities, and people who do not speak or read English.

Unless specifically excluded by the woman, her partner should have the opportunity to be involved in decisions and in the care of the baby. In collaboration with the woman, every opportunity should be taken to provide her partner or other relevant family members with the information and support they need.

2.4 Aim of the guideline

The guideline has been developed with the following aims:

- to advise on appropriate objectives, purpose, content and timing of postnatal contacts and care for the woman and her baby
- to advise on best practices and competencies for assessment of postnatal health and management of postnatal problems in the woman and/or her infant
- to advise on information, education and support required during the postnatal period
- to advise on planning of postnatal care

- to consider good practice in communication between health care providers and women, their partners and other family members.

The guideline covers maternal and infant care in the period following transfer from intra-partum care, or in the case of birth at home, the end of intra-partum care - until the end of the postnatal period. The end of the postnatal period is usually defined as 6-8 weeks following the birth. However, maternal and infant health is a continuum and, as reflected in the NSF for Children, Young People and Maternity Services (Department of Health 2004;Welsh Assembly Government 2005) flexibility is needed in care provision and the end of the postnatal period may vary according to the individual needs of a woman and her baby.

Postnatal care is also about empowering the mother to care for her baby and herself in order to promote their longer-term physiological and emotional well-being. Recommendations advising provision of appropriate information by the relevant healthcare professionals, to enable women to acknowledge and take care of their own and their baby's needs, and take account of their experiences, feelings and need for support, form the basis of much of this guideline. For most women and babies the postnatal period is uncomplicated. However, postnatal care is also about recognising any deviation of a woman's or baby's expected recovery following birth, or of adverse changes in health and wellbeing, and investigating and intervening appropriately. When additional care to address such issues is required, recommendations are identified by the appropriate 'action level.'

Although the given title of this guideline was "'Routine' Postnatal Care," the Guideline Development Group's view, in keeping with the ethos of *Changing Childbirth* (Expert Maternity Group. 1993), was that postnatal care is not routine, but should recognise the uniqueness of each mother and baby. Therefore the guideline aims to identify the essential 'core care' which women and their babies should receive during the postnatal period. While the guideline is aimed at the care for women and babies who have no existing or anticipated complications, the GDG recognised that all women and babies, no matter what

their circumstances, would require core care. However some will require additional or different care over and above that covered here.

These recommendations for core care will help to enhance the continuity and quality of postnatal care for all new mothers and their babies and provide information to enable healthcare professionals, together with women, their partners and families, to make decisions about management in particular circumstances.

The guideline ethos is that:

- core postnatal care provision is undertaken in partnership with women. Therefore, care is always offered to the woman and not imposed upon her.
- care is individualised through a process of education and discussion to meet the needs of each mother-infant dyad
- women's views, beliefs and particular circumstances are respected.
- interventions offered are evidence based and have known benefits.

2.5 Scope

The guideline was developed in accordance with a specified scope prepared by the Institute. The scope set the remit of the guideline and specified those aspects of postnatal care to be included and excluded. The scope was published in 2004 and is reproduced here in Appendix B.

2.5.1 For whom is the guideline intended?

This guideline is of relevance to those who work in or use the National Health Service (NHS) in England and Wales:

- healthcare professionals who work within the acute and primary healthcare sectors who have direct contact with postnatal women and their babies

- those with responsibilities for commissioning and planning health services such as Primary Care Trust commissioners (UK), Welsh Assembly Government officers

- public health and trust managers

- women who have recently given birth, their partners, families and other carers.

The care of healthy women and their babies is most likely to be provided by midwives, maternity support workers working across the acute and primary care sector, health visitors and general practitioners. Each of these professional groups have a range of clinical skills relevant to ensuring the health of women and their babies is promoted, to assess when referral is appropriate if deviation from expected recovery is detected, or to manage a particular health problem if they have the competency to do so. All NHS staff should be working to the level of competency as defined by their professional qualification, and ensure that if they do not have the appropriate competence for a particular aspect of care, that appropriate referral is made. NHS staff who care for postnatal women and their babies are also expected to meet the workforce competence for Maternity and Care of the Newborn developed by Skills for Health, the Sector Skills Council for the health sector (Skills for Health 2005).

2.5.2 Areas outside the remit of the guideline

The guideline will not address interventions that may be needed by a healthy woman or her healthy baby beyond that associated with core postnatal care. It is outside the remit of the guideline to advise on management of medical complications arising for a woman or her baby before, during or after the birth, existing pregnancy and/or non-pregnancy related acute or chronic diseases or conditions, or any aspect of antepartum or intrapartum care, including procedures immediately following the birth. The guideline offers recommendations on the core postnatal care all women and their babies should

be offered. It does not offer information on the additional care that a woman or her baby may require, although aspects of the guideline may continue to be relevant to either or both the woman or her baby. Referral to the guideline may also be appropriate in particular circumstances where elements of core postnatal care may be required, for example women who have had a caesarean section or infants who require special care.

2.5.3 Related documents

The guideline builds on work from other relevant NICE guidelines, including induction of labour, electronic fetal monitoring, antenatal care and caesarean section. It should also be used in conjunction with the guidelines on antenatal and postnatal mental health and intrapartum care which are currently in development. The guideline complements the Children's, Young People and Maternity Services National Service Frameworks for England (Department of Health 2004) and Wales (Welsh Assembly Government 2005) which provide standards for service configuration, with emphasis on how care is delivered and by whom, including issues of ensuring equity of access for disadvantaged women and women's views about service provision. The guideline has also drawn on the evidence-based recommendations of the UK National Screening Committee (NSC). Guideline recommendations which refer to *Birth to Five* (Department of Health. 2005) include both the English and Welsh versions of this publication.

2.6 Responsibility and support for guideline development

2.6.1 The National Collaborating Centre for Primary Care (NCC-PC)

The NCC-PC is a partnership of primary care professional associations and academic units, formed as collaborating centre to develop guidelines under contract to the National Institute for Health and Clinical Excellence (NICE). It is entirely funded by NICE. The NCC-PC is contracted to develop five guidelines at any one time, although there is some overlap at start and finish. Unlike many of the other centres which focus on a particular clinical area, the NCC-PC

has a broad range of topics relevant to primary care. However, it does not develop guidelines exclusively for primary care. Each guideline may, depending on the scope, provide guidance to other health sectors in addition to primary care.

The Royal College of General Practitioners (RCGP) acts as a host organisation. The Royal Pharmaceutical Society and the Community Practitioners and Health Visitors' Association are partner members with representation of other professional and lay bodies on the Board. The RCGP holds the contract with the Institute for the NCC-PC. The work is carried out on two sites in London, where the work on this particular guideline was based, and in Leicester under contract to the University of Leicester.

2.6.2 The Technical Team

The Technical Team had the responsibility for this guideline throughout its development. It is responsible for preparing information for the Guideline Development Group (GDG), for drafting the guideline and for responding to consultation comments. The Technical Team working on this guideline consisted of the:

- Information Scientist, who searched the bibliographic databases for evidence to answer the questions posed by the GDG
- Reviewer, with knowledge of the field, who appraised the literature and abstracted and distilled the relevant evidence for the GDG.
- Health Economist who reviewed the economic evidence, constructed economic models in selected areas and assisted the GDG in considering cost effectiveness
- Project Manager, who was responsible for organising and planning the development, for meetings and minutes and for liaising the Institute and external bodies.

- Clinical Advisor, with an academic understanding of the research in the area and its practical implications to the service, she advised the Technical Team on searches and the interpretation of the literature.

With the exception of the Clinical Advisor, all of the Technical Team was based at the NCC-PC in London. Applications were invited for the post of Clinical Advisor, who was recruited to work on average a half a day a week on the guideline. The members of the Technical Team attended the GDG meetings and participated in them.

The Technical Team met regularly with the Chairman of the GDG during the development of the guideline to review progress and plan work.

2.6.3 The Guideline Development Group (GDG)

A Chairman was chosen for the group for her knowledge of the field and links with the National Collaborating Centre for Women and Children's Health, which is responsible for the development of related guidelines. Her primary role was to facilitate the work at GDG meetings.

Guideline Development Groups are not committees but working groups and therefore the numbers on the group cannot be so large as to preclude discussion. The aim is to get the range of experience and expertise needed to address the scope of the guideline. Nominations for GDG members were invited from the relevant stakeholder organisations which were sent the draft scope of the guideline and some guidance on the expertise needed. From the nominations, three Consumer Representatives and the following healthcare professionals joined the GDG.

- Two Health Visitors
- A General Practitioner
- Two Midwives
- A Community Paediatrician

- An Obstetrician

Nominees who were not selected for the GDG were invited to act as Expert Peer Reviewers and were sent drafts of the guideline by the Institute during the consultation periods and invited to submit comments by the same process as stakeholders.

Each member of the GDG served as an individual expert in their own right and not as a representative of their nominating organisation, although they were encouraged to keep the nominating organisation informed of progress.

In accordance with guidance from the National Institute of Clinical Excellence (NICE), all GDG members' interests were recorded on a standard declaration form that covered consultancies, fee-paid work, share-holdings, fellowships, and support from the healthcare industry.

The names of GDG members appear in the Guideline Development Group list below.

2.6.4 Co-optees

In defined topic areas which would be addressed in only one or two meetings, the GDG co-opted individuals with the relevant expertise. The Co-optees were not members of the GDG, but acted as advisors to the GDG. There were two co-optees

- A Clinical Specialist Physiotherapist advised on postpartum exercise in particular pelvic floor exercises
- A Consultant Neonatologist advised on the newborn examination and other aspects of infant health.

Group membership and co-optee details can be found in the preface to the guideline.

All Co-optees made a formal 'Declaration of Interests' at the start of the guideline development and provided updates throughout the development process.

The names of Co-optees appear at the end of the list below.

Guideline Development Group

Members

Professor Rona McCandlish (Chairman)
Research Fellow, Oxford

Mrs Cheryll Adams
Professional Officer/ Research and Practice Development, Community Practitioners and Health Visitors' Association, London

Dr Chris Barry
General Practitioner, Wiltshire

Professor Debra Bick (Clinical Advisor)
Professor of Midwifery and Women's Health, Thames Valley University, London

Mrs Sheena Byrom
Consultant Midwife, East Lancashire Hospital Trust and University of Central Lancashire.

Dr Kathleen DeMott
Technical Team (Senior Health Service Research Fellow), National Collaborating Centre for Primary Care

Dr David Elliman
Consultant in Community Child Health, Islington PCT and Great Ormond St Hospital for Children, London

Dr Sally Marchant
Midwife/Editor of MIDIRS, Midwives Information and Resource Services, Bristol

Miss Heather Mellows
Consultant Obstetrician and Gynaecologist, Doncaster and Bassetlaw Hospitals NHS Foundation Trust

Ms Cathy Neale
Consumer Representative, London

Mr Richard Norman
Technical Team (Health Economist), National Collaborating Centre for Primary Care

Ms Mustary Parkar
Consumer Representative, Blackburn, Lancs

Ms Phoebe Tait
Consumer Representative, East Sussex

Mrs Carolyn Taylor
Health Visitor Specialist Practice Teacher, Hebburn Health Centre, South Tyneside

Observers

Ms Colette Marshall
Commissioning Manager, National Institute for Health and Clinical Excellence

Ms Gill Ritchie
Information Scientist, National Collaborating Centre for Primary Care

Ms Nancy Turnbull
Chief Executive, National Collaborating Centre for Primary Care

Guideline Development Group Co-optees

Ms Clair Jones

Physiotherapy Clinical Specialist, Norfolk and Norwich University Hospital NHS Trust

Dr Jane Hawdon

Consultant Neonatologist, Clinical Director Women's Health, University College Hospital, London

2.6.5 Guideline Development Group Meetings

The GDG met at 4-5 weekly intervals for 18 months to review the evidence identified by the Technical Team, to comment on its quality and relevance and to develop recommendations for clinical practice based on the available evidence. The final recommendations were agreed by the full GDG which met following each consultation to review and agree any changes to the guideline resulting from stakeholder comments.

2.7 Care Pathway

A clinical care pathway was designed to indicate the essential steps in the care of mother and baby after birth and the expected progress of both the woman and the newborn through the first six to eight weeks postpartum. Three key components of care provide the basic themes for the pathway. These are: maintaining maternal health, infant feeding and maintaining infant health. The pathway is divided into three 'time bands' which cover the postnatal period, and where necessary direction is given about when after birth particular care should be given. Recommendations for core care are indicated as are referral points for raised concern

	Maintaining Maternal Health	Infant Feeding	Maintaining Infant Health
Time Band 1 Within the first 24 hours after delivery	**Core Information** 1. All women should be given information about the physiological process of recovery after birth, and that some health problems are common, with advice to report any health concerns to healthcare professional, in particular: a. Signs and symptoms of PPH: sudden and profuse blood loss or persistent increased blood loss; faintness; dizziness; palpitations/tachycardia. b. Signs and symptoms of infection: fever; shaking; abdominal pain and/or offensive vaginal loss. c. Signs and symptoms of thromboembolism: unilateral calf pain; redness or swelling of calves; shortness of breath or chest pain. d. Signs and symptoms of pre-eclampsia: headaches accompanied by one or more of the symptoms of visual disturbances, nausea, vomiting, feeling faint. 2. Women who have had an epidural or spinal anaesthesia should be advised to report any severe headache, particularly when sitting or standing. **Core Care** 1. Measure and document BP once within 6 hours after the last measurement taken soon after birth as a component of labour care. 2. Toilet facilities that are hygienic and ensure privacy should be provided in the clinical setting. 3. Document urine void within 6 hours. 3. All women should be encouraged to mobilise as soon as appropriate following the birth. **Concern** 1. If infection is suspected a woman's temperature should	**Core Information** 1. Women should be offered information and reassurance on: • colostrum – which will meet the needs of the baby in the first few days after birth • timing of the initial breastfeed, including the protective effect of colostrum ,which is culturally appropriate • The nurturing benefits of putting the baby to the breast in addition to the nutritional benefits of breastfeeding. 2. A woman should be reassured that brief discomfort at the start of breast feeds in the first few days is not uncommon, but this should not persist. 3. Women who leave hospital soon after birth should be reassured that this should not impact on breastfeeding duration. 4. All women and carers who are giving their babies formula feed should be offered appropriate and tailored advice to ensure this is undertaken as safely as possible, and optimises infant development, health and nutritional needs. 5. A woman who wishes to feed her baby formula milk should be taught how to make feeds using correct, measured quantities of formula, as based on the manufacturers instructions, and how to clean/sterilise feeding bottles and teats and store formula milk. **Core Care** 1. During the first hour of life: a. Mother and baby should not be separated b. Skin to skin contact should be encouraged c. Breastfeeding should be initiated. 2. Where postnatal care is provided in a clinical setting, the environment should include:	**Core Information** 1. At each postnatal contact parents should be offered information and guidance to enable them to: • assess their baby's general condition • identify warning signs to look for if their baby is unwell • Contact a healthcare professional or emergency service if required. 2. During any physical examination of a baby both parents should be present where possible to encourage the participation of both in their baby's care and to provide an opportunity for both to learn more about their baby and his/her needs. 3. Parents should be offered information on Vitamin K in order to make an informed decision about its use. 4. Parents should be offered information about physiological jaundice including: • that it normally occurs around 3-4 days after birth • Reasons for monitoring and how to monitor. **Core Care** 1. Assessment for emotional attachment should be carried out at each postnatal contact. 2. Vitamin K should be offered for all infants and administered with a single dose of 1 mg IM. If parents decline IM Vitamin K for their baby, oral Vitamin K should be offered as second line.

	Maintaining Maternal Health	Infant Feeding	Maintaining Infant Health
	be taken and documented. If a woman's temperature is above 38 °C it should be measured again in 4–6 hours. 2. Assessment of vaginal loss and uterine involution and position should be undertaken if a woman has excessive or offensive vaginal loss, abdominal tenderness or fever. Any abnormalities in the size, tone and position of the uterus should be evaluated. If no uterine abnormality is found, consider other causes of symptoms (urgent action). 3. If diastolic blood pressure is greater than 90 mm Hg, and there are no other signs and symptoms of pre-eclampsia, the measurement of blood pressure should be repeated within 4 hours. 4. If a woman has not voided by 6 hours postpartum and measures to encourage micturition, such as taking a warm bath or shower, are not immediately successful, bladder volume should be assessed and catheterisation considered. (urgent action). 5. If a woman is obese she will require individualised care. 6. Immediate referral (emergency action) is required if there is: a. Sudden or profuse blood loss or loss accompanied by any of the signs and symptoms of shock, including tachycardia, hypotension, hypoperfusion and change in consciousness should receive emergency medical action b. Diastolic BP is greater than 90 mm Hg and accompanied by another sign or symptom of pre-eclampsia, or if diastolic BP is greater than 90 mm Hg and is not reduced below 90 mm Hg within 4 hours. c. The temperature remains above 38 °C on the second reading or there are other observable symptoms and measurable signs of sepsis. d. A woman complains of unilateral calf pain, redness, swelling, shortness of breath or chest pain.	• Round the clock rooming-in and continuing maternal skin to baby's skin contact when possible. • Privacy. • Adequate rest for the woman without interruption due to clinical routine. • Access for the woman to food and drink on demand. • Formula milk should not be given to breastfed babies in hospital unless medically indicated. • The distribution of commercial packs, for example those given to women when they are discharged from hospital, which contain formula milk or advertisements for formula should not be used. • Breast pumps should be available in the clinical setting, particularly for women who have been separated from their babies, to establish lactation. All women who use a breast pump should be offered instructions on the correct use. 3. Breastfeeding support to a woman should be made available regardless of the location of care. 4. Women should be offered skilled support including mother-to-mother or peer support from the commencement of breastfeeding. 5. A woman should not be asked about feeding method until after first skin to skin contact. 6. Additional support with positioning and attachment to commence breastfeeding should be offered to all women who have had:	**Concern** 1. Infants who develop jaundice within the first 24 hours should be urgently investigated. (Action level 2)

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		• narcotic analgesia or general anaesthetic, as the baby may not initially be responsive to feeding • a caesarean section, particularly to assist with handling and positioning the baby to protect the woman's abdominal wound • Initial contact with their baby delayed. 7. Unrestricted frequency and duration of breastfeeding should be encouraged. 8. A healthcare professional should discuss a woman's experience with breastfeeding daily after birth, to assess with her if she is on course to breastfeed effectively and identify need for additional support. Breastfeeding progress should then be assessed and documented in the care plan at each postnatal contact. **Concern** 1. Women with flat or inverted nipples should be advised that these are not contraindications to breastfeeding and support offered as needed. 2. If a woman is experiencing breast or nipple pain, the woman or healthcare professional should review positioning and attachment. 3. A baby who is not attaching effectively may be encouraged to open his/her mouth using different stimuli. 4. Skin to skin contact or massaging a baby's feet should be used to wake the baby.	
Time Band 2 Between 2 and 7 days	**Core Information** 1. The Department of Health *Birth to Five* handbook, which offers general information about health and well-being after delivery, should be provided to all postpartum women within the first three days after birth and its use discussed**.**	**Core Information** 1. A woman should be offered information and reassurance: **Feeding patterns:** • that her baby may have a variable feeding pattern, at least over the first few days, as the baby takes small amounts of colostrum and then takes increasingly	**Core Information** 1. Parents should be offered information and reassurance on: • Their infant's social capabilities – as this can promote parent–infant

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(24 – 168 hours)	2. Women should be offered information and reassurance about: • perineal pain and perineal hygiene • urinary incontinence and micturition • bowel function • fatigue • headache • back pain • normal patterns of emotional changes in the postnatal period and that these usually resolve within 10–14 days of giving birth (This information should be offered by the third day) • contraception • contact details for expert contraceptive advice 3. All women should be offered advice on diet, exercise and planning activities, including spending time with her baby **Core Care** 1. Anti-D should be offered as required according to Department of Health guideline within 72 hours of birth. 2. MMR should be offered as required according to Department of Health guideline 2. Enquires should be made about general well being and all common health problems including: micturition and urinary incontinence bowel function healing of any perineal wound headache fatigue	larger feeds as the milk supply comes in. • that when the milk supply is established, a baby will generally feed every 2–3 hours, but this will vary between babies and, if her baby is healthy, the baby's individual pattern should be respected. • That if a baby does not appear satisfied after a good feed from the first breast, the second breast should be offered. **Attachment and position:** • That being pain free during the feed is an indicator of good position and attachment. • Other indicators of good attachment include: • less areola visible underneath the chin than above the nipple • chin touching the breast, with the lower lip rolled down, with the nose free • mouth is wide open • The baby is swallowing. **Signs of successful milk transfer:** The baby has: • audible swallowing • sustained rhythmic suck and swallowing with occasional pauses • relaxed arms and hands • moist mouth • satisfaction after feeding • Regular soaked/heavy nappies. • The woman: • feels no breast or nipple pain	attachment • Nappy rash – frequent nappy changes and cleansing and exposure of the perianal area reduces babies' contact with faeces and urine. Cleansing agents should not be added to bath water nor should lotions or medicated wipes be used. Where required, the only cleansing agent which should be used is mild non-perfumed soap • Cord care – how to keep the umbilical cord clean and dry and that antiseptics should not routinely be used • Safety – how to reduce accidents, particularly scalds and falls. 2. Parents should be advised to report to their healthcare professional changes in the baby's established bowel pattern (which will take up to 7 days to establish), including hard stools that are difficult to pass or increased frequency of loose stools. 3. Parents should be given information in line with the Department of Health guidance about sudden infant death syndrome (SIDS) and co-sleeping. 4. If parents choose to share a bed with their infant, they should be advised never to sleep on a sofa or armchair. They should also be advices and that there is increased risk, especially when the baby is less than 11 weeks old, between sharing a bed all night and cot death if either parent: • is a smoker • has recently drunk any alcohol • has taken medication or drugs that

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	back pain 3. Encourage all women to use self care techniques, such as taking gentle exercise, taking time to rest, having help to care for her baby, talking to someone about her feelings and that she is enabled to access social support networks 4. Ask all women about their emotional well-being, what family and social support they have and their usual coping strategies for dealing with day to day matters. All women and their families/partners should be encouraged to tell their healthcare professional about any changes in mood, emotional state and behaviour that are outside of the woman's normal pattern. 5. Observe for any risks, signs and symptoms of domestic abuse and know who to contact for advice and management. **Concern** The healthcare professional should continue to identify, evaluate and manage common health problems as appropriate: 1. Carry out assessment of perineum if perineal pain is present. For pain relief advise: • Topical cold therapy • Paracetamol • NSAIDs if not contraindicated 2. Signs and symptoms of infection, inadequate repair, wound breakdown or non-healing should be further evaluated (Action level 2). 3. Management of mild postnatal headache should be based on differential diagnosis of headache type and local treatment protocols 4. If a woman has tension or migraine headaches, the healthcare professional should offer advice on relaxation and avoidance of factors associated with the onset of	• experiences her breast softening • may experience uterine discomfort • experiences no compression of the nipple at the end of the feed • feels relaxed and sleepy **Engorgement** – that their breasts may feel tender, firm and painful when milk 'comes in' at or around 3 days after birth. **Safety** – milk, either formula or expressed breast milk, should not be heated in a microwave as there is a danger of scalding (advice family/partner as appropriate). **Benefits of breastfeeding** – that babies who are exclusively breastfed for 6 months will accrue the greatest health benefits and disease prevention. **Local breastfeeding support groups** – how to access and what services and support they provide. 2. A breastfeeding woman who requests information on preparing a formula feed should be advised on how to do this. **Core Care** 1. Healthcare professional should discuss a woman's progress with breastfeeding within the first 2 days postpartum to assess if she is on course to breastfeed effectively. 2. Assess for effective feeding as the woman's breast milk comes in. 3. All breastfeeding women should be offered information about how to hand express their breast milk and advised on how to store and freeze their expressed milk. **Concern** 1. If breastfeeding is not progressing, support and assistance with	make them sleep more heavily • is very tired 5. Parents should be advised that if a baby has become accustomed to using a pacifier (dummy) while sleeping, it should not be stopped suddenly during the first 26 weeks. 6. All women and their families should be given information about availability, access and aims of all postnatal peer, statutory and voluntary groups and organisations in their local community. **Core Care** 1. Complete newborn physical examination should be performed within 72 hours of birth. 2. The parent held child record should be provided to all parents within the first three days of birth. 3. The aims of any physical examination should be fully explained by the healthcare professional and the findings and results shared with the parents and recorded in the postnatal plan and the parent held child record. 4. The Newborn Blood Spot Test should be offered to all parents when their infants are 5-8 days of age. Informed consent should be obtained. 5. A hearing screen should be completed prior to discharge or by week 4 in the hospital programme or by week 5 in the community programme. 6. Home visits should be used as opportunities to promote parent or mother to child emotional attachment. 7. All women should be encouraged to develop

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	headaches 5. Back pain should be managed as in the general population 6. A woman with some involuntary leakage of a small volume of urine should be taught how to do pelvic floor exercises 7. If constipation present advise increased intake of fibre and fluids. If problem persists advise use of gentle stimulant laxative. 8. All women with haemorrhoids should take measures to avoid constipation and should be offered management based on local treatment protocols 9. If a woman has a haemorrhoid which is severe and swollen or prolapsed, or any rectal bleeding, this should be evaluated. (Action level 2). 10. Once assessed, women with the following conditions should be referred for treatment: a. Persistent urinary incontinence (Action level 2) b. Faecal incontinence (Action level 2) c. Severe or persistent headache and/or other symptom of pre-eclampsia (Action level 1) d. If a woman has sustained a postpartum bleeding, or complains of persistent fatigue, her haemoglobin level should be evaluated and if low, treated according to local policy.	positioning and attachment on the breast should be provided. 2. If nipple pain persists after repositioning consider evaluation for thrush. 3. If signs and symptoms of engorgement are present a woman should be encouraged to: • Wear a well-fitting bra • Feed frequently, including prolonged breastfeeding from the affected breast • Massage breasts and if necessary, hand express milk • Take analgesia if necessary. 4. If signs and symptoms of mastitis are present a woman should be advised to: • continue breastfeeding and/or hand expression to ensure effective milk removal and, if necessary, gently massage the breast to relieve any blockage • seek assistance with positioning and attachment • take analgesia compatible with breastfeeding, for example paracetamol • Increase her fluid intake. 5. If signs and symptoms of mastitis persist more than several hours a woman should contact her healthcare provider and may require antibiotic treatment (Action level 2). 6. If an insufficiency of milk is perceived by the woman, her breastfeeding technique and her baby's health should be evaluated by an appropriately trained healthcare professional. Reassurance should be offered to assist the woman in gaining confidence in her ability to produce enough milk for her baby. 7. If the baby is not taking sufficient milk directly from the breast and supplementary feeds are necessary, expressed breast milk should be given by a cup or bottle. Supplementation with fluids other than breast milk is not recommended. 8. Evaluation for ankyloglossia (tongue tie) should be made if	social networks as these promote positive maternal-infant interaction. 8. Group based parent-education programmes designed to promote emotional attachment and improve parenting skills should be available to parents who wish to access them. 9. All home visits should be used as an opportunity to assess relevant safety issues for all family members in the home and environment and promote safety education and use of basic safety equipment. 10. Healthcare professionals should be alert to risk factors and signs and symptoms of child abuse and if there is raised concern should follow local child protection policies. **Concern** 1. If no meconium passed in 24 hours, refer for evaluation. (Action level 2) Check with DE 2. If a baby is suspected of being unwell: a temperature should be taken using an electronic device which has been properly calibrated and are used appropriately. 3. A temperature of ≥38°C is abnormal and the cause should be evaluated (Action level 1). 4. Care for jaundice: • After the first 24 hours, if a carer notices that a baby is jaundiced, or that jaundice is worsening, or the baby is passing pale stools, the carer should be advised to report this to a healthcare professional • If a baby develops jaundice the intensity should be monitored 24 hours later and systematically recorded along with the baby's overall well-being with regard to

	Maintaining Maternal Health	Infant Feeding	Maintaining Infant Health
		breastfeeding problems persist after a review of positioning and attachment by a skilled healthcare professional or peer counsellor. If ankyloglossia is suspected further evaluation is required.	hydration and alertness • A breastfed baby who has signs of jaundice should be breastfeed frequently, and the baby awakened to feed if necessary • Breastfed babies should not be routinely supplemented with formula, water or dextrose water for the treatment of jaundice • If a baby is significantly jaundiced or appears unwell, evaluation of serum bilirubin level should be carried out.(Action level 2) 9. If thrush is identified in her baby, the breastfeeding woman should be offered information and guidance about relevant hygiene practices. Symptomatic thrush requires antifungal treatment. 10. If painful nappy rash persists it is usually caused by thrush (candida albicans)] and treatment with anti fungal treatment should be considered and further evaluation if no response. 11. If a baby is constipated and formula fed the following should be evaluated: • feed preparation technique • quantity of fluid taken • frequency of feeding • Composition of feed . 12. A baby who is experiencing increased frequency and/or looser stools than usual should be evaluated (Action level 3). 13. Care for excessive crying/colic: • A baby who is crying excessively and inconsolably, most often during the

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			evening, either drawing its knees up to its abdomen or arching its back, in the absence of another diagnosis should be assessed for underlying cause, including infant colic (Action level 2). • Assessment of excessive and inconsolable crying should include: • general health of the baby • antenatal and perinatal history • onset and length of crying • nature of the stools • feeding assessment • woman's diet if breastfeeding • family history of allergy • parent's response to the baby's crying • Any factors which lessen or worsen the crying. • Parents of a health baby who has colic, should be reassured that the baby is not rejecting them and that colic is usually a phase that will pass. Holding the baby through the crying episode, accessing peer support and hypoallergenic formula may be helpful. Dicycloverine should not be used.

	Maintaining Maternal Health	Infant Feeding	Maintaining Infant Health
Time Band 3 Weeks 2-8 (From Day 8 onward)	**Core Information** 1. Advise women to report any common health problems (See above). 2. Discuss initiation of sexual activity and possible dyspareunia. **Core Care** 1. At any postnatal contact enquires should continue to be made about general well being and all common health problems (See above.) 2. All women should be asked about resumption of sexual intercourse and possible dyspareunia as part of an assessment of overall well-being 2-6 weeks after birth 3. At 10–14 days after birth, all women should be asked about resolution of symptoms of maternal blues. If symptoms have not resolved, the woman's psychological well-being should continue to be assessed for postnatal depression, and if symptoms persist, evaluated (Action level 2). 4. Continue to observe for any indication of domestic abuse 5. As part of the woman's individual postnatal care plan, the coordinating health professional should ensure that there is a review of the woman's physical, emotional and social well-being at 6-8 weeks postpartum which takes into account screening and medical history **Concern** Any positive responses to queries about common health problems should be evaluated, treated or referred appropriately:	**Core Care** 1. Breastfeeding progress should be assessed at each postnatal contact.	**Core Care** 1. Physical examination should be repeated at 6–8 weeks of age. 2. Offer to commence infant immunisation programme. **Concern** 1. If jaundice first develops after 7 days or remains jaundiced after 14 days in an otherwise healthy baby and a cause has not already been identified, it should be evaluated (Action level 2).

	Maintaining Maternal Health	Infant Feeding	Maintaining Infant Health
	1. Dyspareunia • If a woman expresses anxiety about resuming intercourse, reasons for this should be explored with her • If a woman is experiencing dyspareunia and has sustained perineal trauma, the healthcare professional should offer to assess the woman's perineum • A water based lubricant gel to help to ease discomfort during intercourse may be advised • If a woman continues to express anxiety about sexual health problems, this should be evaluated further (Action level 3). 2. A woman whose postpartum bleeding does not cease by the sixth week postpartum should be referred (Action level 3) 3. If persistent postnatal fatigue is impacting on the woman's care of herself or baby, underlying physical, psychological or social causes should be evaluated (Action level 2)		

2.8 Research Recommendations

Please note that in the NICE short form this section has been abridged

2.8.1 Routine monitoring of the weight of babies

A randomized controlled trial should be carried out to address the question: Does routine monitoring of the weight of all low-risk babies during the first six-eight weeks after birth reduce the incidence of serious morbidities?

Healthy babies normally lose weight in the first week of life. This weight loss is usually transient and of no significance, but may be exaggerated if there is difficulty establishing feeding or if the baby is ill. In the past, all babies were routinely weighed at least twice in the first 10 days after birth (at birth, and before transfer of care from the midwife to the health visitor at around 10-14 days after birth). There is debate about the benefits and harms of routine weighing in the first weeks of life; proponents consider that it is important to identify important but rare conditions such as hypernatraemic dehydration (2.5/10,000 births (Oddie, Richmond & Coulthard 2001)) which could be prevented, or detected early (Laing & Wong 2002; Moritz et al. 2005; McKie, Young & Macdonald 2005). Anecdotal evidence suggests that the number of babies being admitted to hospital for treatment of jaundice and hypernatraemic dehydration has increased since the practice of regularly routinely monitoring babies' weight in the first few weeks of life stopped. However opponents consider routine weighing may cause harm because of:

- unwarranted intervention subsequent to error in measurement of weight (caused, for example when normal physiological processes (urination, defecation) are not taken into account)
- associated anxiety for parents,
- The potential to interfere with exclusive breastfeeding.

The existing evidence base relies on findings from population-based surveillance systems and small-scale evaluations. A large-scale randomized controlled trial is therefore required to evaluate whether there is a significant difference in the incidence of important outcomes between routine regular and expectant weighing of babies at low risk of complications in the first six-eight weeks after birth.

Composite primary outcome: re-hospitalisation for treatment of jaundice or hypernatremic dehydration.

Other outcomes: breast feeding rates, maternal anxiety and experience of monitoring.

2.8.2 Evaluation of Baby Friendly Initiative

Evaluation is required to address the question: What is the impact of the use of the Baby Friendly Initiative on breastfeeding uptake and duration in English and Welsh hospitals and community settings?

The health and social benefits of breastfeeding to both mother and baby are multidimensional, yet, despite consorted and prolonged policy deigned to improve breastfeeding rates, UK rates are amongst the lowest in Europe (UNICEF UK Baby Friendly Initiative 2004) .In the Priorities and Planning Framework 2003-2006 (Department of Health 2002) there is a target for health organisations to deliver a two-percentage point increase per year in the proportion of women who breastfeed their baby, with a focus on those women who are less likely to breastfeed (Health Development Agency 2003). A range of strategies are available to help achieve this target, including the Baby Friendly Initiative (BFI),launched in 1991 by the World Health Organization and the United Nations Children's Fund to promote a health care environment at birth in which breastfeeding is the norm. BFI sets rigorous standards for health care organisations to adopt, with the aim of improving breastfeeding rates. Positive evaluations of the initiative have been published in Scotland (3), and other countries outside the UK but cost-effectiveness studies that deal with the

Baby Friendly Hospital Initiative (BFI) have yet to be carried out in England and Wales.

The Postnatal Care Guideline recommends that 'All health care providers (hospitals and community) should implement an externally evaluated structured programme that encourages breastfeeding, using the Baby Friendly Initiative [BFI] as a minimum standard.'

Further research to evaluate the cost-effectiveness of BFI compared to another programme, or to standard care, should be carried out. Outcomes should include necessarily initiation, duration and exclusive breastfeeding rates and may also attempt to construct Health Economic measures of outcome, such as the QALY.

2.8.3 The effect of peer support on severity of postnatal depression

A randomized controlled trial is required to evaluate whether the severity of postnatal depression amongst socially isolated women is reduced by the provision of peer social support compared to standard care

Postnatal depression affects 10-15% of mothers and can lead to cognitive and emotional disturbance in the baby alongside the effects on the mother. Children of depressed mothers are more likely to access Child and Adolescent Mental Health Services (CAMHS) and suffer mental health problems as adolescents and adults. Social isolation is a known risk factor for postnatal depression and reducing this may have a range of clinical and psycho-social benefits.

These issues are of concern not only to health and social care providers, but to women and families themselves. To meet the perceived need for improved psychosocial support which could lessen the effects and potential consequences of postnatal depression a group of mothers established 'Netmums' information and support website (www.netmums.com) which now has over 110,000 registered members. A recent the online survey of its membership suggested that as many as 50% of those responding thought that they may have suffered from postnatal depression at some time.

Postnatal depression is most common in the first 3 months postnatally and may start as early as 3 or 4 weeks postnatally. Wiggins et al (2004) carried out research funded by the HTA to evaluate providing enhanced health visitor and community based psychosocial support for mothers who were socially isolated compared to standard care The intervention was initiated 4 weeks postnatally and support was then offered monthly. This study did not identify a difference in incidence of postnatal depression, however further research is required to investigate whether intensive needs based psycho/social support in the first few weeks postnatally for women identified as being socially isolated could reduce the incidence and severity of postnatal depression and in turn potential effects on children.

A randomized controlled trial is proposed to evaluate the effect on the rate of postnatal depression of providing enhanced peer support compared to standard care for women who are at risk of social isolation after childbirth

Outcomes should include quality of life and clinical measures: maternal and infant/child psychological wellbeing, depression, social wellbeing, physical health

This research would complement research funded by the HTA evaluating different models of care in the postnatal period.

2.9 Acknowledgements

We gratefully acknowledge the contributions of a number of clinical experts who have provided invaluable assistance in the review of current medical literature and research for this Guideline. These included Dr Chris Redman who advised on postpartum pre-eclampsia; Dr Gwyneth Lewis who commented on risk of thromboembolism and use of TED stockings; Dr Judith Shakespeare who answered queries about the EPDS; Professor Mary Renfrew who generously sent us drafts of her group's systematic review on public health interventions for duration of breastfeeding (now published) and who also provided expert comments on the breastfeeding narrative and recommendations; Dr Sam Oddie

and Dr Sam Richmond who commented on newborn readmission rates; and Dr Magda Sachs, who shared her work on infant weighing. We also wish to acknowledge the contributions of Dr. Angela Cooper, Senior Health Services Research Fellow and Dr. Anusha Bolonna Health Services Research fellow, both of the NCC-PC, for their expert reviews in the areas of maternal health and infant feeding.

We are most grateful these people and others who advised the Technical Team and GDG and so contributed to the guideline process.

2.10 Glossary

Assessment: A core health care professional making a judgement about the well being of a woman or infant.

Breastfeeding Counsellor: Women who have received specific training in counselling skills to provide support to breastfeeding women.

Breastfeeding Peer support: Support offered by women who have themselves breastfed, are usually from similar socio-economic backgrounds and locality to the women they are supporting and who have received minimal training to support breastfeeding women.

Coordinating Healthcare professional: A named Healthcare professional who is responsible for organising the care of a woman and her baby during any stage of the postnatal period.

Dyad: Mother and baby as a couple or pair.

Evaluation: Action based upon assessment of a woman or infant which may require referral or additional competencies to provide treatment.

Exclusive/full breastfeeding: Breast milk feeding without supplementation in the form of other solid or liquids.

First postnatal contact: First contact after the end of intrapartum care.

Formula milk/artificial milk: Modified cow's milk or modified soy liquid used for infant feeding in lieu of breastmilk.

Healthcare professional: Clinically educated and certified individual who provides postnatal care for a woman and/or her baby; most commonly midwives, general practitioners, health visitors and maternity support workers.

Healthy Baby: A healthy baby should have normal colour for his/her ethnicity, maintain a stable body temperature, pass urine and open his/her bowels at regular intervals. A healthy baby initiates feeds, sucks well on the breast (or bottle) and settles between feeds. A healthy baby is not excessively irritable or tense and is not excessively sleepy or floppy. The vital signs of a healthy baby should fall within the following ranges:

- Respiratory rate normally 30-60 breaths per minute
- Pulse rate, normally between 100-160 in a newborn
- Body temperature in a normal room environment of around 37 degrees Centigrade (if measured)

Induration: The hardening of a normally soft tissue or organ.

Maternity support worker: Individual who have received appropriate training and work under midwife or health visitor supervision in hospital or community postnatal care teams, providing basic care and support for women and their babies.

Parents: Presumed to be the biological parents and primary carers of an infant although it is recognised that this term may include other carers, such as grandparents, foster or adoptive parents, etc.

Partners: Individuals in a relationship who may be of either sexual orientation.

Peer counsellor: A woman who has herself breastfed, is from similar socio-economic background and locality to the women she is counselling and who has received specific training in counselling skills to provide support to breastfeeding women.

Postnatal Care: Care during the first 6-8 weeks after birth.

2.11 Urgency action levels

Although for most women and babies the postnatal period is uncomplicated, care during this period needs to address any deviation from expected recovery after birth. This guideline gives advice on when additional care may be needed and these recommendations have been given a status level (indicating the degree of urgency needed in dealing with the problem (see table 1).

Table 2-1 Status levels

Status	Classification
Emergency	Life-threatening or potential life-threatening situation
Urgent	Potentially serious situation, which needs appropriate action
Non-urgent	Continue to monitor and assess

3 Methods

3.1 Introduction

This chapter sets out in detail the methods used to generate the recommendations for clinical practice that are presented in the subsequent chapters of this guideline. The methods are in accordance with those set out by the National Institute for Health and Clinical Excellence (the Institute) in The Guideline Development Process – Information for National Collaborating Centres and Guideline Development Groups (2005) (available at: http://www.nice.org.uk).

3.2 Developing Key Clinical Questions

The first step in the development of the guideline was to refine the guideline scope into a series of key clinical questions (KCQs) which reflected the routine postnatal care pathway. These KCQs formed the starting point for the subsequent review and as a guide to facilitate the development of recommendations by the Guideline Development Group (GDG).

The KCQs were developed by the GDG and with assistance from the Technical Team. The KCQs were refined into specific evidence-based questions (EBQs) specifying interventions to search and outcomes to be searched for by the Technical Team and these EBQs formed the basis of the literature searching, appraisal and synthesis.

The total list of KCQs identified is listed in Appendix E. It was found that for many there was very little literature and what was available overlapped several questions. Where this was the case, the extractions were grouped into topic areas, answering several questions. This is made apparent in the Evidence Tables (see Appendix C & D)

The Technical Team and the GDG agreed that a full literature search and critical appraisal should not be undertaken for all of these KCQs due to the time and resource limitations within the guideline development process. The Technical

Team, in liaison with the GDG, identified those KCQs where a full literature search and critical appraisal were essential. Literature searches were not undertaken where there was already national guidance on the topic to which the guideline could cross refer. This is detailed in Appendix E.

3.3 Literature search strategy

The purpose of searching the literature is to identify all the available published evidence to answer the clinical questions identified by the Technical Team and the GDG. The Information Scientist developed search strategies for each question, with guidance from the GDG, using relevant MeSH (medical subject headings) or indexing terms, and free text terms. Searches were conducted between March 2004 and May 2005. Update searches for each question, to identify recent evidence, were carried out in July and August 2005. Full details of the sources and databases searched and the strategies are available on request.

An initial search for published guidelines or systematic reviews was carried out on the following databases or websites: National Electronic Library for Health (NeLH) Guidelines Finder, National Guidelines Clearinghouse, Scottish Intercollegiate Guidelines Network (SIGN), Guidelines International Network (GIN), Canadian Medical Association (CMA) Infobase (Canadian guidelines) ,National Health and Medical Research Council (NHMRC) Clinical Practice Guidelines (Australian Guidelines), New Zealand Guidelines Group, BMJ Clinical Evidence, MIDIRS (Midwives Information & Resource Service), Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Heath Technology Assessment Database (HTA).

If a recent high quality systematic review or guideline was found that answered the clinical question posed, then in some instances no further searching was carried out.

Depending on the question all or some of the following bibliographic databases were also searched from their inception to the latest date available: MEDLINE, EMBASE, CINAHL, CENTRAL (Cochrane Controlled Trials Register),

PsycINFO, Allied & Complementary Medicine (AMED), DH-Data (Department of Health) & British Nursing Index (BNI).

Databases of the results of the searches for each question or topic area were created using the bibliographic management software Reference Manager.

In most cases it was necessary to search for published literature of any study design because of the nature of the question being posed, and the small amount of published evidence available on the population group relevant to the guideline. However, for questions where the literature was sizeable systematic review filters were used, and for questions about the effectiveness of an intervention a randomised controlled trial filter was employed to limit studies to these designs. The filters used were devised by the Centre of Reviews and Dissemination, and the Cochrane Collaboration respectively.

3.4 Identifying the Evidence

After the search of titles and abstracts was undertaken, full papers were obtained if they appeared to address the GDG's question relevant to the topic. The highest level of evidence was sought. However observational studies, surveys and expert formal consensus results were used when randomised control trials were not available. Only English language papers were reviewed. The review focused on U.K. research where possible. Following a critical review of the full version of the study, articles not relevant to the subject in question were excluded. Studies that did not report on relevant outcomes were also excluded. Submitted evidence from stakeholders was included where the evidence was relevant to the GDG clinical question and when it was either better or equivalent in quality to the research identified in the literature searches.

The reasons for rejecting any paper ordered were recorded.

Competencies for care delivery were searched in accordance with the remit for this Guideline. Little evidence was found and thus the group reviewed and investigated ongoing work within the Department of Health. As defining competencies is the responsibility of the professional registration bodies, the GDG did not regard it as its remit to define all competencies. The GDG did

however review the recommendations for care and derived competency recommendations based on these where it was felt that these were particularly important for the implementation of the guideline.

3.5 Critical appraisal of the evidence

From the papers retrieved the Health Service Research Fellow (HSFR) synthesised the evidence for each question or questions into a narrative summary. These form the basis of this guideline and are presented in Chapters 4-6. Each study was critically appraised using the Institute's criteria for quality assessment and the information extracted about included studies is given in Appendix C. Background papers, for example those used to set the clinical scene in the narrative summaries, were referenced but not extracted.

3.6 Economic analysis

A systematic literature review was conducted to assess the economic evidence, applying an economic search filter developed and supplied by the Centre for Reviews and Dissemination to the general search results. The Information Scientist carried out these searches for health economics evidence. The databases searched under this approach were MEDLINE, EMBASE and the NHS Economic Evaluation Database (NHS EED).

Given the limited economic evidence it was decided to perform a broad search for evidence that was designed to identify information about the costs or resources used in providing a service or intervention and /or the benefits that could be attributed to it. No criteria for study design were imposed a priori. In this way the searches were not constrained to RCT's or formal economic evaluations. Papers included were limited to studies of post-natal care, written in English, and reporting health economic information that could be generalised to U.K.

Identified titles and abstracts from the economics searches were reviewed by a single health economist and full papers obtained as appropriate. The full papers were critically appraisal by the health economist using a standard validated checklist (Drummond MF & Jefferson TO 1996). A general descriptive overview

of the studies, their qualities, and conclusions was presented and summarized in the form of a short narrative review. The economic evidence was not summarized in the form of meta-analyses given the limited evidence found. The extractions of economic papers are found in Appendix D

The GDG identified three areas which required further economic investigation. These were the costs of provision of Vitamin K to prevent Vitamin K Deficiency Bleeding, the cost implications of the Baby Friendly Hospital Initiative in England and Wales, and the planning and delivery of routine postnatal care. These areas were chosen because it was felt either there was a significant clinical or cost implication, or both. The results of these analyses are presented in the relevant chapters.

3.7 Assigning levels to the evidence

The evidence levels and recommendation are based on the Institute's technical manual. (http://www.nice.org.uk/page.aspx?o=guidelinestechnicalmanual). Evidence levels for included studies were assigned based upon the table below.

Table 3-1 Evidence Levels

Level of evidence	Type of evidence
1^{++}	• High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1^{+}	• Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1^{-}	• Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2^{++}	• High-quality systematic reviews of case–control or cohort studies • High-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2^{+}	• Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2^{-}	• Case–control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	• Non-analytical studies (for example, case reports, case series)
4	• Expert opinion, formal consensus

The grading of recommendations was carried out in accordance with the NICE Technical Manual in use at the outset of the guideline development process. However, during the development of the Postnatal Care guidance NICE protocols were revised and grading of recommendations was abolished. Therefore, the recommendations for postnatal care are not graded in the NICE version of the guideline. They have been retained, as a matter of record, in the full guideline per Table 3-2 below.

Table 3-2 Classification of recommendations on interventions

Recommendation grade	Evidence
A	• At least one meta-analysis, systematic review, or randomised controlled trial (RCT) that is rated as 1^{++}, and is directly applicable to the target population, **or** • A systematic review of RCTs or a body of evidence that consists principally of studies rated as 1+, is directly applicable to the target population and demonstrates overall consistency of results, **or** • Evidence drawn from a NICE technology appraisal
B	• A body of evidence that includes studies rated as 2^{++}, is directly applicable to the target population and demonstrates overall consistency of results, **or** • Extrapolated evidence from studies rated as 1^{++} or 1^{+}
C	• A body of evidence that includes studies rated as 2^{+}, is directly applicable to the target population and demonstrates overall consistency of results, **or** • Extrapolated evidence from studies rated as 2^{++}
D	• Evidence level 3 or 4, **or** • Extrapolated evidence from studies rated as 2^{+}, **or** • Formal consensus
D(GPP)	• A good practice point D(GPP) is a recommendation for best practice based on the experience of the Guideline Development Group
IP	• Recommendation from NICE Interventional Procedures guidance

In the case of this guideline however, RCT evidence was not the most appropriate study design for many questions, as in the SIDS case control studies. There are also many topics covered in this guideline for which there is simply no RCT evidence. Routine postnatal care is a complex social intervention provided by different health professionals, intended to respond to a range of

physical and psychosocial needs in a range of settings, for mothers and babies whose backgrounds and circumstances vary widely. There are therefore diverse, and many interdependent, factors involved in determining effectiveness of care and few completely clear cut or categorical answers. Therefore, the best evidence available is observational or expert opinion. Thus, although there is a formal hierarchy, it does not reflect the clinical importance of many of the evidence statements and recommendations.

3.8 Forming recommendations

In preparation for each meeting, the narrative and extractions together with a list of rejected papers for the questions to be addressed were made available to the GDG one week before the scheduled GDG meeting. These documents were available on a closed intranet site and sent by post to those members who requested it.

GDG members were expected to have read the narratives and extractions before attending each meeting. From the evidence, the Technical Team drafted evidence statements which synthesised the research evidence. These were presented to the GDG at the meeting and discussed and agreed. Any changes were made to the electronic version of the text on a laptop and projected onto a screen until the GDG were satisfied with the statements. From the evidence statements and the experience of GDG members recommendations were drafted.

All work from the meetings was posted on the closed intranet site following the meeting as a matter of record and for referral by the GDG members.

3.9 Areas without evidence and consensus methodology

The table of clinical questions in Appendix E, indicates which questions were searched. Questions not searched were those which were answered by other national guidance, for example from the National Screening Committee or, questions for which no evidence was available. In some cases, the answers to a question were derived from a related search or recommendation; for example,

answers to questions relating to the information needs of women were frequently supplied by the evidence reviewed for the associated condition.

In cases where evidence was sparse, the GDG derived the recommendations via informal consensus methods. Relevant experts in the field were contacted for further information as necessary. Two expert cooptees were nominated by their professional organizations and other experts listed in Section 1.8 were nominated by the GDG to inform their decisions.

In addition, while the scope of the guideline is routine (or "normal") postnatal care, the vast majority of the research is directed at abnormality or at high risk groups or situations. Therefore, despite extensive literature searches which provided a sound background , many of the recommendations regarding what is core or normal care were derived through informal consensus methods.

3.10 Consultation

The guideline has been developed in accordance with the Institute's guideline development process. This has included allowing registered stakeholders the opportunity to comment on the scope of the guideline, the first draft of the full and short form guideline and the final draft of the guideline. In addition, the first draft was reviewed by individuals with an interest in postnatal care including those who expressed an interest in being a member of the GDG and an independent Guideline Review Panel (GRP) established by the Institute.

The comments made by the stakeholders, peer reviewers and the GRP were collated and presented for consideration by the GDG. All comments were considered systematically by the GDG and the project team recorded the agreed responses.

3.11 The Relationship between the guideline and other national guidance

3.11.1 National Service Frameworks

In formulating recommendations regarding visits and competencies consideration was given to the NSF's for Children for both England and Wales.

3.11.2 National Screening Committee

The GDG did not review the evidence for neonatal screening or immunisation but accepted the guidance of the NSC to which the guideline cross refers.

3.11.3 Related NICE Guidance

The guideline builds on work from other relevant NICE guidelines, including induction of labour, electronic fetal monitoring, antenatal care and caesarean section. It should also be used in conjunction with the guideline on antenatal and postnatal mental health and intrapartum care, which are currently in development.

Division of ankyloglossia (tongue-tie) for breastfeeding. *Interventional procedure guidance* no. 149 (2005). Available from: www.nice.org.uk/IPG149

Caesarean section. *NICE clinical guideline* no. 13 (2004). Available from: www.nice.org/CG013

Antenatal care: routine care for the healthy pregnant woman. *NICE clinical guideline* no. 6 (2003). Available from www.nice.org/CG006

Induction of labour. *Inherited clinical guideline D* (2001). Available from: www.nice.org.uk

The use of electronic fetal monitoring: the use and interpretation of cardiotocography in intrapartum fetal surveillance. *Inherited clinical guideline C* (2001). Available from: www.nice.org.uk

NICE is in the process of developing the following guidance (details available from www.nice.org.uk):

Antenatal and postnatal mental health: clinical management and service guidance. *NICE clinical guideline*. (Publication expected February 2007.)

Intrapartum care: management and delivery of care to women in labour. *NICE clinical guideline*. (Publication expected February 2007.)

Maternal and child nutrition. *NICE public health programme guidance.* (Publication expected May 2007.)

Through review of published guidance, personal contact and commenting on guideline scope, endeavours were made to ensure that boundaries between guidance were clear and advice was consistent.

3.11.4 Centre for Public Health Excellence

The *Evidence into practice briefing (EIP)on the promotion, initiation and duration of breastfeeding'* (Dyson et al 2006) presents evidence-based actions for promoting the initiation and continuation of breastfeeding, particularly among population groups where breastfeeding rates are low. The report also describes the characteristics of effective programmes for these groups and for different settings as well as strategies for overcoming barriers to change.

The EIP was commissioned from the Public Health Collaborating Centre in Maternal and Child Nutrition by the Health Development Agency (HDA) before the HDA merged with NICE on April 1 2005

The actions focus on effective public health interventions that can help increase and maintain breastfeeding rates, promoting health in the long term for both baby and mother. They are intended to complement Chapter 5 (Infant Feeding) of the clinical guideline on routine postnatal care of recently delivered women and their babies.

3.11.5 Department of Health

The guideline did not search or address a number of lifestyle issues which are covered in the DH publication *Birth to Five* (Department of Health. 2005) to which the guideline refers.

The guideline also refers to DH guidance on immunisation. (Salisbury & Begg 1996)

The guideline also refers to DH guidance on the need for administration of vitamin K and does review the method of administration. (Department of Health. 1998)

The guideline also refers to DH guidance on bottle feeding. (Department of Health. 2005)

4 Planning the Content and Delivery of Care

4.1 Recommendations

Principles of care

1 Each postnatal contact should be provided in accordance with the principles of individualised care. In order to deliver the core care recommended in this guideline postnatal services should be planned locally to achieve the most efficient and effective service for women and babies. **[D(GPP)]**

2 A coordinating healthcare professional should be identified for each woman. Based on the changing needs of the woman and baby, this professional is likely to change over time. **[D(GPP)]**

3 A documented, individualised postnatal care plan should be developed with the woman, as soon as possible (ideally in the antenatal period) to include:

- relevant factors from the antenatal, intrapartum and immediate postnatal period
- details of the healthcare professionals involved in her care and that of her baby including roles and contact details
- plans for the postnatal period.

This should be reviewed at each postnatal contact. **[D(GPP)]**

4 Women should be offered an opportunity to talk about their birth experiences and to ask questions about the care they received during labour. **[GPP]**

5 Women should be offered relevant and timely information to enable them to promote their own and their babies' health and well-being and to recognise and respond to problems. **[D(GPP)]**

6 At each postnatal contact the healthcare professional should:

- ask the woman about her health and well-being and that of her baby. This should include asking women about their experience of common physical health problems. Any symptoms reported by the woman or identified through clinical observations should be assessed.
- offer consistent information and clear explanations to empower the woman to take care of her own health and that of her baby, and to recognise symptoms that may require discussion
- encourage the woman and her family to report any concerns in relation to their physical, social, mental or emotional health, discuss issues and ask questions
- document in the care plan any specific problems and follow-up. **[D(GPP)]**

7 Length of stay in a maternity unit should be discussed between the individual woman and her healthcare professional, taking into account the health and well-being of the woman and her baby and the level of support available following discharge. **[D(GPP)]**

Professional communication

8 There should be local protocols about written communication, in particular about the transfer of care between clinical sectors and healthcare professionals. These protocols should be audited. **[D(GPP)]**

9 Healthcare professionals should use hand-held maternity records, the postnatal care plans and personal child health records, to promote communication with women. **[C]**

Competencies

10 All healthcare professionals who care for mothers and babies should work within the relevant competencies developed by Skills for Health (www.skillsforhealth.org.uk). Relevant healthcare professionals should also have demonstrated competency and sufficient ongoing clinical experience in:

- undertaking maternal and newborn physical examinations and recognising abnormalities
- supporting breastfeeding women including a sound understanding of the physiology of lactation and neonatal metabolic adaptation and the ability to communicate this to parents
- recognising the risks, signs and symptoms of domestic abuse and whom to contact for advice and management, as recommended by Department of Health guidance (Department of Health. 2005)
- in recognizing the risks, signs and symptoms of child abuse and whom to contact for advice and management, as recommended by Department of Health guidance(Department of Health. 2005).**[D(GPP)]**

4.2 Evidence Statements for Planning Care

Note: The title of each section is linked to the relevant narrative for ease of reference

Professional communication

1 Hand held records appear to be well retained by women and parents and are more thoroughly completed by health professionals than clinic held records. Level 3

2 Hand held records improve women's communication with their own and their child's health care provider .Level 3

3 Health care providers who have experience with hand held records favour this method of documentation. Level 3

Is there an optimal length of stay?

4 In a systematic review of discharge, the quality of the studies on length of stay has been inadequate to show any difference in outcomes between early and standard discharge for healthy mothers and term infants Level 1++

5 In one Swiss study of a mixed birth cohort (including CS), discharge of women who had had uncomplicated pregnancies and non-caesarean births between 24-48 hours was a cost-effective approach compared to discharge between 4-5 days. Level 1 ++

6 There is no evidence relating to cost-effectiveness concerning discharge prior to 24 hours.

7 It is not possible to compare the cost savings of first day discharge with any possible harm since there is no clear measure of this harm due to 'healthy baby' bias.

What are the models for delivering the care?

8 Satisfaction with midwifery led care is high among women. Level 3

9 Women who received continuity of care are more likely to be satisfied with their postpartum experience. Level 1++

10 Care from a small team of midwives may be comparable to one-to-one midwifery in terms of maternal satisfaction, continuity and clinical outcomes, and is at least as cost effective. Level 3

11 An extended midwifery based protocol package of care, which included the use of symptom checklists to identify physical and psychological health problems at postpartum visits, was associated with improvements in psychological well being as measured by the Edinburgh Depression Scale and SF36. As costs were the same it was therefore more cost-effective relative to the control group. Level 1+

12 In the USA, home visits appear to be preferable to clinic visits, and clinic visits preferable to telephone contacts, when mothers are surveyed. There are no significant clinical differences among these models. Level 3

13 A model which used non-professional support workers to provide daily home visits for 28 days, in addition to routine midwifery care, did not improve maternal outcomes (physical, breastfeeding, psychological). However a model providing non-professional support workers making monthly visits to families in deprived areas for 12 months was able to deliver both a child development programme and improvements in maternal health and well-being effectively. Level 2+

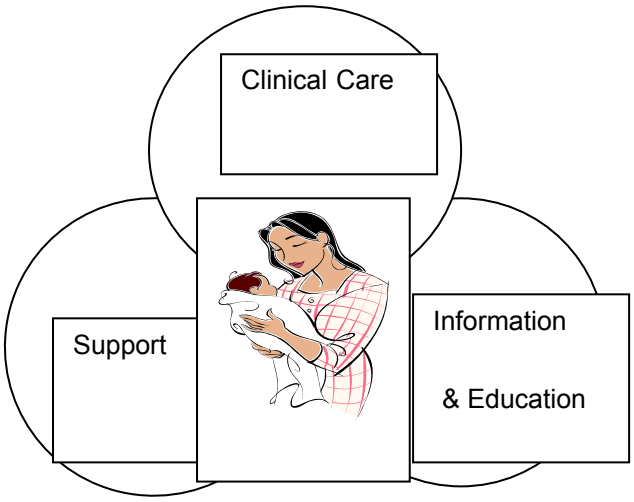
14 The use of non-professional community support workers postpartum is unlikely to be a cost-effective use of resources. Level 1+

15 In one Canadian study, when telephone contact was compared to two postnatal home visits following an unproblematic pregnancy, outcomes, as measured by maternal confidence, infant health and breastfeeding, were similar and more cost effective. Level 1+

16 On the basis of the current very limited data for the UK, there is no evidence to support the cost-effectiveness of voluntary community support groups compared with Health Visitors in disadvantaged areas. Level 1+

4.3 Principles of care

In March 1992, following a comprehensive enquiry in response to widespread concern about provision of services, the House of Commons Health Select Committee published a report on the maternity services (House of Commons Health Select Committee. 1992) .This report concluded that 'a medical model of care' should no longer dominate maternity services and that women should be offered choice in the type of maternity care they received. An Expert Maternity Committee was established soon after to examine policy and develop recommendations for care. The Committee's report 'Changing Childbirth' was published in 1993, making explicit the right of women to be involved in decisions about all aspects of their maternity care, to be at the centre of care and to be able to make choices about their care. These priorities for care are at the core of the NICE maternity guideline programme (National Collaborating Centre for Women's and Children's Health. 2003). In relation to this guideline, there is an expectation that postnatal health services will be delivered with the full involvement and participation of the woman, in a respectful manner which ensures her safety, takes account of cultural sensitivity and facilitates clear communication with the woman, her partner and family. As illustrated below the conceptual framework for the postnatal guideline places the mother-infant dyad at the centre of service delivery, and acknowledges the role of clinical care, information, education and support which may all be required by the woman, her partner and family, during the first weeks and months following the birth.



Postnatal care should be a continuation of the care the woman has received through her pregnancy, labour and the birth of her baby. It therefore aims to provide consistency of advice and support for recovery from pregnancy and the birth, early identification and appropriate management of physical and psychological, emotional and social health needs, and facilitate the start of family life.

Postnatal maternity services should be organised to reflect the principles of care and clinical components of this Guideline. Flexibility in designing care delivery systems within individual NHS Trusts should reflect the ethos of this Guideline which advocates the individualisation of care for women and their babies from the systems which serve them.

4.4 Professional Communication

No studies were identified on communication at transfer of postnatal care or at discharge from care. A survey involving 35 of 42 health visitors working alongside a team midwifery scheme in the south-east of England raised

concerns about professional communication (Farquhar, Camilleri-Ferrante, & Todd 1998). Only 38% of the health visitors reported excellent/good communication with the community midwives while 62% reported fair/poor communication. Twenty six of the health visitors made suggestions to improve the working situation with midwives including: better communications (8/26), regular meetings (6/26), reduce size of team/area/caseload (3/26).

An RCT was conducted in Newbury, West Berkshire (Elbourne, Richardson, & Chalmers 1987) in which 290 women were randomly allocated to hold either their full maternity case notes until 10 days after delivery (n=161) or to hold the more commonly used cooperation card while their maternity case notes were held by the medical records department (n=156). Women holding their full case notes were significantly more likely to feel it was easier to talk to doctors and midwives (rate ratio 1.73, CI 1.16-2.59) and there was no evidence of negative effects such as increased anxiety or lost notes. There were also savings in clerical time. Concerns about data protection and the need for emergency access to records were raised by the authors. It was also speculated that as computerised records become more available access to records between providers may be more easily facilitated.

Parent held Personal Child Health Records (PCHRs) were introduced into primary care trusts in the late 1980's to promote partnership between health professionals and parents, improve communication between health professionals, improve continuity of care and increase parents' understanding of their child's health and development. By the early 1990's 75% of NHS Trusts were using the PCHR.

Macfarlane and Saffin (Macfarlane & Saffin 1990) assessed the reactions of general practitioners and health visitors to parents holding the main record of their own child's health and development. The parent held record was introduced into one part of Oxfordshire in 1986. In April 1987 questionnaires were sent to every health visitor and every general practitioner working in the Oxfordshire District Health Authority. There was an 83% GP response rate and 92% response rate from health visitors. Fifty seven percent of the GPs had worked in an area where the child health record was held by parents. Sixty one percent of

health visitors had experience with PCHRs. The results showed that over 90% of the GPs and health visitors with experience of the PCHR were in favour of them. The major concerns of the primary health care teams were possible loss of the record, the problem of documenting sensitive information and the possibility that parents might be unnecessarily worried about something written in the record.

In a follow-up study published in 1991 (Saffin & Macfarlane 1991) an audit evaluated the lost/forgotten rate for both the parent held record and the clinic held record and assessed the content of the records. The audit was carried out between August 1988 and February 1989 in Oxfordshire and recruited 452 parents, 284 of whom had been given parent held records and 168 of whom had clinic records. The lost/forgotten rate was assessed on the basis of whether the record was available for the researcher to see at the audit. Ninety percent of records held by parents and 95% of records held by the clinic were available. Thirteen percent of parent held records included additional comments written by the parents. Overall the parent held records were more thoroughly completed by professionals than were the clinic held records; 9 of 15 items had a higher completion rate in the parent held records.

A study by Charles (Charles 1994) aimed to determine if parent held records were an effective means of communication between professionals and between professionals and parents. Six general practices in Newcastle-under-Lyme in North Staffordshire were surveyed by postal questionnaire. Professionals working in this area and parents with children registered in any of the six local general practices were sent questionnaires. There was an 85% response rate from professionals and a 71% response rate from parents. Of the professionals who had used the record, 92% of health visitor respondents liked the PCHR, compared with only 60% of the GPs. Nearly all of the parents who responded liked the record (98%). When considering the record as a means of communication, 90% of health visitors and 53% of GPs believed it would improve communication. Parents felt that the record gave them a better understanding of advice given by professionals (87%) and enabled them to play a more active role in their child's health care (93%). The writing of sensitive

information in the record caused concern among some of the professionals: 83% of practice nurses, 44% of GPs and 45% of health visitors said they would not write sensitive information in the record. When audited the PCHRs were found to be more detailed and complete than the traditional clinic cards (93% vs 36% respectively). Only the PCHRs had parent entries recorded. Although health visitors used both types of records equally, 84% of GPs had used the parent held record compared to just 50% making entries in the traditional clinic cards.

In Australia the “blue book” parent held record (PHR) was introduced in the 1980’s. A study conducted ten years after the introduction of the PHR in South Australia surveyed 313 parents in attendance at one of eight child health centres in Adelaide (Volkmer, Gouldstone, & Ninnes 1993). Nearly 90% of parents found the PHR somewhat or very useful. Only 46% of parents usually took the PHR to GP visits and only 23% of parents reported that GPs used the PHR. The immunisation section of the record was most useful for parents (92%) followed by growth charts (73%) and health check (67%).

Another Australian study conducted five years after the PHR was introduced in New South Wales evaluated retention rate over time, rates of documentation of immunisation status and other important child health information and its perceived usefulness to parents (Jeffs et al 1994). In this study two concurrent surveys were conducted between March and May 1992. One survey studied a stratified random sample of households with children under 4 years of age (n=622, 97% response). The second survey studied the opinions of a randomly selected representative sample of general practitioners and community based nurses, paediatricians and A & E staff (n=574, 63% response). Results showed that 89% of parents claimed to still have the records at 4 years and over 78% of parents were able to produce the record for inspection at interview. Overall, 93% of parents expressed satisfaction with the PHR. Although 64% of all health care providers felt the PHR was beneficial only 53% of them used it regularly to record their findings. There was a marked differential in use across professional groups (96% of community based nurses, 53% of paediatricians, 32% of A & E staff, and 30% of general practitioners).

Another study from New South Wales aimed to evaluate whether parents brought the PHR to GP appointments and use of the PHR, by studying documentation in the record (Young & Fasher 1994). The PHRs of parents in the waiting room of the author's surgery were audited for content. There were 825 initial patient contacts. Four hundred and twenty-five parents did not have the PHR with them, 16 of whom said they had never received a record. Parents of younger children (ages <1 and 1-2 years) were significantly more likely to carry the record ($p<0.0001$). Records of immunisation were well kept, with an overall 92% completion rate. Only 40% of the progress notes had entries by doctors. Fifteen percent of the progress notes contained parent entries.

4.5 What are the necessary competencies for postnatal care?

The competencies for postnatal care have been identified in the chapters which relate to clinical care of the woman and her baby. Health care professionals should ensure they work within the relevant Maternity and Care for the Newborn competencies developed by Skills for Health (Skills for Health 2005). The guidance for competencies has been collated within Section 1.3 of the Recommendations.

4.6 Is there an optimal length of stay on the postnatal ward?

Narrative Summary

Since the 1950's there has been controversy around the issue of whether early discharge from the postnatal ward of mothers and babies is safe. Evaluation of the literature on this topic is difficult. The definition of 'early discharge' varies considerably in different settings, ranging from 2 hours postpartum to three or four days after birth. 'Early discharge' may also be accompanied by a variety of co-interventions including antenatal preparation and postnatal support. In 2002 a Cochrane review evaluated early postnatal discharge from hospital for healthy mothers and term infants (Brown et al. 2002). This review updated and

expanded upon two previous Cochrane Pregnancy and Childbirth Group reviews (Hay-Smith, 1995, Renfrew, 1999). The authors reviewed the literature for nine outcomes including measures of maternal and infant health, maternal depression, parental anxiety, breastfeeding problems and duration, maternal satisfaction and cost implications. Eight trials involving 3600 women met the inclusion criteria. No statistically significant differences in infant or maternal readmissions were found in six trials reporting data on these outcomes. Three trials assessed women's emotional well-being in the months after the birth but none used validated instruments with known sensitivity or specificity for identifying maternal depression in the postnatal period (i.e., the Multiple Affect Adjective Checklist, the Beck Depression Inventory and a single item self report measure). Initially, both mothers and fathers in early discharge groups exhibited more confidence in child care in the two studies which evaluated this outcome. However within a month there was no significant difference in either group. The pooled estimate from six trials on partial or exclusive breastfeeding at one month or two months postpartum indicated no significant difference between early discharge groups and controls. In three trials that reported data for maternal satisfaction as mean scores, all found greater satisfaction with postnatal care among women randomised to early discharge. In two other studies where a comparison of proportions was done (128/1941 versus 5/316) there was highly significant heterogeneity between the results and a pooled analysis was not undertaken. No trials reported data on costs in a format consistent with the outcomes specified in the review protocol and no U.K. cost data were available. The reviewers determined that overall the findings were inconclusive. There was no evidence of adverse outcomes but due to methodological inconsistencies among studies, this possibility could not be ruled out.

A Medline only review of the effect of early postpartum discharge (less than 48 hours after any vaginal birth or 96 hours after caesarean delivery) on maternal and neonatal complications, maternal concerns, patient satisfaction and cost savings reached a similar conclusion after evaluating 5 RCTs, 10 cohort studies, 1 case control study and 12 case-series reports (Grullon & Grimes 1997;Johnson, Howell, & Molloy 1993). Methodological flaws which introduced

selection bias, inadequate power and exclusions of patients after randomisation limited the study validity. Highly selected patient populations, that is mothers and infants who met strict criteria for early discharge, restrict generalisability of findings. The authors concluded that the evidence was insufficient to judge the safety and practicality of early discharge in the general postnatal population.

A similar review was undertaken in Canada (Conseil d'Evaluation des Technologies de la Sante du Quebec 1997). The same concerns about methodology and sample size were highlighted and the link between early discharge and neonatal or maternal mortality and morbidity could not be confirmed or ruled out. There was no association between early discharge and the duration of breastfeeding, mothers' satisfaction, or use of ambulatory services. A cost evaluation undertaken as part of the review showed potential savings could be made if there were no maternal or neonatal complications.

In an earlier review of the literature Margolis (Margolis 1995) identified the potential for 'healthy baby' bias in studies on early discharge. The decision to discharge was made by health care providers who may have observed signs or symptoms that caused them to alter discharge plans. This extra vigilance could result in only the healthiest infants experiencing early discharge. In this review the definition of 'early discharge' was found to vary widely from 2 hours to 5 days. Although the thirteen studies reviewed suggest that there are no differences between infants discharged early and those receiving standard care the study limitations were felt to limit generalisability of findings.

Waldenstrom (Waldenstrom 1988) studied fatigue and emotional reactions in women and their partners, comparing discharge at 24-48 hours with traditional hospital stays of 6 days. One hundred and four women who had a vaginal delivery of a single baby were randomly allocated to the experimental (n=50) or control group (n=54). Information was collected from diaries completed daily for two weeks. Questionnaires were also mailed at 6 weeks postpartum to both women and their partners. There were no statistically significant differences in fatigue when comparing the mean values for all 14 days but women in the experimental group were more tired during the first 2-4 days after birth (p value

not given). The partners of women in the experimental group were also more tired but the difference was not statistically significant. There were no statistically significant differences between the groups and reports of being tearful during the first two weeks after the birth, or in self reported depressed mood up to 6 weeks after the birth.

Heck and colleagues (Heck et al. 2003) used data from 10,519 respondents to the California Maternal and Infant Health Assessment surveys from 1999 to 2001 to examine the relationship between length of postnatal in-patient stay and length of time breastfeeding. After adjustment for potential confounders, women with a short stay (less than 2 nights stay) were slightly more likely to give up breastfeeding earlier than women with the standard 2-4 nights stay (RR 1.11, 1.01-1.23). Women with long hospital stays were the most likely to stop breastfeeding (RR 1.30, 1.14-1.48) although these were usually the mother infant dyads with serious health problems.

Two hospital sites in Canada were used to evaluate an early discharge programme (Dalby et al. 1996). Discharge occurred as early as 6 hours postpartum and home visit services were available to the woman including a lactation consultant, home nursing visits, domestic help and 24 hour hospital telephone line as well as information about community based resources. Women agreed to discharge within 48 hours (n=319) or opted not to go home early but participate in the study (n=456). Women decided which services they felt they would need. A nurse coordinator at each hospital site was responsible for arranging services. Safety and satisfaction were the outcomes of interest. Safety was measured by the number of visits to a physician or hospital emergency department and reports of hospital readmission and satisfaction was measured through a mailed postpartum questionnaire. A pre programme group (average stay 4.2 days), an early discharge group (average stay 2.7 days) and a standard care group (average stay 3.5 days) were assessed. There were no significant differences between the early discharge group and the other two groups and readmission during the first week postpartum. The early discharge group was significantly more satisfied than the pre programme group (p=0.04). However, the early discharge group was self selected and information on non-

respondents to a patient questionnaire was not collected. Nonetheless, the researchers concluded that the early discharge programme with home follow up appeared to provide a feasible, safe and effective alternative to traditional discharge procedures.

A study conducted at St. Joseph's Hospital in Denver Colorado reviewed records of 4323 women and their infants and divided length of stay into three time periods: < 24 hours, 25-48 hours and >48 hours (Meikle et al. 1998). For the women, a longer initial hospital stay (>48 hours) was significantly associated with readmission ($p<0.01$) and increased outpatient care use ($p=.01$). Once again, the 'healthy mother effect' was operational. Women with potential and observed problems were rarely discharged in < 24 hours. There were no statistically significant problems among neonates that were related to the length of their initial hospital stay. Those neonates receiving home care and discharged in less than 48 hours were less likely to require hospital readmission or to require outpatient care.

A study carried out in Oklahoma City in the USA compared three policies in three consecutive months: routine care in month one; early discharge on the first postpartum day after vaginal delivery or the second day after a caesarean delivery in month two; and in month three, early discharge with a 'stay-over mom' option if the baby was not yet discharged (Bossert et al. 2001). The primary outcome measures were length of hospital stay and women's willingness to have early discharge. With proper review of written instructions, all women eligible for study inclusion were willing to be discharged early. The need for maternal readmission was rare (0.8%). The stay-over policy was more desirable for women whose infants required continued observation.

A retrospective record review of infants born from January, 1994 to December, 1998 at Norton Hospital in Louisville, Kentucky USA, was undertaken to assess readmission rates of infants in the first week of life (Radmacher, Massey, & Adamkin 2001). The hospital criteria for early discharge at <48 hours was carefully adhered to and 21,628 infants were discharged during the study period. Late discharge infants were readmitted at a rate almost twice that of early discharge infants ($p<0.05$) (late discharge infants were likely to have had a

problem which kept them in hospital). Infants discharged prior to 48 hours of age were at higher risk of hospital admission for jaundice with higher bilirubin levels than those who stayed longer, especially if they were breast-fed. The authors considered that coupling of the time of discharge with the onset of lactogenesis and bilirubin production may exaggerate physiologic hyperbilirubinemia and be the result of too little volume and too few feeds. Increasing the frequency and duration of breast feeding enhances bilirubin loss via the stool and may lower serum bilirubin. The American Academy of Pediatrics recommends a formal evaluation of breastfeeding during the first 24 to 48 hours after delivery and again at an early follow up visit which should occur 48 to 72 hours after hospital discharge (American Academy of Pediatrics.American College of Obstetricians and Gynecologists. 1997)

An Australian study assessed the impact of shorter length of stay on breast feeding and women's psychological well-being (Brown et al. 2004). Postal surveys were completed by 3742 women at 5-8 months postpartum. The primary outcome measures were infant feeding at 6 weeks postpartum and maternal depression at 5-8 months postpartum as measured by the Edinburgh Postnatal Depression Scale (score > 13). There were no significant differences by length of stay in breast feeding rates or in EPDS scores in the adjusted analysis.

In an RCT carried out in Switzerland, women were randomised to either early discharge with home based care (n=228) or routine hospital-based care for four to five days (n=231) (Boulvain et al. 2004). The home based postnatal care consisted of discharge from hospital at 24-48 hours postpartum and additional home visits by a midwife (4.8 average visits); women in the hospital based care group were hospitalised for four to five days with limited midwifery visits (1.7 average visits). The outcome measures were continuation of breastfeeding to 28 days postpartum, women's views of their care and readmission to hospital. There was no significant difference in the prevalence of breast feeding between the groups at 28 days but women in the home based care group reported fewer problems with breast feeding (RR 0.55, 0.33-0.90). There were no differences in satisfaction with care, women's hospital readmissions, postnatal depression

scores (EPDS) and health status scores (SF-12). A higher percentage of babies in the home based care group were readmitted to hospital during the first six months (p=0.004). Readmission diagnoses were not provided but five infants in the home based care group were readmitted for the treatment of hyperbilirubinaemia compared with two infants in the hospital based group.

An economic analysis of this study looked at the cost-effectiveness of earlier postnatal discharge (Petrou et al. 2004). Regarding the clinical outcomes, as noted previously, the paper found few statistically significant differences in any of the indicators used to compare the two groups, therefore, the intervention and control were compared solely through their cost-implications. Whichever has the lower cost will weakly dominate the other, meaning it is at least as effective and less expensive.

The costs of the home care group averaged to 7798 Swiss Francs (2000), compared with 9019 Swiss Francs (2000) in the hospital group. Costs were then subdivided into postnatal hospital care, hospital readmissions, hospital outpatient care, community care, direct non-medical costs and indirect costs. The only mean differences between the two groups which were statistically significant were the cost of postnatal hospital care ($p<0.001$) suggesting early discharge is cheaper and the cost of community care ($p<0.001$) suggesting that midwifery care in the early discharge wing increases community costs. The mean difference between the two groups of 1221 Swiss Francs (2000) had a p-value of 0.017.

The authors also undertook a one-way sensitivity analysis, altering each model input systematically and noting the effect this change had on the conclusion. Using a non-parametric approach, the mean difference estimate remained between 847 Swiss Francs (2000) and 1516 Swiss Francs (2000), and the p-value remained statistically significant at the 5% level under each alternative scenario.

Regarding the generalisability of this result, there are three issues to consider. The first is that this paper takes a societal perspective. NICE guidance demands a recommendation based on costs attributable only to the NHS and personal

social services. However, this is of limited importance since the indirect costs of the intervention and the control were not significantly different (p=0.422). Thus, there is no evidence that adapting the model to a NHS and personal social services perspective would change the result.

The second issue is that the clinical results are not transferable to England and Wales. Thus, while the Swiss population had similar results for the control and intervention groups, this may not be true for the English and Welsh population (making a cost-minimisation approach incomplete). This objection might be valid but assumptions such as this are often necessary to draw conclusions from the literature base.

The third and potentially most relevant issue to the study generalisability is whether the Swiss costs that are used in the article are readily adaptable to England and Wales. If only costs of midwifery care and the cost of hospital care were considered (since these are the only statistically significant inputs), the evidence for England and Wales suggests the results are transferable. There were 2.9 extra midwife visits in the early discharge group. NHS Reference Costs estimate the cost of a health visitor visit to be £32.20 including travel costs (unfortunately, they do not cost midwife time: Arguably, health visitor costs are most approximate)(Curtis & Netten 2004). Thus, the expected extra costs will be £93.38 per mother. In the Swiss data, the length of hospital stay under the Early Discharge scheme was 41 hours shorter than usual. There is no readily available estimate of the cost of 41 hours in hospital in the literature. However, a systematic review puts a cost estimate of £444 on a spontaneous vaginal delivery without postnatal stay and £678 with stay (Petrou, Henderson, & Glazener 2001). They also find that the mean length of stay for spontaneous vaginal births after 37 weeks is 1.49 days. If the difference between the two costs is divided by the average length of stay in this group, a cost per day of £157 can be used as an estimate. Thus, 41 hours is valued at £268.21, more than the extra cost of the midwife visitation, suggesting the result is transferable to England and Wales.

4.7 What are the models for delivering the care?

Background

The House of Commons Health Select Committee 1992 report on the maternity services highlighted postnatal care as 'poorly evaluated and researched, delivered in often inappropriate and fragmented ways, and has dissipated managerial focus which mitigates against efficient use of resources', (p iv) (House of Commons Health Select Committee. 1992).

The report of the Expert Maternity Group 'Changing Childbirth' (Expert Maternity Group. 1993) advocated that maternity services should be designed to allow women more control over their care, choice of treatment and place of delivery, and greater continuity of care. They recommended that women have sufficient information made available to them and that they could choose their place of birth, type of care and which professionals provided it. Moreover, women were entitled to a named midwife or lead professional who would help facilitate continuity of care. Specific recommendations for postnatal care included that research in this area be broadened, that in redesigning services, the need for continuity be placed at the centre, and that attention be turned away from a medical model of care.

In March 1997 the Audit Commission published its report 'First Class Delivery: Improving Maternity Services—England and Wales'(Audit Commission 1997). This was the first large-scale audit of the maternity services since the implementation of 'Changing Childbirth', and data were collected from samples of Trusts, GPs and a random selection of women who had recently given birth. In relation to postnatal care The Audit Commission found that although postnatal home visits were popular with most women their purpose was largely unspecified and effectiveness could not be demonstrated.

Alongside the main report a survey of women's views of maternity care, including their postnatal care, was published (Audit Commission 1997). This was based on responses from a random selection of 2406 women (67% response rate) who had given birth in England and Wales in 1995. Women made more negative comments about hospital postnatal services than any other aspects of

their maternity care. When asked about their postnatal care at home and the number of visits made by their midwife, many women reported receiving daily home visits, despite an amendment to the Midwives Rules in 1986, which introduced the concept of 'selective home visits', and the subsequent reflection of this in the Midwives Rules published in 1992 (United Kingdom Central Council for Nursing Midwifery and Health Visiting 1992). More recently, national standards for health and social care have been published for a range of areas including maternity care. The National Service Framework for Children, Young People and Maternity Services in England (Department of Health 2004) developed eleven core evidence based standards, one of which concerns maternity care (Standard 11). NHS acute and primary care trusts are expected to implement the maternity standards across their services by 2009. Standard 11 recommends the following with regard to maternity service delivery:

> *'Women need to be provided with a postnatal care service that identifies and responds in a structured and systematic way, to their individual physical, psychological, emotional and social needs; and which is based on the best available evidence. This should be achieved through a multi-disciplinary team-based approach, with a co-ordinating health professional who has the appropriate clinical skills to ensure that the mother receives the postnatal care she needs, and that the parents are able to care for their child. Within this framework, midwives and health visitors work closely together. When the mother and her baby's postnatal needs have been met, responsibility for her care and support can be transferred to the health visitor.*
>
> *The current duration of community postnatal care, with routine midwife discharge at 10 to 14 days and routine discharge from maternity care at six to eight weeks, now appears too short for a full assessment of health needs, given the long term nature of many health problems. A survey by the National Childbirth Trust found that women reported not having enough help and information between 11 to 30 days after birth, compared with the first ten days. Accordingly, midwifery led services should provide for the mother and her baby for at least a month after*

birth or discharge from hospital, and up to three months or longer depending on individual need.

The National Service Framework for Wales (Welsh Assembly Government 2005) includes similar recommendations for postnatal care:

- 'Shortly after birth an identified lead professional, normally the named midwife, is responsible for reassessing individual needs and co-ordinating the postnatal care of all babies and women.
- Mothers, babies and their families have access to services in the postnatal period from:
    - A midwife for up to 28 days following birth;
    - A health visitor from 10-14 days following birth
    - Other professionals according to assessed need

Provision and organisation of care

Many of the studies identified included interventions to revise care delivery across the entire antenatal, intrapartum and postnatal episode. This review focuses only on the postnatal outcomes in these studies.

There are two methodological weaknesses which consistently arise when reviewing the literature in this subject area.

- Blinding is frequently not possible due to study design
- The validity of the evaluation tools used to measure outcomes such as maternal satisfaction and mental health is, in many cases, unclear.

Several evaluations of alternative models of midwifery care were undertaken in response to 'Changing Childbirth' (Expert Maternity Group. 1993) and are reviewed in the following narrative. No studies were identified which evaluated reviews of alternative models of care provided by other health care professionals during the postnatal period.

The South East Thames Regional Health Authority (SETRHA) invited bids from providers of maternity services to establish woman-centred care and delivery schemes in midwifery group practices. The Policy Studies Institute was commissioned to evaluate these projects (Allen, Bourke Dowling, & Williams 1997). Using both qualitative and quantitative methods, their report assessed the following areas:

- Comparative costs of the models
- Role clarification of practitioners
- Access to midwives
- Improvement in the continuity of care and availability of choice for women
- Client satisfaction
- Clinical effectiveness including mother and baby morbidity and mortality.

Three different team midwifery models of care were set up in Deptford, Ashford and Lewisham. The teams included 6-7 midwives who carried their own caseloads and provided 24 hour cover for the women in their practices. The research involved three different modes of care delivery: individual caseloading, shared caseloading and traditional community midwifery care. Women reported a high level of satisfaction with the care they received from all three different models of care. This evaluation highlighted several points relevant to postnatal service delivery.

The main aspect of the postnatal care that the women liked was that the midwife was always available when needed. In some cases visits were very frequent, and the 28 day postnatal visit offered by the Deptford midwives was noted to be of great comfort to some women. There was concern about the dependant relationships some women formed with their midwives.

All three teams felt that they achieved a high level of continuity of care and carer. However, as the midwives established trust among themselves, they began to

share care, recognising that continuity of care could be achieved without total continuity of carer.

An early team midwifery pilot was set up in South East England in 1992 (Farquhar, Camilleri, & Todd 2000). Seven teams which each had seven whole time equivalent midwives were established. The midwives cared for women throughout their antenatal, intrapartum and postnatal periods. Farquar et al surveyed women who used the scheme (n=946) and two comparison groups (n=238 and n=120) who received traditional care through community and hospital based midwives. There were no significant differences between groups in terms of the satisfaction with postnatal care and advice received in hospital and after discharge. Eighty one percent of the hospital—based midwives care group reported seeing just one or two midwives postnatally compared to 22% of the team midwives group and 52% of the traditional care by community midwives group. The researchers postulated that because continuity schemes emphasised the intrapartum period, less attention was paid to continuity throughout the postnatal period. They suggest that teams of seven are too large and that the smaller the size of the team the better.

One to one midwifery practice, where one midwife carries main responsibility for the woman's care throughout her pregnancy and postnatal period, was introduced into one London maternity service in 1993. McCourt et al (1998) evaluated women's responses to this style of care. Questionnaires, interviews and focus groups were employed to assess satisfaction. Women in the study group (n=728) received one to one care and women in the control group (n=675) received conventional care. Staffing constraints made it impossible to randomise care. Women in the relevant geographic area were referred to a 'one to one' midwife. Only about half of each group were "very satisfied" with their postnatal care in hospital. There were generally more positive responses to postnatal home care. The main problem identified in the control group was one of receiving inconsistent advice from different midwives visiting on different days. One to one midwives used a more flexible schedule with more selective visits, of longer duration, which could be continued to 28 days after birth if needed. No

clear differences emerged between the groups in postnatal physical health symptoms or in postnatal depression.

An RCT of midwife managed care was carried out in Glasgow by Turnbull et al (Turnbull et al. 1996). Care was provided by a group of 20 midwives who joined the newly formed Midwifery Development Unit (MDU) and compared to routine shared care divided among midwives, hospital doctors and general practitioners. Each pregnant woman randomised to the MDU group had a named midwife whom she met at the first antenatal visit and who aimed to provide the majority of planned episodes of care from booking to discharge to the health visitor. There was no alteration to the content and duration of postnatal care. When the named midwife was unavailable, the woman was cared for by an associate midwife from the MDU team. Clinical data were gathered through a retrospective chart review and satisfaction was measured via self report questionnaires

Six hundred and fifty one women were randomised to shared care and 648 to MDU care. The greatest difference between the groups was in satisfaction with antenatal and hospital based postnatal care, with the MDU group significantly more satisfied with these aspects of their care ($p<0.00001$). Women in the MDU care group also reported greater satisfaction for choice, information, decision making and individualised care ($p<0.00001$).

Additional measures of psychosocial outcomes for this study were presented in a paper by Shields et al (Shields et al. 1997). The major differences between the two groups were found for hospital based postnatal care, which included comfort on the ward, pleasantness of surroundings and discussion of where to get advice upon leaving hospital (all $p<0.00001$). Both groups appeared to rate their care as better at preparing them for practicalities of parenting rather than how to cope with physical and emotional problems. Fifteen percent of the MDU group compared to 22% of the traditional care group exhibited signs of susceptibility to postnatal depression, as assessed using a modified version of the EPDS, in which item 10 which assesses thoughts about self harm was omitted. Women who received MDU care were not more likely to attempt breastfeeding. They were however, more likely to rate the support and advice

they received from staff with their chosen method of feeding as better ($p<0.00001$).

A systematic review published in 1998 evaluated continuity of care during pregnancy childbirth and the puerperium and compared it to usual care by multiple caregivers (Hodnett 1998). Two studies met the inclusion criteria, Flint (1998) from the U.K. and Rowley (1995) from Australia. Both trials compared continuity of care by midwives with non-continuity of care by a combination of obstetricians and midwives. In terms of infant outcomes, there were no differences in Apgar scores, low birth weight, stillbirths and neonatal deaths. Women who received continuity of care were more likely to be pleased with their postpartum experience. They felt able to discuss postnatal problems (OR 0.64, 0.49-0.85) and felt prepared for child care (OR 0.57, 0.41-0.80). The authors concluded that overall (including antenatal and intrapartum factors), these two studies showed beneficial effects of continuity of care but it was not clear whether these were due to greater continuity of care or to midwifery care.

A survey of satisfaction was carried out by Spurgeon et al (2001) to evaluate midwife led care versus traditional care. Two pilot groups of 112 (Group A) and 103 women (Group B) were randomly selected from GP practices within a single NHS Trust's catchment area. The third group of 118 women was selected from the Trust's obstetric unit. In Group A each woman was cared for by one of five named midwives; in Group B each woman was cared for any one of five midwives working together as a team; Group C were referred to hospital for usual obstetrician led care. A questionnaire was developed by the researchers which included details of postnatal care, health care professionals involved in the care, length of stay in hospital, subsequent problems and an evaluation of the care provided. No significant differences in clinical outcomes were observed between the groups. There were significant differences in the number of visits made with fewer visits in Group C compared to Groups A and B ($p<0.001$). Significant differences in satisfaction were found between the groups on all aspects of postnatal care with Groups A and B being more satisfied, a statistically significant finding ($p<0.05$-$p<0.001$).

The researchers also noted that the small team approach showed no reduction in maternal satisfaction levels or other maternal outcome measures. As burn out and stress have been identified as features of one to one midwifery care they suggested that this model might have potential for offsetting this problem while still providing care in keeping with the spirit of 'Changing Childbirth.'

In 2003 some members of this same research team published the results of a pilot project which evaluated satisfaction and clinical outcomes for two groups of women cared for either by a team of 8 midwives or in a traditional model of care (Hicks, Spurgeon, & Barwell 2003). One hundred women were randomly allocated to each arm of the study. The validated questionnaire used by Spurgeon et al (2001) was slightly adapted to assess women's experiences of maternity services. The experimental group were significantly more satisfied with the following aspects of postnatal care:

- Care and sensitivity of staff
- Explanation/consultation
- Contact with midwives
- Not rushed/under pressure
- Own views taken into account
- Consistency of information
- Willingness of midwives to attend to needs.

This model offered continuity of care from a known, small group of midwives rather than continuity of a single carer. The researchers acknowledged previous work which demonstrated that pressures engendered by the single carer model were responsible for extensive burnout and stress noted among participating midwives.

A 'before and after' study was undertaken to compare outcomes of traditional routine care consisting of daily midwifery visits for the first 10 days postpartum

and tailoring of individualised care based on an assessment of maternal need and planning of visits with the woman (Twaddle, Hui, & Fyvie 1993). The evaluation of postnatal women included educational and emotional factors as well as physical and social factors. One hundred and six women received traditional care and 114 women received individualised care. There were no statistically significant differences in the proportion of women reporting common postnatal problems in the two time periods. There was however a significant reduction in the number of women who felt that the midwife should visit every day which fell from 72% to 42%. Continuity of care was also improved with a reduction in the number of different midwives seen ($p<0.005$).

A protocol-based midwifery-led model of postpartum care was developed, implemented and evaluated in a cluster randomised controlled trial by MacArthur et al (2003). This study aimed to tailor care based on an individual woman's needs, with a focus on the identification and management of common maternal physical and psychological health problems. Care of the infant was not revised. The effectiveness and cost of the new model of care was compared with current care. Thirty-six general practices were randomly selected from the West Midlands, and care delivered by the attached midwives; 2064 women were recruited, 1087 in the intervention group and 977 in the control group.

The midwives working in practices allocated to the intervention model of care planned visits based on the individual woman's needs from the first postnatal home contact. The duration of midwifery visits was extended to 28 days rather than 10 – 14 days, which was the current model of care. A visit was to occur only if the midwife or woman considered it to be necessary, and there was no routine GP contact. The midwives made a final visit at 10 – 12 weeks, which replaced the GP 6 – 8 week check, with the aim of giving women more time to consider their own health needs. The intervention model midwives undertook systematic identification of health problems using a symptom checklist on days 10 and 28 and at 10 – 12 weeks. The Edinburgh Postnatal Depression Scale (EPDS) was administered on day 28 and at the 10 – 12 week visit. Evidence based guidelines developed by the study team were used to manage identified health concerns, and included information on when referral to another health

care professional should be made. Women's health at 4 and 12 months was assessed using the Physical and Mental Health Component Scores of the SF-36 and the EPDS.

There was no significant difference in physical health scores. The mental health component of the SF-36 and the EPDS at 4 and 12 months were significantly better in the intervention group (Regression coefficient at 4 months 3.03 [1.53-4.52], $p<0.00007$; at 12 months 2.74 [1.48-4.0], $p<0.00002$).

The study also looked at the cost-effectiveness of the new model of midwifery-led care relative to current practice. The assessment produced a thorough costing analysis from the perspective of the NHS. It was reported that costs were lower in the intervention group (if statistically insignificant). However, this result was unclear from the underlying data.

The approach used by the authors was to average the clusters rather than the mothers. The cluster averages in the intervention group are relatively close to each other (range £305.64-£653.40). Thus, the cluster average is within £11 of the average across all intervention mothers.

The proximity of the two averages to each other is not replicated in the control group. The main reason is that there is a cluster which can be considered a major outlier, covering just one mother. Using a cluster average approach, this one result takes on a weighting equivalent to that of the larger clusters. However, if the costs are weighted to reflect the size of the clusters, there is a small increase in costs of £31 in the intervention group. The choice of average will depend on whether the cause of the outlier can be ascertained. If it is a result of a tendency in a group of mothers represented by that one case to have higher costs under the control, the cluster average is preferable. It is however uncertain whether this will affect the major conclusions of the assessment regarding cost-effectiveness of the intervention relative to the control.

In the paper, a sensitivity analysis was undertaken on the conclusion, allowing for the uncertainty surrounding under-recording in control group midwives. The report found that the relative cost of the intervention compared to the control varies marginally around zero (they suggest between £82 more and £78 less).

The Scottish study by Turnbull et al looked at the cost implications of routine shared care divided among midwives, hospital doctors and general practitioners relative to midwife-led care (Turnbull 1996). Using an assumption of a 29-mother caseload per midwife per annum, the shared care approach led to a statistically significant reduction in costs (£352.03 versus £470.34, $p<0.01$) in the postnatal period.

The largest caseload in the study was 39 so the authors assessed the average costs if each midwife could take this workload. Under this assumption, the postnatal costs of the two approaches converged to some extent although remained statistically significant (£352.03 versus £404.17, $p<0.01$).

Postnatal Care Centres

There is no mention in the literature of postnatal care centres in the United Kingdom. However, this alternative delivery system has been trialed in the United States where economic pressures to reduce health care costs have resulted in shortened hospital stays in all specialties, including maternity care. In many places women are leaving the hospital within 24 hours of a vaginal delivery and within 2-3 days of caesarean section. Traditionally, there has been no postpartum follow up of new mothers in the U.S. until the six week postpartum check. However, in response to increased need for additional care due to early hospital discharge, several innovative models of care have been developed.

One such model was begun in February 1991 in a community district hospital in the northwestern United States (Keppler 1995). This programme featured a Postpartum Care Centre (PCC) and a telephone follow up programme which provided early postpartum assessment and support to mothers, infants and their families for one third the cost of a home visit. Although the report of this model is essentially a case study, without experimental design or comparison group, there are some interesting findings. The PCC was nurse led and located on the hospital campus adjacent to the Family Maternity Centre. Within three years of beginning operation 1944 (81%) of all women giving birth at the affiliated hospital (2400 births per year) were seen in the PCC within eight days of delivery. The

remainder received a postpartum follow up telephone call. The average age of infants at first visit to the PCC was 4.1 days. During the first three years of operation four mothers were readmitted from the PCC, one for mastitis, two for endometritis and one for a bowel obstruction. Breast engorgement, sore nipples, postnatal anxiety and depression, mastitis, wound dehiscence and infection and urinary tract infections were treated on an outpatient basis (numbers not provided). Between1991-1994 twelve infants were readmitted, four for hyperbilirubinemia, three to rule out sepsis and five for significant weight loss and dehydration. Feeding difficulty, inadequate weight gain, hyperbilirubinemia, conjunctivitis and rashes were the most common infant problems detected and treated at the PCC.

In 1992 a formal telephone survey was conducted by an independent research group to assess patient satisfaction with the PCC programme. One hundred and eight patients were randomly selected from the list of women seen in the previous three months. All 188 respondents had positive comments. The only criticisms were that 12 women thought the clinic was difficult to find, 4 wished the visit had been longer.

A before and after study was conducted by Lieu et al in a California medical centre (Lieu et al. 1998). A comparison of cohorts in which women were discharged at 48 hours or less was made. In the pre-intervention study women received education on routine newborn care during their postnatal inpatient stay. Home visits at 2-3 days postnatal were provided only to first time breastfeeding mothers. In the revised model a new 2 hour class on infant care was held antenatally, at 34 weeks gestation. A postnatal care centre staffed by paediatric nurse practitioners was established and a follow up visit recommended for all women and their babies discharged at <24 hours, or those breastfeeding who were discharged at <36 hours or any breastfeeding teenagers. Babies who needed blood tests were also scheduled at the clinic. Telephone interviews were attempted with all women at 3 weeks after the birth. Data on clinical outcomes during the first 14 postnatal days were collected from computerized databases and chart review. There were no significant group differences in maternal readmissions, attendance at accident and emergency departments (A & E) or

urgent clinic visits or infant attendance at A & E departments or readmissions. Women in the revised care group were significantly more satisfied with information giving and infant care ($p<0.01$).

An RCT conducted by the same research group evaluated home visits by nurses within 48 hours post discharge versus paediatric clinic visits by nurse practitioners or physicians on the third or fourth postnatal day (Lieu et al. 2000). There were 1,163 women randomized to either home health visits or clinic visits. Outcome measures included rehospitalization rates, emergency department visits, and urgent clinic visits by the woman or infant during the 10 days after delivery. A two week interview provided information on breastfeeding discontinuation and maternal depressive symptoms (measurement method not identified). No significant differences occurred between the groups in any clinical outcomes. Satisfaction with all aspects of care were rated as significantly higher among the home visit women when compared to those who attended clinic ($p<0.001$). Costs for home visits were more than twice as high as the clinic visits.

A Canadian research team investigated differences in breastfeeding frequency, infant weight gain, maternal anxiety and satisfaction with services for women discharged within 36 hours postpartum from an urban, university hospital (Gagnon et al. 1997). Participants received either community nurse home visit follow-up or hospital nurse clinic follow-up. Five hundred and eighty six women were randomised into this trial. The experimental group (n=292) received a home visit at 3,5 and 10 days postpartum to coincide with peak bilirubin levels in breastfed infants and other physical and psychosocial needs of newborns and mothers. Nurse contacts continued when community follow-up was judged to be required. The control group received usual care which included a 48 hour postpartum telephone contact and a day 3 postpartum hospital visit. Clinic contacts lasted a maximum of 45 minutes during which time a standardized plan of care was provided. There were no statistically significant differences between the two groups in breastfeeding frequency, infant weight gain, maternal anxiety, health service satisfaction and health and community services use.

Home Visit Programmes

A systematic review was conducted by the Ontario Public Health Research Education & Development Program (Ciliska et al. 1999) to evaluate the evidence for home visiting as a programme delivery strategy compared with clinic or telephone services for pregnant and postnatal women. Twelve studies were assessed, 2 antenatal, 6 postnatal and four included interventions for both periods. A meta analysis was not conducted. There were no reported negative effects of home visiting. Outcomes included infant behaviour, safety and maternal depression. The most effective interventions were as follows:

Those which involved multiple community agencies and primary care services
Those which were more intensive, with weekly home visits
Those which targeted women at risk due to social disadvantage.

An American study compared a hospital based postpartum programme with home visiting (Escobar et al. 2001). A largely middle class low risk population was randomised to the intervention of a home visit within 48 hours of discharge from the hospital (n=508) versus a standard package of care which included group visits to a hospital based clinic (n=506), focused primarily on infant care and breastfeeding problems. Telephone interviews at two weeks post discharge showed that there were no significant differences in newborn or maternal hospitalizations or urgent care visits, breastfeeding discontinuation, maternal depressive symptoms (measurement tool not described). However, the group visits were more cost effective.

An RCT was carried out in the London boroughs of Camden and Islington and examined whether increased postnatal support could affect maternal and child health outcomes (Wiggins et al. 2004). There were three allocation groups. In one group Health Visitors offered monthly home visits for one year. The focus of the visits was on listening to women and exploring any issues they wanted to discuss. In the second group community support was offered from one of eight local community groups that provided services to postnatal women. Routine NHS health visiting services were available to women in the control group (group three) and both intervention arms. Outcome data were collected through

questionnaires at 12 and 18 months and had response rates of 90% and 82% respectively. The primary outcome measures were child injury, maternal smoking and maternal psychological well being. Child injury and maternal smoking were assessed by maternal report and depression was measured at 12 months by the EPDS and at 18 months by the General Health Questionnaire. At both follow up points there were no significant differences for any of the primary outcomes. Uptake of the community group intervention was low: 19% compared with 94% for the health visitor support program.

The authors included cost data which was used in an economic evaluation of the interventions. On the cost side, there was no statistically significant difference between standard care and either intervention at 12 months. This result remains constant if costs are subdivided into hospital costs and primary care costs, and when looking into different elements of cost to the woman (which is outside the NICE remit). This pattern was largely replicated at 18 months although the mean total healthcare spending in the community group support wing was £26 higher (95% C.I. £0 to £63). However, the pattern of resource use was different in the group receiving the support health visitor in that they made fewer visits to the GP and to the hospital and instigated more contact with health visitors. Overall, the cost implication of this was negligible but this result may be of use if there is a benefit to transferring contact between the health visitor and the G.P.

On the benefit side, there was no evidence to suggest an improvement in the main outcome measures as a result of either intervention relative to standard care. There were some limited data to suggest a less anxious experience of motherhood.

The authors performed sensitivity analysis on the conclusions of the investigation, based around the costing assumptions. Using the non-parametric bootstrapping technique, the cost differences between either of the interventions and the control remained statistically insignificant at the 5% level, other than the support health visitor approach becoming relatively more expensive when the assumption of constant monthly costs was relaxed.

A Canadian study evaluated the outcomes of routine home visiting by public health nurses after early hospital discharge (2 days) versus making a screening telephone call designed to identify mothers who needed further intervention (Steel O'Connor et al. 2003). Low risk primiparous women were recruited from two sites for this study. Three hundred and sixty women were allocated to the telephone screen intervention and received one telephone call on the first working day following discharge. Three hundred and thirty six women received two home visits by a public health nurse. Outcome measures included maternal confidence at two weeks as measured by the Maternal Confidence Scale (Carty and Bradley 1990); health problems of the infants between discharge and four weeks by maternal report (verified by medical records for 250 women); breastfeeding rates at six months by maternal report; and the costs of the two models. No differences were detected between the groups in maternal confidence, health problems of infants or rates of breastfeeding at six months. Approximately one third of women in the home visit group refused a visit. There was no discussion of failure to reach women by telephone or a plan for reaching women who did not speak English.

Healthcare resource usage was recorded and contrasted with clinical outcomes. The authors summed routine and unscheduled visits to family physicians and other health professionals, emergency department visits, hospital admissions, laboratory tests, public health nurse contacts, costs to parents[1] and medication. The telephone screening infants incurred $15 265 per 100 infants while the figure for the home visit group incurred $24 338 per 100 infants. Thus, the telephone screening method seemed to offer comparable clinical outcomes and prevented around $9 expenditure per 100 infants.

Community Support Programmes

[1] This category of costs falls outside the NICE reference case. The difference between the two groups in this category is that the parents of home-visited infants spend approximately $3 more per infant.

The roles of social support in the postnatal period were investigated in Scotland by Reid et al (2002). The study tested three interventions, a self help manual; an invitation to attend a support group; and reciept of both the manual and invitation, which were sent to women in each group at two weeks postpartum. Outcomes were compared with a control group of women who only received routine postnatal care. Outcome measures included the EPDS to screen for those at risk of postnatal depression, the SF-36 which rates mental and physical wellbeing and the SSQ6, a well validated measure of social support.

One thousand and four women were recruited and allocated to one of the four study groups. Eighty three percent of women completed a baseline questionnaire, 73% returned a three month questionnaire and 71% returned a six month questionnaire. The trial did not demonstrate any effect of either intervention on psychological, physical or social wellbeing. The low take up rate for the support group intervention (18%) reduced the likelihood of finding an effect.

Morrell et al (2000a) evaluated the costs and benefits of community postnatal support workers. This intervention aimed to test the effect of providing women with additional postnatal support at home through the introduction of a support worker (maternity aide) during the first 28 days after birth for up to 3 hours per day. The support workers were non-professionals who received an eight week training course. Women were not eligible for study recruitment if they could not give informed consent, communicate in English or had a baby admitted to a special care unit for more than 48 hours. Women randomised to the intervention (n=311) or control (n=312) were asked to complete a questionnaire at 6 weeks postpartum, which had an 88.4% response rate. Outcome measures included the SF-36, EPDS and the DUFSS social support scale and the EQ-5D health related quality of life scale. The controls had significantly better physical function, social function and self perceived health status than the intervention group. There was some evidence of lower mean EPDS scores in the control group. There was no difference in mean DUFSS scores or in breastfeeding rates. Women had a high level of satisfaction with the support worker service.

On the costs side, there was no significant mean difference between control and intervention in any area of expense other than the cost of the support worker. Thus, the quantity and cost of visits by community midwives, health visitors, child health care clinics, GP contacts or prescriptions for mothers or babies, hospital contacts and secondary mental health contacts were not significantly different between control and intervention. The only difference was the cost of the support worker leading to a statistically significant mean difference in total costs of £179.58 (p=0.001).

A community based mothers' programme was evaluated in an RCT in Dublin (Johnson, Howell, & Molloy 1993). Two hundred and eighty first time mothers from a deprived area were identified. All women received standard public health nursing support. One hundred and twenty seven women were randomly assigned to receive an additional programme which used experienced volunteer mothers to give support and encouragement to first time parents. A child development programme was implemented which consisted of modules on educational development, language development and cognitive development. The essential feature of this programme was empowerment of the parents. Visits were scheduled monthly for the first year. At the end of the study the children in the intervention group were more likely to have received all of their primary immunisations (RR 1.31, 1.12-1.54; p<0.001), to have played more cognitive games (difference between means 2.13, CI 1.65-2.60) and to know more nursery rhymes (difference between means 4.24, CI 3.59-4.88). They were less likely to start drinking cows' milk before 26 weeks and to receive an appropriate energy intake and appropriate amounts of animal protein, non-animal protein, whole foods and vegetables, fruit and milk (p<0.01). Women randomised to receive the additional programme also had a better diet than controls (p<0.01), were less likely to be tired (p<0.01), feel miserable (p<0.003) and want to stay indoors (p<0001).

The researchers concluded that non professionals can deliver a health promotion programme on child development effectively. Whether they can do so as effectively as professionals requires further study.

4.8 What is the optimal number of postnatal contacts for the best outcomes? What needs to be done at what time?

In 2004, there were 639,721 live births in England and Wales. As a result, any modifications to service delivery designed to alter current practice towards the planning and delivery of care in line with government policy will have significant cost-effectiveness consequences. Therefore, the postnatal care Guideline Development Group (GDG) were presented with an example of a care pathway which included all potential healthcare professional contacts a healthy woman and her infant may receive during the postnatal period, either based on clinical judgement, to undertake routine screening or requested by the woman, the cost implications for the health care professional making the contact, and competency required to undertake the contact.

Potential postnatal contacts are indicated on the care pathway (See section 2.7). Some contacts will be made to comply with components of the National Screening Programmes, however other contacts will be based on evidence-based recommendations for maintaining and promoting good maternal and infant health, individual need as determined by the attending health care professional or requested by the woman, and as such are not included on the pathway. Other areas have been specified as definite contacts but their method of delivery has not.

Time and financial costs of visits

In Table 4-1 the financial costs are based on NHS Reference Costs (Curtis & Netten 2004). These include qualification costs, direct and indirect costs, thus representing average cost. The length of contact has been approximately equalized.

Table 4-1 Time and financial costs of visits

Contact type	Contact HCP	Location	Time spent	Financial cost (including travel costs)
General home contact	Midwife / Health visitor	Home	20 minutes	£31
	Health care Assistant	Home	20 minutes	£7
	GP	Home	13.2 minutes	£65
Initial physical examination / Newborn Blood Spot Screening	Midwife / Health visitor	Home	30 minutes	£40.20
Telephone contact	Midwife / health visitor	N/A	15 minutes	£15.50
	GP	N/A	16.2 minutes	£39
Clinic contact	Midwife / Health visitor	Clinic	20 minutes	£20.67
	GP	Clinic	18.9 minutes	£42

In the construction of the individualised careplan for each mother and baby in the postnatal period, it is important to consider not only clinical judgement but also the cost implications for the health care professional making the contact, and competency required to undertake the contact.

5 Maintaining Maternal Health

5.1 Recommendations

General advice

1 At the first postnatal contact, women should be advised of the signs and symptoms of potentially life-threatening conditions (given in Table 5-1 below) and to contact their healthcare professional immediately or call for emergency help if any signs and symptoms occur.

Table 5-1 Signs and symptoms of potentially life threatening conditions

Signs and symptoms	Condition
Sudden and profuse blood loss or persistent increased blood loss Faintness, dizziness or palpitations/tachycardia	Postpartum haemorrhage
Fever, shivering, abdominal pain and/or offensive vaginal loss	Infection
Headaches accompanied by one or more of the following symptoms within the first 72 hours after birth: • visual disturbances • nausea, vomiting	Pre-eclampsia/eclampsia
Unilateral calf pain, redness or swelling Shortness of breath or chest pain	Thromboembolism

- [C]

2 The Department of Health booklet *Birth to Five* (2005), which is a guide to parenthood and the first 5 years of a child's life, should be given to all women within 3 days of birth (if it has not been received antenatally). **[GPP]**

3 The personal child health record should be given to all women as soon as possible (if it has not been received antenatally) and its use explained. **[GPP]**

4 Women should be offered information and reassurance on:

- the physiological process of recovery after birth (within the first 24 hours)
- normal patterns of emotional changes in the postnatal period and that these usually resolve within 10–14 days of giving birth (within 3 days)
- common health concerns as appropriate **[GPP]**

Life threatening conditions: core care and raised concern

Postpartum haemorrhage

5 In the absence of abnormal vaginal loss, assessment of the uterus by abdominal palpation or measurement as a routine observation is unnecessary. **[B]**

6 Assessment of vaginal loss and uterine involution and position should be undertaken if a woman has excessive or offensive vaginal loss, abdominal tenderness or fever. Any abnormalities in the size, tone and position of the uterus should be evaluated. If no uterine abnormality is found, consider other causes of symptoms (urgent action). **[D(GPP)]**

7 Sudden or profuse blood loss or loss accompanied by any of the signs

and symptoms of shock, including tachycardia, hypotension, hypoperfusion and change in consciousness should be evaluated (emergency action). **[D(GPP)]**

Genital tract sepsis

8 In the absence of any signs and symptoms of infection, routine assessment of maternal temperature is unnecessary. **[D(GPP)]**

9 Temperature should be taken and documented if infection is suspected. If the temperature is above 38°C, repeat measurement in 4–6 hours. **[D(GPP)]**

10 If the temperature remains above 38°C on the second reading or there are other observable symptoms and measurable signs of sepsis, evaluate further (emergency action). **[D(GPP)]**

Pre-eclampsia/eclampsia

11 A minimum of one blood pressure measurement should be carried out and documented within 6 hours of the birth **[D(GPP)]**

12 Routine assessment of proteinuria is not recommended. **[D(GPP)]**

13 Women with severe or persistent headache should be evaluated and pre-eclampsia considered (emergency action). **[A]**

14 If diastolic blood pressure is greater than 90 mm Hg, and there are no other signs and symptoms of pre-eclampsia, the measurement of blood pressure should be repeated within 4 hours. **[D(GPP)]**

15 If diastolic BP is greater than 90 mm Hg and accompanied by another sign or symptom of pre-eclampsia, evaluate further (emergency action). **[A]**

16 If diastolic BP is greater than 90 mm Hg and does not fall below 90 mm Hg within 4 hours, evaluate for pre-eclampsia (emergency action). **[A]**

Thromboembolism

17 Women should be encouraged to mobilise as soon as appropriate following the birth. **[D(GPP)]**

18 Women with unilateral calf pain, redness or swelling should be evaluated for deep venous thrombosis (emergency action). **[D(GPP)]**

19 Women experiencing shortness of breath or chest pain should be evaluated for pulmonary thromboembolism (emergency action). **[D(GPP)]**

20 Routine use of Homan's sign as a tool for evaluation of thromboembolism is not recommended. **[C]**

21 Obese women are at higher risk of thromboemolism and should receive individualised care. **[GPP]**

Mental health and well-being

22 At each postpartum contact, women should be asked about their emotional well-being, what family and social support they have and their usual coping strategies for dealing with day to day matters. Women and their families/partners should be encouraged to tell their healthcare professional about any changes in mood, emotional state and behaviour that are outside of the woman's normal pattern. **[D(GPP)]**

23 Formal debriefing of the birth experience is not recommended. **[A]**

24 All health care professionals should be aware of signs and symptoms

of maternal mental health problems which may be experienced in the weeks and months after the birth **[D (GPP)]**

25 At 10–14 days after birth, all women should be asked about resolution of symptoms of baby blues (for example, tearfulness, feelings of anxiety and low mood). If symptoms have not resolved, the woman should be assessed for postnatal depression, and if symptoms persist, further evaluated (urgent action; refer to Antenatal and Postnatal Mental Health Guideline, in development). **[D(GPP)]**

26 Women should be encouraged to help look after their mental health by looking after themselves. This includes taking gentle exercise, taking time to rest, getting help with caring for the baby, talking to someone about their feelings and ensuring they can access social support networks. **[D(GPP)]**

Physical health and well-being

Perineal care

27 At each postpartum contact women should be asked whether they have any concerns about the healing process of any perineal wound; this might include experience of perineal pain, discomfort or stinging, offensive odour or dyspareunia **[D(GPP)]**

28 The healthcare professional should offer to assess the woman's perineum if the woman has pain or discomfort. **[D(GPP)]**

29 Women should be advised that topical cold therapy for example, crushed ice or gel pads are effective methods of pain relief for perineal pain. **[A]**

30 If oral analgesia is required, paracetamol should be used in the first instance unless contraindicated. **[A]**

31 If cold therapy or paracetamol is not effective a prescription for oral or rectal non-steroidal anti-inflammatory (NSAID) medication should be considered in the absence of any contraindications (non-urgent action). **[A]**

32 Signs and symptoms of infection, inadequate repair, wound breakdown or non-healing should be evaluated (urgent action). **[D(GPP)]**

33 Women should be advised of importance of perineal hygiene, including frequent changing of sanitary pads, washing hands before and after doing this, and daily bathing or showering to keep their perineum clean. **[D(GPP)]**

Dyspareunia

34 Women should be asked about resumption of sexual intercourse and possible dyspareunia 2-6 weeks after birth. **[C]**

35 If a woman expresses anxiety about resuming intercourse, reasons for this should be explored. **[D(GPP)]**

36 Women with perineal trauma who experience dyspareunia should be offered an assessment of the perineum. (See perineal care section) **[D(GPP)]**

37 A water based lubricant gel to help to ease discomfort during intercourse may be advised, particularly if a woman is breastfeeding. **[D(GPP)]**

38 Women who continue to express anxiety about sexual health problems should be evaluated (non-urgent action). **[D(GPP)]**

Headache

For severe headache see section on pre-eclampsia/eclampsia

39 Women should be asked about headache symptoms at each postpartum contact. **[C]**

40 Women who have had epidural or spinal anaesthesia should be advised to report any severe headache, particularly one which occurs while sitting or standing. **[C]**

41 Management of mild postnatal headache should be based on differential diagnosis of headache type and local treatment protocols. **[D(GPP)]**

42 Women with tension or migraine headaches should be offered advice on relaxation and how to avoid factors associated with the onset of headaches. **[D(GPP)]**

Fatigue

43 Women who report persistent fatigue should be asked about their general well-being, and offered advice on diet, exercise and planning activities, including spending time with her baby. **[D(GPP)]**

44 If persistent postnatal fatigue impacts on the woman's care of herself or baby, underlying physical, psychological or social causes should be evaluated **[D(GPP)]**

45 If a woman has sustained a postpartum haemorrhage, or is experiencing persistent fatigue, her haemoglobin level should be evaluated and if low, treated according to local policy. **[D(GPP)]**

Backache

46 Women experiencing backache postnatally should be managed as in the general population. **[D(GPP)]**

Constipation

47 Women should be asked if they have opened their bowels within three days of the birth. **[D(GPP)]**

48 Women who are constipated and uncomfortable should have their diet and fluid intake assessed and offered advice on how to improve their diet. **[D(GPP)]**

49 A gentle laxative may be recommended if dietary measures are not effective. **[A]**

Haemorrhoids

50 Women with haemorrhoids should be advised to take dietary measures to avoid constipation and should be offered management based on local treatment protocols. **[D(GPP)]**

51 Women with a severe, swollen or prolapsed haemorrhoid or any rectal bleeding, this should be evaluated. (Urgent action). **[D(GPP)]**

Faecal incontinence

52 Women with faecal incontinence should be assessed for severity, duration and frequency of symptoms. If symptoms do not resolve, evaluate further (urgent action).**[D(GPP)]**

Urinary retention

53 Urine passed within 6 hours of urination during labour should be documented. **[D(GPP)]**

54 If urine has not been passed within 6 hours after the birth, efforts to assist urination should be advised, such as taking a warm bath or shower.

[D(GPP)]

55 If urine has not been passed by 6 hours after the birth and measures to encourage micturition are not immediately successful, bladder volume should be assessed and catheterisation considered (urgent action). **[D(GPP)]**

Urinary incontinence

56 Women with some involuntary leakage of a small volume of urine should be taught to do pelvic floor exercises. **[A]**

57 Women with involuntary leakage of urine which does not resolve or becomes worse should be evaluated. **[D(GPP)]**

Contraception

58 Methods and timing of resumption of contraception should be discussed within the first week of the birth. **[D(GPP)]**

59 The coordinating healthcare professional should provide proactive assistance to women who may have difficulty accessing contraceptive care. This includes providing contact details for expert contraceptive advice. **[D(GPP)]**

Immunisation

60 Anti-D immunoglobulin should be offered to every non-sensitised Rh-D negative woman within 72 hours following the delivery of a RhD-positive baby. **[D(GPP)]**

61 Women found to be sero-negative on antenatal screening for rubella should be offered an MMR (measles, mumps rubella) vaccination following birth and before discharge from the maternity unit if they are in hospital. **[D(GPP)]**

62 MMR vaccine may be given in the postpartum period with anti-D (Rh_0) immunoglobulin injection provided that separate syringes are used and the products are administered into different limbs... If not given simultaneously, MMR should be given 3 months after anti-Rho (D) **[D(GPP)]**'

63 Women should be advised that pregnancy should be avoided for one month after receiving MMR, but that breastfeeding may continue. **[D(GPP)]**

Safety

Domestic abuse

64 Healthcare professionals should be aware of the risks, signs and symptoms of domestic abuse and know who to contact for advice and management, following guidance from the Department of Health. **[D(GPP)]**

6-8 week check

65 At the end of the postnatal period, the coordinating healthcare professional should ensure that the woman's physical, emotional and social well-being is reviewed. Screening and medical history should also be taken into account. **[D(GPP)]**

Table 5-1

Maternal health and wellbeing core information and advice

All women should be offered information about their own health and well-being

Time Band 1: First 24 hours
Women should be offered information on: The physiological process of recovery after birth, and that some health problems are common. **[C]**
Women should be advised to immediately report to a healthcare professional: • signs and symptoms of potentially life threatening conditions (see Recommendation 1.2.1) **[C]** • If they have not passed urine within 6 hours of birth. **[C]**
Time Band 2: 2–7 days (add hours to match pathway)
Women should be offered information and reassurance on: • normal patterns of emotional changes in the postnatal period and that these usually resolve within 10–14 days of giving birth (This information should be offered by the third day) **[B]** • perineal hygiene **[D(GPP)]** • contraceptive use which should be commenced by 3 weeks post partum **[D]** • male and female condoms – which may be used at any time after delivery **[D]** • location and contact details for expert contraceptive advice, which may be from their general practitioner or from a family planning clinic **[D(GPP)]** • tiredness – which is a normal consequence of new parenthood **[D(GPP)]** • haemorrhoids – which are common in the postnatal period **[D(GPP)]** • involuntary leakage of a small volume of urine – which is commonly experienced after birth **[C]**

• Importance of appropriate diet, including high fibre foods, and adequate intake of water. **[A]**
Women should be advised to report to their healthcare professional: • any changes in mood and emotional state outside of their normal pattern (seek information from families/partners if appropriate) **[D(GPP)]** • itching or bleeding around the anus **[D(GPP]** • Faecal urgency or frank faecal incontinence. **[C]**
Time band 3: Weeks 2–8 (Day 8 onward)
All women should be offered information that: • penetrative sex may be uncomfortable at first **[D(GPP)]** All women should be advised to report to a healthcare professional: • Any vaginal loss that does not stop by the sixth week after birth. **[D(GPP)]** • if pain persists with intercourse **[D(GPP)]** • Severe or persistent backache which is limiting daily activities. **[D(GPP)]** All women should be offered a six - eight week review which focuses on their physical and mental health and well-being. **[D(GPP)]**

5.2 Evidence Statements for Maternal Health

Note: The title of each section is linked to the relevant narrative for ease of use

Major Physical Morbidities

Postpartum Haemorrhage

Core Care

1 Primary and secondary PPH are excessive vaginal blood loss [Level 2+, 1^0 PPH; Level 4, 2^0 PPH].

2 The amount of vaginal loss is highly variable in individual women and the measurement of loss is imprecise. [Level 2+]

3 If a woman's post birth profile is normal (i.e. the uterus is well contracted, and the placenta and membranes appeared to be intact, and there is no previous history of PPH) primary postpartum haemorrhage is rare. [Level 3]

4 There is no evidence to support the routine measurement of fundal height.

5 There is no evidence to support how often uterine assessment should be undertaken.

Raised concern

6 PPH may be accompanied by other clinical signs and symptoms depending on the amount of blood loss:

- Palpitations
- Dizziness
- Tachycardia
- Weakness
- Sweating
- Restlessness
- Pallor
- Collapse [Level 3]

Action/Referral

7 The evidence does not identify an accurate method to measure vaginal loss.

8 The evidence does not identify referral pathways for PPH but in life threatening situations procedures for immediate action are available in local emergency guidelines. [Level 4]

9 Descriptive studies have identified methods for assessment of vaginal loss by women and professionals. These methods include visual assessment of colour of vaginal loss, size of blood clots, and estimate of absorption on sanitary pads. [Level 3]

10 There is no reliable evidence that uterine assessment alone is of value, but it can be used to discount or confirm morbidity in combination with other symptoms a woman may experience, which may include abnormal vaginal loss, fever or abdominal tenderness. [Level 2+]

11 Assessment of the uterus has several components, including measurement from the top of the fundus to the top of the symphysis pubis, tone, central uterine location and uterine sensation or tenderness. [Level 4]

Genital tract sepsis

Core Care

12 Sepsis may be suspected in the presence of two or more of these signs and symptoms:

- Fever >38.5^0 C on one occasion or fever of 38^0 C taken 4 hours apart

- Chills
- Abdominal tenderness and no other recognized source of infection
- Uterine sub-involution
- Offensive and/or heavy lochia
- Tachycardia [Level 4]

Raised Concern

13 Fever >38.5^0 C on one occasion or fever of 38^0 C, taken 4-6 hours after initial reading is a sign of sepsis. [Level 4]

Action/Referral

14 If a woman has an elevated temperature of 38^0 C, expert opinion suggests that readings should be repeated between 4-6 hours. [Level 4]

Pre-eclampsia and eclampsia

Raised Concern

15 Neurological symptoms of pre-eclampsia including cortical blindness, headache, scotoma and malaise as well as nausea and vomiting unrelated to other causes, are more prevalent in the postnatal periods. [Level 2+]

16 The evidence does not describe accurate non-invasive measurement techniques for proteinuria in the postnatal woman.

17 According to the NICE Antenatal Care Guideline and the RCOG Pre-eclampsia Community Guideline the diagnostic criteria for blood

pressure is a diastolic blood pressure threshold of 90 mm Hg. [Level 1++]

18 No studies were identified which evaluated the frequency with which blood pressure should be taken or repeated.

Action/Referral

19 The RCOG Pre-eclampsia Study Group Recommendations (Royal College of Obstetricians and Gynaecologists 2003) state that all
20 pregnant women with a blood pressure greater than 140/90 mm Hg with or without proteinuria should be referred for further investigation. (Referral Level 2). [Level1++]

Thrombosis

21 Thromboembolism is the leading cause of direct maternal mortality. Fifty

Percent of women who died of thromboembolism were obese. [Level 3]

22 Signs and symptoms of DVT are: unilateral leg pain/discomfort (especially

left leg), swelling, tenderness; [Level 2++ for left leg evidence; Level 4

Remainder of evidence].

23 Signs and symptoms of PTE are: dyspnoea, collapse, chest pain,

haemoptysis, faintness, raised jugular vein pressure, focal signs in

Chest and symptoms associated with DVT. [Level 3 & 4]

Mental Health and Well being

24 There is variation in definition of postnatal blues. [Level 2+]

25 Depending on the definition, postnatal blues peak on day 5 thereafter resolving by day 10-14. [Level 2+]

26 The International Childbirth Education Association Position Statement and Review of Postpartum Emotional Disorders (2003) suggests that postnatal blues can be improved by a new mother using good self care techniques and making use of support systems. [Level 4]

27 Experts suggest that women with postnatal blues should be encouraged to seek further evaluation if symptoms persist beyond 7-10 days or 2 weeks. [Level 4].

28 Individual risk factors associated with postnatal depression include previous history of depression, a lack of social support and a poor partner relationship. [Level 1++]

29 A single session debriefing intervention does not appear to reduce postpartum psychological morbidity. [Level 1+]

30 No studies have assessed PTSD debriefing after traumatic birth for subsequent PTSD symptomatology [Level 2++].

31 The main risk factor for puerperal psychosis is previous psychotic illness [Level 1+]

Physical Health and Well being

32 Many common health problems after delivery are unreported to health care professionals by women and are not identified by healthcare professionals during routine postnatal care. [Level 3]

Perineal Care

33 The degree of perineal pain experienced is a subjective assessment, made by the woman herself. [Level 4]

34 Controlled trials of topical therapy show that cold therapy provides short term pain relief and does not delay healing. [Level 1+]

35 Randomised controlled trials of oral analgesia for perineal pain show that paracetamol and non-steroidal anti-inflammatories are as effective as oral narcotic medications in the treatment of perineal pain. [Level 1+]

36 Non steroidal anti-inflammatories given rectally are associated with less discomfort up to 24 hours after birth than placebo. [Level 1++]

Dyspareunia

37 Women may feel uncomfortable introducing the subject of dyspareunia at health care visits. [Level 3]

Headache

38 Women are more likely to report headache symptoms following discharge from the postnatal ward [Level 3]

39 Postdural puncture headache may occur following the administration of an epidural or spinal anaesthesia. [Level 1++]

Fatigue

40 There is no robust evidence about treatment of fatigue in the postnatal period.

Backache

41 Backache is a common postnatal problem, which may affect up to

half of all women. [Level 3]

42 Evidence of an association with postpartum backache and use of epidural analgesia is weak. [Level 2]

43 There is no evidence to support management of postnatal backache. Evidence to support the most effective management of backache in the general population is inconclusive. [Level 3]

Constipation

44 Dietary supplements of fibre in the form of bran or wheat fibre are likely to help women experiencing constipation in pregnancy. [Level 1++]

45 If constipation in pregnancy fails to resolve, stimulant laxatives are likely to prove more effective. [Level 1++]

Faecal Incontinence

46 Instrumental delivery is a risk factor for faecal incontinence (incontinence of faeces or flatus) and occult anal sphincter defects [Level 2]

47 Women with anal sphincter defects may remain symptom free. [Level 2]

48 Many women experiencing faecal incontinence do not report it. [Level 4]

Urinary Retention

49 Management principles for urinary retention based on research evidence were not identified.

Urinary Incontinence

50 Vaginal delivery and forceps assisted deliveries are risk factors for urinary incontinence [Level 2] ? delete – don't refer to risk factors in narrative

51 Experts define three categories of urinary incontinence:

a. Stress incontinence: the involuntary leakage on effort or exertion or on sneezing or coughing

b. Urge incontinence: the complaint of involuntary leakage accompanied by or immediately preceded by urgency

c. Mixed incontinence: the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing. [Level 4]

52 Evidence of the benefit of pelvic floor exercise for prevention is equivocal. [Level 1++]

53 Pelvic floor muscle training is better than no treatment or placebo treatments for women with stress or mixed incontinence. [Level 1++]

Postpartum Contraception

54 There is a variety of contraceptive methods available each of which has a particular timing of initiation and particular indications related to breastfeeding status. [Level 4]

Maternal immunisation

55 Giving anti-D immunoglobulin to RhD-negative women delivering RhD-positive infants within 72 hours reduces the risk of RhD alloimmunisation. [Level 1]

56 Women who do not have serological immunity to rubella can be safely immunized after delivery and prior to discharge from hospital.

[Level 4]

57 Maternal rubella infection in the first eight to ten weeks of pregnancy results in fetal damage in up to 90% of infants [Level 3]

58 Neither pregnancy nor lactation are contraindications for Hep B vaccination of susceptible women. [Level 4]

Domestic Violence

59 There are no studies which evaluate the performance of a screening instrument for domestic violence by using decreased violence or health of the woman as outcome measures. [Level 2++]

The Six to Eight Week Maternal Postnatal Consultation

60 The content of the six – eight week postnatal consultation is not routinely based upon discussion of a woman's obstetric history or her experience of common health problems. [Level 3]

5.3 Introduction

Most women who give birth in the UK today can expect to have a safe pregnancy, birth and postnatal recovery. However, this is not a universal expectation for all women. The World Health Organization reports that more than one woman worldwide dies every minute from the complications of pregnancy and childbirth. Approximately 529,000 maternal deaths occurred in the year 2000 (Abou Zahr & Wardlaw 2004). The Maternal Mortality Ratio (MMR) worldwide figure is estimated to be 400 per 100,000 live births. Less than one percent of these deaths occur in developed countries where high quality, accessible health care services are available (Abou Zahr & Wardlaw 2004).

Despite the dramatic reductions in maternal mortality which occurred in the UK at around the time of the Second World War, maternal deaths continue to be reported in the UK and care for pregnant and postpartum women continues to be based upon the potential for rare but serious complications, which may be preventable. The report on Confidential Enquiries into Maternal Deaths 2000-2002, "Why Mothers Die," (Confidential Enquiry into Maternal Deaths. 2002) highlighted both the direct and indirect causes of maternal death in the United Kingdom. There were four leading direct causes of maternal mortality in the U.K. which have implications for diagnosis and treatment during the postpartum period. The most common cause of direct deaths was thromboembolism, the rates of which have remained largely unchanged since 1997. There were increases in the mortality rates from haemorrhage from 2000 to 2002 and no significant decreases in deaths from other direct causes including pre-eclampsia and genital sepsis. The most common cause of indirect deaths and the largest cause of maternal deaths overall was psychiatric illness.These conditions were therefore chosen as the focus for our review on major postpartum maternal morbidities.

Symptoms of common health problems identified by epidemiological studies as frequently experienced after childbirth have also been addressed (Brown & Lumley 1998;Glazener et al. 1991;Thompson & Alibhai 2003). Whilst not life-threatening, these symptoms may impact on varying aspects of a woman's daily life. Prompt identification and management could not only reassure women but also inform the provision of appropriate, tailored postnatal care.

Recommendations for core care for all postpartum women are based upon a review of risk factors, observations and referral pathways for each morbidity.

There was no suitable cost-effectiveness evidence found on the topics contained within this chapter. It was therefore felt that the focus of any economic analysis would be most appropriately assigned to other topics.

5.4 Major Physical Morbidities

5.4.1 Postpartum Haemorrhage

Narrative Summary

5.4.1.1 Definition and incidence of Primary and Secondary PPH

The definition of postpartum haemorrhage (PPH) is based on an estimation of blood loss and whether symptoms occurred within the first 24 hours of the birth (primary) or after the first 24 hours and up to six weeks after the birth (secondary). PPH has been defined as:

'vaginal bleeding in excess of 500ml after childbirth within or following the first 24 hours (constitutes immediate or delayed PPH)' (World Health Organization 2003d)

'haemorrhage that occurs within the first 24 hours postpartum is termed early postpartum haemorrhage while excessive bleeding after this time is referred to as late postpartum haemorrhage' (Schuurmans et al. 2000)

'primary postpartum haemorrhage (PPH) is conventionally defined as a blood loss of >500ml following the birth of the baby' (Gilbert, Porter, & Brown 1987)

'secondary postpartum haemorrhage is any abnormal or excessive bleeding from the birth canal occurring between 24 hours and 12 weeks postnatally.' (Alexander, Thomas, & Sanghera 2002)

There is no consensus on the exact amount of vaginal blood loss that constitutes a PPH. Precise measurement of blood loss is subject to underestimation (e.g. due to dispersal of blood on bed linen) and impact on maternal health and well-being may also vary according to the individual's haemoglobin level (e.g. a woman with anaemia may be less tolerant of blood loss) (World Health Organization 2003d) Furthermore, studies examining postnatal women's experiences of blood loss imply that there is variability in the normal range of blood loss (duration, character and amount) and reports may only describe most adverse outcomes(Bick et al. 2002)

Traditionally, a blood loss greater than 500ml is considered a valid measurement for diagnosing PPH (Gilbert, Porter, & Brown 1987;Hall, Halliwell, & Carr-Hill 1985;World Health Organization 2003d) whilst a loss in excess of 1000ml (Stones, Paterson, & Saunders 1993) to 1500ml (Waterstone, Bewley, & Wolfe 2001) is proposed to indicate severe or major obstetric haemorrhage.

A recent survey of 258 maternity units in the UK also failed to establish a consistent definition for major PPH, but the majority of units identified blood loss ≥ 1000ml (46%) or ≥ 1500ml (36%) as an indicator of major PPH (Mousa & Alfirevic 2002).

Based on a US case study, Combs et al (1991) proposed that a decrease in a woman's haematocrit level of 10 points or more between admission and post-delivery could be used as a reliable indicator of PPH, because it is a relatively simple procedure to undertake and provides a clinically valid measurement for assessing the requirement for a blood transfusion or iron therapy. Of 9598 women who had an instrumental or spontaneous vaginal delivery 374 (3.9%) cases were identified as having a PPH using inclusion criteria of a haematocrit decrease of 10 points or more or the need for a blood transfusion. However, authors of a Canadian clinical practice guideline suggest that the definition of PPH based on haematocrit changes or the requirement for a blood transfusion (Schuurmans, MacKinnon, Lane, & Etches 2000) is not practical for use in a clinical setting. They suggest that a diagnosis of PPH should be based on any blood loss that affects a woman's haemodynamic balance.

5.4.1.2 What are the signs and symptoms of PPH?

The major symptom of PPH is significant abnormal vaginal blood loss (as described above), which may be accompanied by one or more clinical signs and symptoms depending on the amount of blood loss. These may include palpitations, dizziness, tachycardia, weakness, sweating, restlessness, pallor and ultimately, collapse (Schuurmans, MacKinnon, Lane, & Etches 2000).

5.4.1.3 What are the risk factors for PPH?

There are few robust studies investigating risk factors for PPH, but five observational studies were identified that reported maternal and obstetric risk factors associated with PPH.

In a recent UK-based, case-control study (Waterstone, Bewley, & Wolfe 2001) which investigated the incidence and predictors of severe obstetric morbidities (severe sepsis, severe haemorrhage, uterine rupture and severe pre-eclamptic conditions) in 48 865 women, 327 subjects met the eligibility criteria for severe haemorrhage (estimated blood loss>1500ml, peripartum Hb drop ≥ 4g/l or transfused ≥ 4 units of blood). Several maternal and obstetric factors were identified as predictive for severe haemorrhage including manual removal of placenta, taking antidepressants, antiepileptics or iron at booking, emergency caesarean section, social exclusion, previous PPH, multiple pregnancy, antenatal admission, other race (not Black or White), oxytocin augmentation, age ≥35 years, high blood pressure at booking and smoking. The authors could not identify any potential causation to explain the association between taking antidepressants or antiepileptics and PPH.

In the case control study undertaken by Combs (Combs, Murphy, & Laros, Jr. 1991) significant risk factors associated with PPH were prolonged third stage of labour, pre-eclampsia, episiotomy (midline and mediolateral), previous PPH, twins, arrest of descent, soft-tissue lacerations, augmented labour, forceps/vacuum delivery, ethnicity (Asian/Hispanic), and nulliparity.

A retrospective analysis of 37, 497 women who delivered in NHS maternity units in the North West Thames region in 1988 identified 498 women who fulfilled the criteria for a diagnosis of major obstetric haemorrhage (defined as a blood loss of 1000ml or greater) (Stones, Paterson, & Saunders 1993). Significant risk factors associated with major obstetric haemorrhage were placental abruption, placenta praevia, multiple pregnancy, obesity, retained placenta, induced labour, episiotomy, birthweight >4kg, oxytocin-induced labour, emergency caesarean section (C-section) vs. elective C-section, emergency C-section vs. spontaneous delivery, emergency C-section vs. operative vaginal delivery, elective C-section vs. spontaneous vaginal delivery,

operative vaginal delivery vs. spontaneous delivery, pyrexia in labour (>38 degrees C) and prolonged labour (>12h). In 59 women with major obstetric haemorrhage and 'low risk' delivery (vaginal delivery and intact perineum), significant risk factors were retained placenta (RR 13.7, 5.92-31.8) and induced labour (RR 2.35, 1.11-4.98).

Two cohort studies were identified that investigated risk factors based on the traditional definition of PPH as blood loss>500ml (Gilbert, Porter, & Brown 1987;Hall, Halliwell, & Carr-Hill 1985). Hall et al conducted a longitudinal cohort study of 36 312 women having one or more singleton, vaginal births in Scotland between 1967 and 1981. The researchers identified primiparity, induced labour and a previous history of PPH as risk factors for PPH. A further UK cohort study of 437 women having singleton, vaginal deliveries, 86 of whom had a PPH, reported primiparity, prolonged 1st stage of labour, >1h duration of 2nd stage and forceps delivery as risk factors associated with PPH (Gilbert, Porter, & Brown 1987).

5.4.1.4 What observations should be undertaken to diagnose and treat PPH?

As noted in the narrative on signs and symptoms above, there is no standard measurement technique for the amount of bleeding which occurs after birth.

5.4.1.5 Fundal Height

Fundal height measurement has traditionally been undertaken to assess and monitor uterine involution, as retained products of conception, subinvolution of the placental site and infection are considered to be potential causes of postpartum haemorrhage.

A two stage survey of postpartum women was conducted by Marchant et al (Marchant et al. 1999). The first stage asked women to complete a questionnaire on their experiences of postnatal vaginal bleeding between 48 hours and 5 days after delivery. The second stage questionnaire, conducted at three months postpartum asked about the duration and description of vaginal loss and any problems women had experienced with prolonged or excessive loss after 28

days of giving birth. One percent of the 325 women who responded to this survey reported having a diagnosis of uterine sub-involution.

A robust evidence base to support the use of uterine sub-involution as an initial diagnostic criterion for PPH is lacking (i.e. initial manual assessment as opposed to ultrasound scan). Uterine sub-involution may be detected by abdominal palpation or measurement of the symphysis-fundal distance (S-FD) (by tape measure) (Bick, MacArthur, Knowles, & Winter 2002).

5.4.1.6 How is deviation from normality detected?

Cluett et al (Cluett, Alexander, & Pickering 1997) evaluated uterine involution in 28 primiparous women who had a normal vaginal delivery from 18 hours after delivery until the fundus was no longer palpable. There was considerable variability in the pattern of uterine involution. On day one measurements ranged from 12.3 - 20.5 cm. The day on which the uterine fundus was no longer palpable was variable, ranging from 11-22 days. The authors recommended the discontinuation of this measurement.

Bergstrom and Libombo (Bergstrom & Libombo 1992) undertook a case control study to assess the value of postpartum measurement of symphysis-fundal distance. They compared two groups of puerperal women at one hospital in Mozambique. Fifty-one women with clinically evident signs of endometritis were matched for age, parity and number of days post birth with 51 women who had no signs of infection. Uterine size did not vary between the groups. The authors concluded that fundal height is not a reliable sign of postpartum endometritis, however results should be interpreted with caution, as accuracy of the measurements obtained was not assessed, and controls were only matched to within 2 days post delivery.

5.4.1.7 When and how often should fundal height be measured?

There are no studies which address this issue.

5.4.1.8 What is the optimal method of measuring fundal height and what competencies are required to measure it?

Cluett and colleagues in a study published in 1995, examined the precision of fundal height measurements undertaken by midwives using a tape measure for intra-rater and inter-rater reliability (Cluett, Alexander, & Pickering 1995). The intra-rater observations had a repeatability coefficient of 2.94 cm and the inter-rater observations had a 5.01 cm repeatability coefficient. The authors recommend that due to lack of precision the practice of measuring fundal height with a tape measure should be discontinued, as it was not precise enough to enable clinical judgements to be made about progress of uterine involution.

5.4.1.9 Postpartum Vaginal Loss

The literature on postpartum vaginal loss highlights the variability of this physiological process and the difficulties encountered in the accurate quantification of vaginal loss, from the immediate post delivery period to the conclusion of the postpartum period.

5.4.1.10 What is defined as normal/abnormal vaginal blood loss and how is deviation from normality detected?

Patterns of normal and abnormal postpartum vaginal blood loss have not been well defined and the measurement of vaginal blood loss has not been standardised.

Luegenbiehl (Luegenbiehl et al. 1990;Luegenbiehl 1997) conducted two studies in the U.S. to introduce a standardised method of measuring and describing blood loss on sanitary pads. Because the first few hours after birth have the highest probability of a bleeding crisis, it was standard practice in the research hospital to make a nursing assessment of blood loss at least every 15 minutes and more often if indicated by the woman's condition during the first hour after the birth. This assessment involved palpation of the fundus and inspection of sanitary pads and perineum, blood pressure and pulse monitoring, and subjective data gathered from the woman. After the initial postpartum period, ongoing assessments included monitoring temperature, pulse, and respirations, and noting the amount and type of lochial discharge, the condition, position and level of the uterine fundus and any other signs of haemorrhage, such as tachycardia, hypotension, vertigo, extreme fatigue and cool or clammy skin.

Luegenbiehl's work with nurses in the two studies on assessment of vaginal loss used brands of sanitary pads familiar to the nurses and assessed their ability to estimate amounts of vaginal blood loss correctly. In both studies estimates of blood loss were made by participating qualified and student nurses after attendance at an educational program. Repeated estimates were taken. Prior to the educational program participants both overestimated and underestimated blood loss but more often overestimated. In the second study of 387 nurses, participants overestimated blood volumes by 102% before the educational programme and by 47 % after the programme.

The survey undertaken by Marchant et al (1999) referred to earlier described the variability of postpartum vaginal loss in relation to duration, amount and colour. A later study published in 2002 by the same study group on GP consultations by women concerned about their vaginal loss reported that 20% of the 325 women had a problem with postnatal loss between 28 days and 3 months postpartum (Marchant, Alexander, & Garcia 2002). The poor response from the general practices who were asked to participate in the survey (only 18 of 115 practices asked to participate did so) limits the generalisability of findings.

5.4.1.11 When and how often should postpartum vaginal blood loss be observed?

No studies were identified which had examined this question.

5.4.1.12 What is the optimal method of measurement of vaginal blood loss and what competencies are required to measure it?

The literature is clear that the estimation of vaginal blood loss is very imprecise. An optimal method has not been determined.

5.4.1.13 What are the referral pathways for post-partum haemorrhage and postpartum vaginal loss?

No studies were identified which had examined this question.

5.4.1.14 Post-partum haemorrhage

The Scottish Obstetric Guidelines and Audit Project has published The Management of Postpartum Haemorrhage (Scottish Programme for Clinical Effectiveness in Reproductive Health 2002) (updated 2002). The recommendations for hospital based management of PPH include:

Once PPH has been identified, management may be considered to involve four components – all of which must be undertaken simultaneously:

- Communication
- Resuscitation
- Monitoring and investigation
- Arresting the bleeding

5.4.1.15 Postpartum vaginal loss

The survey of referral patterns for women with postnatal vaginal bleeding problems in general practices undertaken by Marchant et al (2002) revealed several referral pathways including direct referral for ultrasound scan, hospital out-patient department and hospital admission (Marchant, Alexander, & Garcia 2002). However, caution should be applied to the findings due to the low response rate especially from General Practices...

5.4.2 Genital tract sepsis

Narrative Summary

5.4.2.1 Definition and incidence of endometritis

Puerperal sepsis is a potentially life-threatening infection during the postnatal period, which may occur following vaginal or abdominal delivery. Puerperal sepsis is most likely to arise from infection of the genital tract, in particular, infection of the uterus (endometritis/metritis), although other sites of infection such as surgical wound infections may occur. This review of major morbidities focuses upon endometritis. Post operative infection is addressed in the NICE

guideline on caesarean section (National Collaborating Centre for Women's and Children's Health. 2004).

The reported incidence of endometritis appears to vary according to the mode of delivery. However, some of the variation may be as a consequence of data obtained from retrospective data reviews which may be incomplete, as women may have been treated in the community or admitted to a different acute unit. Rates are also difficult to ascertain due to the lack of standard definition of endometritis and the rigour with which sources of infection are identified. The incidence of endometritis after abdominal delivery has been reported to range from 12% to 95%, with incidence rates rarely exceeding 3% after vaginal delivery. The risk of endometritis is 5-10 times greater after caesarean section (Gibbs 1980). An epidemiological survey supported by the Centers for Disease Control in the U.S. in 2001 (Yokoe et al. 2001) screened records of 2,826 postpartum women. The rate of endometritis (number of infections/100 deliveries) following normal vaginal delivery was 0.2% and following caesarean delivery was 0.8%. Although evidence from cohort studies shows an increased risk of endometritis among women who had CS compared to those who had spontaneous vaginal birth, when prophylactic antibiotics are administered for CS there is a significant reduction in the incidence (Smaill & Hofmeyr 2002) hence estimates may be confounded.

5.4.2.2 What are the signs and symptoms of genital tract sepsis?

A standard definition of postpartum genital sepsis/endometritis, including clinical signs and symptoms, was not identified. There are no systematic reviews available on this topic. Some evidence focuses on physical symptoms while other sources base diagnosis on bacteriological findings.

In their study of the incidence and predictors of severe obstetric morbidity Waterson, et al (Waterstone, Bewley, & Wolfe 2001) searched Medline for keywords relevant to each condition. No definition for postpartum sepsis was found and the researchers chose to modify the standard definition of sepsis in

the general population to take into account the physiological changes in pregnancy. Their definition of sepsis is as follows:

Sepsis is a systemic response to infection manifested by two or more of the following signs or symptoms:

- Temperature>38^{0}C
- Heart rate>100 beats /minute
- Respiratory rate>20/min or PaCO2 <32mm Hg
- White cell count>17 x 109/l or <4 x 109/l or >10% immature forms
- Plus bacteraemia (+ blood cultures) or positive swab culture.

Other researchers have diagnosed genital sepsis or endometritis based on clinical symptoms alone (D'Angelo & Sokol 1980;Suonio et al. 1989). Suonio et al defined endometritis as:

Axillary temperature over 38^{o}C degrees centigrade on two different occasions with local symptoms such as pain and tenderness over the uterine site and lochia putrida.

D'Angelo and Sokol defined endometritis as:

Postpartum temperature elevation to 38^{o}C or more accompanied by uterine tenderness, with or without foul-smelling lochia, which required antibiotic therapy.

The CDC Definitions of Nosocomial Infections (Garner et al. 1996) include the criteria used to develop standard definitions of infection in the U.S. Endometritis must meet at least one of the following criteria:

Criterion 1: Patient has organisms cultured from fluid or tissue from endometrium obtained during surgical operation, by needle aspiration, or by brush biopsy.

Criterion 2: Patient has at least two of the following signs or symptoms with no other recognized cause: fever (>38^0 C), abdominal pain, uterine tenderness, or purulent drainage from uterus.

The WHO Managing Complications in Pregnancy and Childbirth,(World Health Organization 2003c) identifies the signs and symptoms of endometritis as:

Fever/chills
Lower abdominal pain/tenderness
Purulent, foul-smelling lochia
Tender uterus

5.4.2.3 What are the risk factors for genital tract sepsis?

No systematic reviews of risk factors for postpartum infection after vaginal delivery were identified. As incidence rates for endometritis are much higher post caesarean section than post vaginal delivery (see "Incidence"), studies of risk factors have generally focused on post operative complications. One study, by Newton et al (1990) evaluated risk factors for postpartum endometritis in vaginal versus caesarean deliveries. Six hundred and seven women were followed prospectively, 100 of whom (16.5%) developed postpartum endometritis. Multivariate analysis identified caesarean delivery (RR12.8; p<.0001) as the dominant overall predictor of endometrial infection. In vaginal delivery, "bacterial vaginosis organisms" (RR 14.2; p<0.01) predicted endometritis. Clinical variables such as duration of labour, rupture of membranes and internal fetal monitoring were not significant in the multivariate analysis. In a study by Gilstrap and Cunningham (1979) fifty-six women with rupture of membranes for 6 hours or greater were observed. Among those women who ultimately delivered by caesarean section, 95% developed endometritis. They reported, however, that <10% of women with prolonged

rupture of membranes who delivered vaginally became febrile. In a retrospective analysis of 12,147 singleton births, Seo et al (1992) found that after controlling for the effects of mode of delivery, postpartum endometritis was significantly increased only among women with preterm PROM delivered by caesarean section. A diagnosis of chorioamnionitis (infection of the placental membranes) was not significantly associated with increased occurrence of maternal endometritis but as all women with diagnosed chorioamnionitis were treated with parenteral antibiotics, rates of postpartum endometritis may have been reduced.

Other studies, which focused on infectious complications of caesarean section, may have some relevance to infection after normal vaginal delivery. Killian et al (2001) surveyed 765 women who had delivered by caesarean section for any reason, 39 of whom developed endometritis. Three variables were independently associated with increased risk of endometritis: absence of antibiotic prophylaxis (OR2.58, CI 1.3-5.1), fewer than seven antenatal visits (OR 5.59, CI 2.28-13.7) and prolonged active labour or ruptured membranes (OR 2.30, CI 1.09-4.82). Gibbs et al (1978) did a prospective cohort study of 419 women undergoing either planned or emergency caesarean section. One hundred sixty-six women (39.6%) developed either chorioamnionitis and/or postpartum endometritis. Statistically significant risk factors included mothers' age, race, duration of labour, duration of ruptured membranes, internal fetal monitoring, vaginal examination, repeat caesarean section and blood loss/transfusion.

In the introduction to their Cochrane Review of "Antibiotic Regimens for Endometritis After Delivery" French and Smaill (2001) discuss predictive factors for genital infection after vaginal delivery including the presence of "BV" organisms (organisms characteristic of bacterial vaginosis); genital cultures positive for aerobic gram negative organisms ; prolonged rupture of membranes and multiple vaginal examinations. The latter two risk factors are not referenced.

5.4.2.4 What observations should be undertaken to diagnose and treat genital tract sepsis?

The signs and symptoms of genital tract sepsis described previously form the basis for clinical observations.

5.4.2.5 Temperature

The primary sign of sepsis is fever; however the effectiveness of routine observation of temperature during the puerperium has not been studied extensively.

5.4.2.6 What is defined as normal/abnormal and how is deviation from normality detected?

The preceding narrative on signs and symptoms of sepsis, describes abnormal temperature range. Maternal temperature can be obtained via oral, axillary, rectal or ear canal routes using a variety of measurement instruments including mercury thermometer, test tapes and electronic machines.

Only one small study was found which evaluated routine postpartum temperature check. Takahashi (Takahashi 1998) defined temperature measurement as a screening test and evaluated it using standard screening criteria. Records of 200 women who delivered in 1990 in the John Radcliffe Hospital in Oxford where twice daily routine temperature measurement was standard protocol, were reviewed. One hundred and forty one women had a temperature recorded more than once on postpartum day two. Less than one third of women (59) had their temperature checked twice or more on the third day postpartum. Methods of obtaining an accurate temperature were observed and found to be unsatisfactory. Many health care workers did not leave mercury thermometers in place for the recommended length of time, and the use of electronic thermometers was not addressed in this study. When temperature screening was tested for sensitivity and specificity on three different cut off points (37.1^0C, 37.5^0C and 38.0^0C) none of the measurements was sensitive enough to enable pyrexia to be ascertained in more than 40% of

cases. The author questioned the value of routine observation of maternal temperature checking as a screening test.

5.4.2.7 When and how often should it be observed?

This question is not addressed by any studies searched.

5.4.2.8 What is the optimal method of measuring maternal temperature and what are the competencies required to measure it?

No studies comparing methods of temperature screening were located.

5.4.2.9 What competencies are required to identify and treat genital tract sepsis?

No evidence based competencies were identified for genital tract sepsis.

5.4.2.10 What are the referral pathways for genital tract sepsis?

Specific evidence based referral pathways are not identified in the literature for genital tract sepsis.

5.4.3 Pre-eclampsia and eclampsia

Narrative Summary

5.4.3.1 Definition and incidence of pre-eclampsia

Pre-eclampsia and eclampsia are hypertensive disorders in pregnancy and the postnatal period.

Incidence reporting of postnatal pre-eclampsia/eclampsia is confounded by the definition of the postnatal period and a paucity of relevant studies.

A recent five year prospective study conducted by Tuffnell et al (2005) reviewed the records of 210,631 women who delivered in 16 maternity units in Yorkshire between 1 January 1999 and 31 December 2003. There were 82 cases of eclampsia, 26 of which occurred following delivery (32%).

A prospective survey conducted by Douglas & Redman (1994) examined the incidence of eclampsia in the United Kingdom in 1992. Requests for notification of possible eclampsia cases or unexplained seizures occurring antenatally, intrapartum or in the first 10 days postnatally were sent every three months to all 1011 consultant obstetricians then in the U.K. There were 383 cases of eclampsia identified from 774436 maternities in the UK during 1992. The incidence of eclampsia was 4.9 per 10 000 maternities, and 1 in 50 women died. The percentage of total eclampsia cases occurring in the postnatal period was 44%.

Lubarsky et al (1994) conducted a retrospective case note review investigating late postpartum eclampsia. The 15 year study (1977-1992) was conducted in one unit in the USA involving 112 500 women. Postpartum eclampsia was defined as convulsions occurring after delivery to 4 weeks postpartum. Three hundred and thirty four cases of eclampsia were identified, 97 (27%) of which occurred postpartum. The number of late postpartum cases (defined as occurring after 48 hours but before 4 weeks post partum) was 54, an incidence of 1 per 2083 deliveries.

Atterbury et al (1998) undertook a retrospective case control study in one unit in the USA and identified 53 postnatal women from 32 762 maternity cases who were readmitted with severe pre-eclampsia or eclampsia (1.7 per 1000 maternities). Of these, 32 (60.4%) had postnatal severe pre-eclampsia and 21 (39.6%) had eclampsia.

5.4.3.2 What are the signs and symptoms of pre-eclampsia and eclampsia?

The NICE Guideline on Antenatal Care; Routine Care for the Healthy Pregnant Woman (National Collaborating Centre for Women's and Children's Health. 2003) produced by the National Collaborating Centre for Woman's and Children's Health defines pre-eclampsia as:

'Hypertension new to pregnancy manifesting after 20 weeks of gestation that is associated with a new onset of proteinuria, which resolves after pregnancy.'

The Guideline states that hypertension and proteinuria are easily measured signs associated with pre-eclampsia, although they are surrogate markers indicating end-organ damage. The Guideline recommends that whenever blood pressure is measured in pregnancy, a urine sample should be tested at the same time for proteinuria. Neither specific blood pressure levels nor urinary protein measurements are adopted. However, research described in the Antenatal Guideline and recommendations made in the RCOG Pre-eclampsia Community Guideline set a diagnositic threshhold of 90 mm Hg for diastolic blood pressure (National Collaborating Centre for Women's and Children's Health. 2003;Royal College of Obstetricians and Gynaecologists 1999;Tuffnell et al. 2005)}. Urine protein excretion >300mg per 24 hr is regarded as significant in both documents.

The Guideline found no evidence on when and how often blood pressure measurements should be taken during the antenatal period. A systematic review found no difference in the rates of pre-eclampsia reported between women who received the standard number of antenatal appointments, compared with reduced numbers of antenatal appointments (pooled OR 0.37, 95%CI: 0.22 to 1.64) (Villar et al. 2001).

The Guideline recommended that an initial proteinuria reading of 1+ should be confirmed by a 24-hour urinary protein measurement. Although a finding of 300mg/24 hours or more is usually considered significant, a proteinuria threshold of 500 mg/24 hours has been suggested to be more predictive in relation to the likelihood of adverse outcome.

The Guideline has recommended that oedema is abandoned as one of the signs and symptoms associated with pre-eclampsia because it occurs in too many pregnant women (up to 80%) to be discriminatory.

The WHO Managing Complications in Pregnancy and Childbirth Guide (World Health Organization 2003b) identifies the signs and symptoms of mild pre-eclampsia as:

- two readings of diastolic blood pressure of 90-110mmHg or higher, 4 hours apart after 20 weeks gestation
- proteinuria up to 2+

Severe pre-eclampsia is identified by WHO (World Health Organization 2003b) as:

- diastolic blood pressure of 90-110mm Hg or higher after 20 weeks gestation
- proteinuria 3+ or more
- and any one or more of the following:
- headache (increasing frequency, unrelieved by regular analgesics)
- hyperreflexia
- clouding of vision
- oliguria (passing less than 400 mL urine in 24 hours)
- upper abdominal pain (epigastric pain or pain in right upper quadrant)
- pulmonary oedema
- Eclampsia is identified as:
- convulsions
- coma (unconscious)

Few studies have been conducted on specific signs and symptoms of pre-eclampsia/eclampsia in the postpartum period. One small study by Atterbury et al (1998) based on 53 women found that neurological symptoms (cortical blindness, headache and scotoma) occurred more frequently in postpartum severe pre-eclamptic and eclamptic women compared with case control

matched severe pre-eclamptic and eclamptic women during pregnancy. They also had more nausea and vomiting. There was no difference in oedema, epigastric pain or right upper quadrant tenderness. Another small study by Chames et al (Chames et al. 2002) which included 89 eclamptic women, 29 of whom had postpartum eclampsia, reported that the 23 women with late postpartum eclampsia (> 48 hours post- delivery to 14 days) were more likely to have headaches, visual symptoms and at least one symptom of pre-eclampsia compared with eclamptic women before delivery or early post-partum. Epigastric pain and nausea/vomiting were not statistically significant.

5.4.3.3 What are the risk factors for pre-eclampsia?

The NICE Antenatal guideline (National Collaborating Centre for Women's and Children's Health. 2003) details the following as risk factors for developing pre-eclampsia during pregnancy

- nulliparous
- age 40 years or over
- family history of pre-eclampsia (e.g., pre-eclampsia in a mother or sister)
- prior history of pre-eclampsia
- BMI at or above 35 at first contact
- multiple pregnancy or pre-existing vascular disease (e.g., hypertension or diabetes)

For postpartum pre-eclampsia/eclampsia, there have been no studies to assess whether risk factors differ from those during pregnancy.

5.4.3.4 What observations should be undertaken to diagnose and treat pre-eclampsia?

The primary indicator of pre-eclampsia is elevated blood pressure. This condition can also occur in the post partum period.

5.4.3.5 *What is defined as normal/abnormal and how is deviation from normality detected?*

The definition of abnormal ranges of blood pressure is discussed in the signs and symptoms of pre-eclampsia above. Deviations from normal are detected by measuring blood pressure with a sphygmomanometer.

5.4.3.6 *When and how often should blood pressure be observed?*

There were no studies located in the literature search to guide health care providers in the timing or frequency of blood pressure measurement.

5.4.3.7 *What is the optimal method of measuring blood pressure and what competencies are required to measure it?*

Brown et al (1998) described a RCT of measuring Kortokoff 4/5 sounds but did not include any mention of electronic blood pressure measurement which is frequently used in western hospitals. Detailed information on methods of measuring blood pressure are available in the NICE Guideline on Hypertension, a draft of which is available on the NICE website (http://www.nice.org.uk/) and in the British Hypertension Society Guidelines for Management of Hypertension (Ramsay et al. 1999).

5.4.3.8 *Are there additional observations which should be made in suspected pre-eclampsia?*

Atterbury et al (1998) based on the findings of their study described above recommended that health care professionals should observe for neurological and gastrointestinal symptoms, as well as noting blood pressure elevations.

5.4.3.9 *What are the competencies required to identify and treat pre-eclampsia?*

The diagnosis of hypertension is dependent upon the accurate measurement of blood pressure. The NICE Antenatal Guideline (National Collaborating Centre for Women's and Children's Health. 2003) details the recommended technique to be employed by the clinician.

The diagnosis of pre-eclampsia depends on the presence of significant proteinuria as well as high blood pressure. The NICE Antenatal Guideline (National Collaborating Centre for Women's and Children's Health. 2003) recommends that automated dipstick readers be used to assess protein levels in urine because of the considerable observer errors involved in dipstick assessment.

5.4.3.10 What are the referral pathways for pre-eclampsia?

The Pre-eclampsia Study Group Recommendations (2003) from the Royal College of Obstetricians and Gynaecologists (Royal College of Obstetricians and Gynaecologists 2003) details the following recommendations for referral in clinical practice during pregnancy:

- all women with blood pressure greater than 140/90 mmHg with or without proteinuria should be referred to a day assessment or obstetric unit.
- all women with persistent proteinuria, even in the absence of hypertension should be referred for further investigation.

5.4.4 Thrombosis

Narrative Summary

5.4.4.1 Definition and incidence of thrombosis

Venous thromboembolism (VTE) is a condition that encompasses deep venous thrombosis (DVT) and pulmonary thromboembolism (PTE). It is reported that the risk of VTE is highest in the postnatal period (Royal College of Obstetricians and Gynaecologists. 2001). PTE, which arises from DVT, accounted for 31 deaths in the latest report of the Confidential Enquiries into Maternal Deaths in the UK (CEMD) (Confidential Enquiry into Maternal Deaths. 2002). Of these, 17 deaths occurred postpartum. Postpartum DVT is reported to occur at an event rate of 0.3 per 1000 births in women under 35 years of age and increase to a rate of 0.7 per 1000 births in women over 35 (Macklon & Greer 1997).

A recently published American study (Heit et al. 2005) studied a cohort of 105 women who developed venous thrombosis or pulmonary embolism between 1966 and 1995 in Olmsted County, Minnesota. The overall incidence of venous thromboembolism was 5 times higher among postpartum women than pregnant women (511.2 vs 95.8 per 100,000). The observed incidence of pulmonary embolism was more than 15 times higher in the first 3 postpartum months than during pregnancy (159.7 vs 10.6 per 100,000).

5.4.4.2 What are the signs and symptoms of thromboembolism?

An evidence-based strategy for the management of acute pulmonary embolism (PTE), which was subsequently updated in a clinical guideline (British Thoracic Society Standards of Care Committee Pulmonary Embolism Guideline Development Group. 2003;British Thoracic Society. 1997) listed the signs and symptoms of PTE as:

Dyspnoea, tachypnoea, pleuritic pain, apprehension, tachycardia, cough, haemoptysis, leg pain, clinical DVT.

(NB. This guideline does not specifically relate to pregnancy or postpartum PTE)

The signs and symptoms of DVT and PTE (in pregnancy and the puerperium) (Royal College of Obstetricians and Gynaecologists. 2001) are stated as:

- DVT: leg pain or discomfort (especially in the left leg), swelling, tenderness, increased temperature and oedema, lower abdominal pain and elevated white cell count.
- PTE: dyspnoea, collapse, chest pain, haemoptysis, faintness, raised JVP (jugular vein pressure), focal signs in chest and symptoms and signs associated with DVT.

According to WHO (World Health Organization 2003d), the signs and symptoms of DVT are: ‘spiking fever despite antibiotics, calf tenderness’.

A meta-analysis of published reports of DVT during pregnancy and the puerperium (12/18 studies that used objective testing to diagnose DVT)

concluded that DVT arises more frequently in the left leg: 77.2% (95% CI 69.7-83.3) compared with 21.5% (95% CI 15.3-29.2) (Ray & Chan 1999).

5.4.4.3 What are the risk factors for thromboembolism?

The risk factors for venous thromboembolism (VTE) are outlined in Table 5-2 which was reproduced with permission from RCOG guidelines (Royal College of Obstetricians and Gynaecologists. 2004b;Royal College of Obstetricians and Gynaecologists. 2001).

The CEMD report (Confidential Enquiry into Maternal Deaths. 2002) states that risk factors for thromboembolism were present in 25 of the 31 recorded maternal deaths: 'thirteen women were overweight, five had had a period of bed rest, four had a family history, two had undertaken long-haul flights during pregnancy and one had varicose veins'. Some women had more than one risk factor and 18 women were over 30 years of age.

Table 5-2

Risk factors for venous thromboembolism in pregnancy and the puerperium[1]	
Pre-existing	New onset or transient
Previous VTE	Surgical procedure in pregnancy or puerperium, e.g. evacuation of retained products of conception
Thrombophilia	Hyperemesis
Congenital	Dehydration
Antithrombin deficiency	Ovarian hyperstimulation syndrome
Protein C deficiency	Severe infection, e.g. pyelonephritis
Protein S deficiency	Immobility (>4 days bed rest)
Factor V Leiden	Pre-eclampsia
Prothrombin gene variant	Excessive blood loss
Acquired (antiphospholipid syndrome)	Long-haul travel
Lupus anticoagulant	Prolonged labour[2]
Anticardiolipin antibodies	Midcavity instrumental delivery[2]
Age (>35 years)	Immobility after delivery[2]
Obesity (BMI>30kg/m2) either pregnancy or in early pregnancy	
Parity	
Gross varicose veins	
Paraplegia	
Sickle cell disease	
Inflammatory disorders, e.g. inflammatory bowel disease	
Some medical disorders, e.g. nephritic syndrome, certain cardiac diseases	

Myeloproliferative disorders, e.g. essential thrombocythaemia, polycythaemia vera	

1. Although these are all accepted as thromboembolic risk factors, there is little data to support the degree of increased risk associated with many of them.
2. Risk factors specific to postpartum VTE only.
(Royal College of Obstetricians and Gynaecologists. 2004b;Royal College of Obstetricians and Gynaecologists. 2001).
Permission for reproduction granted.

5.4.4.4 What observations should be undertaken to diagnose and treat thromboembolism?

The signs and symptoms of DVT and PTE described above also relate to the clinical observations that would be undertaken to exclude or confirm a possible diagnosis of VTE (excluding elevated white cell count).

Due to the difficulty in accurately diagnosing PTE, British Thoracic Society guidelines for the management of suspected acute pulmonary embolism suggest a model for assessing clinical probability:

'The patient has clinical features compatible with PTE-namely, breathlessness and/or tachypnoea, with or without pleuritic chest pain and/or haemoptysis. Two other factors are sought: a) the absence of another reasonable clinical explanation and b) the presence of a major risk factor.' If "a" and "b" are true, there is a high probability of PTE.

5.4.4.5 What is defined as normal/abnormal and how is deviation from normality detected?

In clinical practice the presence of calf pain, redness and swelling are seen as indictors of a possible DVT. These clinical signs were evaluated in several studies of venographic findings in thromboembolic disease.

Four studies compared clinical signs and symptoms to measurements of I-labelled fibrinogen. Jackson (1973) found that among 100 postpartum women evaluated only one actually had a DVT and that clinical signs of calf tenderness and pain developed 48 hours after the scan became positive. These signs were also present in 13 women who had normal scans. Nicolaides et al (1971)

and Flanc et al (1968) both found that only 50% of those with thrombi in their studies had any clinical signs. In his 1968 study Negus et al (1968) found 32 patients with positive phlebograms. Only 6 of these had physical signs of any sort and these appeared 2 or more days after the thrombosis was detected.

Gherman et al (1999) provide contrasting evidence in their study. They report that 85.7% (109) of 127 pregnant and postpartum women with DVT had pain, redness and unilateral leg swelling at initial presentation. However, only 46.5% (59) had a positive Homan's sign.

5.4.4.6 When and how often should observations be made?

There are no studies which provide guidance on this question.

5.4.4.7 What are the optimal methods of measuring and what competencies are required?

The evidence indicates that radiologic methods are actually the optimal method for detecting DVT (see above). However, this is not a primary care intervention. It is unclear if routine observation of leg symptoms is precise enough to screen adequately for DVT.

5.4.4.8 What competencies are required to identify and treat thromboembolism?

Evidence is lacking on relevant competencies.

5.4.4.9 What are the referral pathways for thromboembolism?

No evidence on referral pathways was identified.

5.5 Mental Health and Well being

This section relates to the identification of women who experience transient low mood (postnatal blues), a common psychological problem after giving birth, and the identification of mental health problems such as depression and puerperal psychosis which may present for the first time in the postnatal period.

Supportive interventions for women with postnatal blues are presented. Guidance covering the management of pregnant women with bipolar disorder is included in the NICE guideline on the management of bipolar disorder (www.nice.org.uk). Care for pregnant and postpartum women with other mental disorders, including depression and puerperal psychosis, will be presented in the forthcoming NICE guideline 'Antenatal and postnatal mental health: clinical management and service guidance' (www.nice.org.uk).

5.5.1 Postnatal blues

Narrative Summary

In studying postnatal blues, the greatest difficulty has been the lack of a standard method of measuring women's experiences of symptoms, which may include feelings of anxiety, restlessness, tearfulness and low mood. Observational studies have estimated the prevalence of postnatal blues to range from 15% (Pitt 1973) to 85% (Stein, Marsh, & Morton 1981). These large differences in reported rates may be due to different identification criteria. The following methods have been used:

1. Standardised psychiatric interviews

2. Self rating scales originally designed to measure depressive symptoms

3. Questionnaires designed specifically for measuring postnatal blues that do not rely on depressive symptoms being the main feature of postnatal blues. (Kennerley & Gath 1989;Pitt 1973;Stein 1980).

5.5.1.1 Signs and Symptoms of postnatal blues

There is no precise definition of the blues, but several observational studies have identified similar symptoms. Commonly reported symptoms include fatigue, tearfulness, anxiety, depression, confusion, headache, insomnia and irritability (Pitt 1973), Stein (Stein 1980).

Kennerley and Gath (1989) interviewed 100 newly delivered women once in the ten days following the birth. Women described in their own words the feelings they were experiencing, and whether these experiences differed from their normal feelings. From this, 49 items or mood adjectives were described. These were incorporated into a draft questionnaire and tested on a further 100 women. Following revision, 28 items remained on the questionnaire and these were given to a further 50 recently delivered women. Cluster analysis identified 7 symptoms associated with 'primary blues', namely; tearfulness, fatigue, anxiety, feeling overemotional, changeability in mood, low spiritedness, forgetfulness/muddled thinking. Primary blues emerged as a separate cluster from depression and was more frequent (36% versus 16%, respectively). The final questionnaire was validated on a further sample of 87 newly delivered women, - comparing prenatal scores to the mean of scores obtained on days 1 to 10 postpartum. The scores for the primary blues cluster significantly increased postpartum, while scores for depression did not change. These findings may indicate that changes in depression are not characteristic in the early puerperium. A second study by Kennerley and Gath (Kennerley 1989) on 112 women compared maternal blue questionnaire scores with the women's social environment and personality type (Eysenck Personality Inventory). Postnatal blues was significantly associated with neuroticism, poor social adjustment with the role as a houseworker, and a poor relationship in either the family unit, extended family or marriage.

5.5.1.2 Natural history of postnatal blues

Stein (1980) found that postnatal blues peaked on days 4-5. Day to day mood changes in the first three weeks after childbirth were examined by Kendall et al (1984). In 81 unselected women, there was a sharp peak in ratings of depression, tears and lability on day 5 postpartum, and thereafter the ratings declined steadily. Levy (1987) used the Stein (1980) blues rating questionnaire to compare postpartum women with women undergoing major or minor surgery. The number of postpartum women experiencing symptoms peaked on days 3 to 4, and declined on days 5 and 6. The numbers in the surgical groups

declined progressively to day 6, without showing a peak. Hau and Levy (2003) also used the Stein questionnaire on 88 women recruited on the first day after the birth. Postnatal blues scores were found to peak on day 5 after the birth.

Kennerley and Gath (1989) found that mean symptom scores peaked on day 5 and declined thereafter to day 10 postnatal. A case control study of 20 women showed that day 5 postnatal blues symptoms resolved by one month when compared with the scores of the control women (Ijuin et al. 1998).

5.5.1.3 Risk factors for postnatal blues

A prospective study of 182 women (O'Hara et al. 1991b) found the following to be predictors of postnatal blues: personal and family history of depression, social adjustment, stressful life events, and levels of free and total oestriol. Age, education and parity were not associated with postnatal blues. Similarly, Hapgood et al (1988) found that age, race, marital status, and socio-economic status were not risk factors for postnatal blues. Hau and Levy (2003) found that women aged between 35 and 39 had a lower incidence of postnatal blues compared with women aged 18 to 34. However, they found the following demographic variables did not differ significantly between the postnatal women with maternal blues compared with those with no symptoms: parity, education level and marital status.

Ehlert et al (1990) compared psychological factors that discriminated between women with or without postnatal blues. Symptoms of postnatal blues occurred more frequently in woman who reported high levels of trait-anxiety, passive coping strategies, marital dissatisfaction or non acceptance of their roles as mothers. Kendell et al (1984) used the Eysenck Personality Questionnaire to identify personality traits in 51 women who had taken part in their earlier study (Kendell et al. 1981). The depression, tearfulness and lability of mood that peaked on day 5 postpartum were largely restricted to women with high neuroticism.

Evidence regarding parity has been conflicting. A number of studies (Gard 1986;Ijuin, Douchi et al. 1998;Nott 1976;Yalom et al. 1968) have found

primiparous women to be at greater risk for postnatal blues. Davidson (Davidson 1972) reported greater vulnerability in multiparous women. Other studies have found no association between parity and postnatal blues (Ballinger et al. 1979;Hapgood 1988;Hau & Levy 2003;O'Hara et al. 1991a; Pitt 1973;Stein 1980).

Increased risk of postnatal blues appears to be associated with poor family and/or marital relationships (Ballinger et al. 1979;Ehlert et al. 1990;Kennerley 1989)

5.5.1.4 Observations of postnatal blues

No specific literature was found on postnatal blues and observations for referral. In terms of postnatal blues as a prelude to the development of depression, the literature is conflicting. O'Hara et al (1991a) found up to 25% of women with postnatal blues went on to develop postnatal depression. However, Gard et al (1986) and Kennerley and Gath (1989) did not find an association between postnatal blues and depression. It has been suggested that women with postnatal blues should be encouraged to seek further evaluation if symptoms persist beyond 7 to 10 days (Jones & Craddock 2001) or 2 weeks (Seyfried 2003).

5.5.1.5 Interventions for postnatal blues

No intervention studies were found in the literature for postnatal blues. Expert opinion reviews on postnatal blues (Jones & Craddock 2001;Seyfried 2003) point out that due to the transient nature of postnatal blues, professional intervention is not typically indicated. However, they suggest that pregnant and newly delivered women should be educated about symptoms and reassured that postnatal blues are common and should resolve quickly without treatment. However, there is no evidence of the effectiveness of these interventions. The International Childbirth Education Association Position Statement and Review of Postpartum Emotional disorders (Steen 2003) suggests that postnatal blues can be improved by a new mother using good self-care techniques and making use of support systems. These include good nutrition, regular physical activity and

sleep, developing of a support system, having realistic expectations of motherhood, taking breaks to rest, practicing deep breathing, expressing and accepting negative feelings, structuring of the day, nurturing a sense of humour and postponing major life changes. Again, there is no validation of these self help suggestions.

5.5.1.6 Competencies for postnatal blues

There is no literature available on the competencies required for identification, intervention or referral.

5.5.1.7 Referral pathways for postnatal blues

There is no literature available on the appropriate referral pathways. Referral may not be appropriate in the majority of cases.

5.5.2 Identifying Mental Health Problems

Narrative Summary

Mental health problems that health professionals should be particularly alert to in the postnatal period include the onset of new disorders such as postnatal depression, puerperal psychosis, PTSD and panic disorder and relapse of other psychotic illnesses such as schizophrenia,. Women with existing diagnoses should be identified at booking (National Collaborating Centre for Women's and Children's Health. 2003) and care plans for postnatal management adhered to, based on their current mental state and risk of relapse (see NICE guideline on antenatal and postnatal mental health in development, www.nice.org.uk)..

5.5.2.1 Signs and symptoms

Postnatal depression

The term postnatal depression is usually used in clinical practice to refer to depression that presents at any time during the first year of giving birth. There is debate as to whether depression with onset in the first three months

postnatal differs from depression with antenatal onset that persists following the birth, or ‘late onset’ depression beginning after three months of the birth. Whatever the timing of onset, depression is an important issue for the woman, her baby and family, and early detection should be a priority. The prevalence of postnatal depression ranges from 4.5% to 28% (Scottish Intercollegiate Guidelines Network (SIGN) 2002). The variation in prevalence rates is due to use of different diagnostic criteria and assessment times. There is little evidence to indicate that symptoms of postpartum depression are different from symptoms of depression occurring at other times within the general population (Scottish Intercollegiate Guidelines Network (SIGN) 2002)

According to the American Psychiatric Association Diagnostic Manual of Mental Disorders (American Psychiatric Association Task Force on DSM-IV. 2000) 5 or more of the following symptoms must be present daily for at least two consecutive weeks:

- depressed mood
- loss of interest or pleasure (at least 1 of the 5 symptoms must be these)
- significant increases or decreases in appetite
- insomnia or hypersomnia
- psychomotor agitation or retardation
- fatigue or loss of energy
- feelings of worthlessness or guilt
- diminished concentration
- recurrent thoughts of suicide

For the definition of postnatal onset, an episode begins within four weeks after childbirth (American Psychiatric Association Task Force on DSM-IV. 2000).

The Edinburgh Postnatal Depression Scale was developed as a screening instrument to identify women at risk of postnatal depression (Cox et al. 1996;Cox, Murray, & Chapman 1993) and includes 10 items which ask the woman to choose the response which is closest to how she has felt in the last seven days. Each item is scored from 0 – 3. A score of ≥ 13 has been found to identify those women more likely to have depression (Cox, Holden, & Sagovsky 1987). It is not a diagnostic tool, and diagnosis should be made following psychiatric interview. The scale developers recommended three screening times within the first 6 months of birth to maximise identification of depression; 5 – 6 weeks, 10 – 14 weeks and 20 – 26 weeks (Cox et al. 1996). Variation in the timing of administration has not been reported to affect the scale's validity (Brown & Lumley 1998;Holden, Sagovsky, & Cox 1989)). Some postnatal studies have not included item 10 when using the EPDS (this asks women if the thought of harming themselves had occurred to them) and the EPDS has not been validated as a 9 item scale. Therefore, caution is suggested in evaluating these studies.

The potential benefit of using the EPDS as a community screening tool was recently reviewed on behalf of the National Screening Committee (NSC) (Shakespeare 2001). Six English language validation studies for the EPDS were included in the review. These studies assessed different populations, chosen and recruited in different ways, with variation in the timing of the administration of the EPDS. In only one study did a woman's own health visitor administer the questionnaire. There was marked variation in the Positive Predictive Value obtained in different studies, with no clear cut –off between "cases" and "non-cases."

Based on this review, the NSC recommended in 2002 that until more research was conducted into its potential for routine use in screening for postnatal depression the EPDS should not be used as a screening tool. It may, however, serve as part of a mood assessment for postnatal mothers, when it should be used alongside professional judgement and a clinical interview. Both the NICE Antenatal Guideline and the NICE Antenatal and Postnatal Mental Health Guideline which is in development have taken account of the NSC

recommendation. An update to the review was published in 2004, which did not present further evidence to alter the NSC recommendation.

It is considered to be good practice to ask women who have recently given birth about their emotional well-being, however several studies have shown that women may not find the EPDS or the way it is used to be acceptable, with the consequence that they may produce ratings that do not adequately reflect their feelings (Shakespeare, Blake, & Garcia 2004). The NICE guideline for antenatal and postnatal mental health will provide guidance on appropriate postnatal services for women who have depression.

Puerperal psychosis

Puerperal psychosis, the most severe form of de novo postpartum psychiatric disorder, affects one to two women per thousand (Scottish Intercollegiate Guidelines Network (SIGN) 2002). It usually presents in the early postpartum period, within the first month. Kendell et al (Kendell, Chalmers, & Platz 1987) found that psychoses admissions to hospital peaked in the first 30 days postpartum thereafter falling fairly rapidly. Puerperal psychosis is largely affective in nature (disorder of mood), although a few studies have shown atypical presentation such as mixed affective state, confusion and disturbed behaviour (Scottish Intercollegiate Guidelines Network (SIGN) 2002).

Presentation of cycloid psychosis among the general population frequently has a rapid onset (within 48 hours) and presents with several types of hallucination or delusion, changing in both type and intensity from day to day, or within the same day. The patient's emotional state varies in a similar fashion (American Psychiatric Association Task Force on DSM-IV. 2000). Motility psychosis presents with the addition of hyperkinesias or akinesia (Pfuhlmann et al. 1998;Wisner, Peindl, & Hanusa 1994). Psychotic illnesses which may have previously experienced, such as bipolar disorder or schizophrenia may also present as postpartum psychosis. These women may have a rapid onset of psychotic symptoms within the first few days or weeks after the birth.

The NICE guideline for antenatal and postnatal mental health will provide guidance on appropriate services for women with puerperal psychosis and other psychotic disorders.

Post-traumatic stress disorder (PTSD)

PTSD is an anxiety disorder that may occur after a confrontation with an extreme traumatic stressor, which could include giving birth. A prospective study of incidence of PTSD in 289 postpartum women showed that 2.8% of women fulfilled the criteria for the disorder at 6 weeks postpartum, and this decreased to 1.5% at 6 months postpartum (Ayers & Pickering 2001). The authors of the study used the MMPI-2-Post-traumatic Stress Disorder Scale. Czarnocka and Slade (Czarnocka 2000) found that 3% of postpartum women showed significant levels of PTDS symptoms at six weeks, as measured by the Post-traumatic Disorder Questionnaire measure (this was based on the American DSM-IV symptoms for PTSD). Creedy et al (2000) found that 5.6% of 499 postpartum women met DSM-IV-TR criteria for acute PTSD (PSS) at 4 to 6 weeks postpartum. Women were recruited in the third trimester and were identified as being at low risk for obstetric complications. Wijma et al (Wijma, Soderquist, & Wijma 1997) found that 1.7% of 1640 postpartum women met the DSM-IV criteria for PTSD. A traumatic event scale questionnaire was used that linked DSM -IV criteria for PTSD symptoms with the experiences of childbirth. The questionnaire was completed by the women between 1 to 13 months post delivery.

The signs and symptoms of PTSD according to the DSM-IV are: -

- persistent re-experiencing of the traumatic event
- persistent avoidance of stimuli associated with the event
- numbing of general responsiveness
- irritability
- poor concentration

- insomnia
- increased arousal

Symptoms must persist for at least 1 month and cause significant impairment in daily life.

Panic disorder

The DSM-IVTR states that the essential feature of panic disorder is the occurrence of recurrent and unexpected attacks of severe anxiety (panic), worry as to the significance of the attack or its consequences or significant changes in behaviour related to the attacks. A panic attack develops suddenly and is not restricted to a particular situation or set of circumstances. During an episode one or more of the following symptoms occur;

- choking sensation
- derealisation or depersonalisation
- dizzy, light headed, faint or unsteady
- fear of dying
- fears of loss of control or becoming insane
- heart pounds, races or skips a beat
- nausea or other abdominal discomfort
- numbness or tingling
- sweating
- shortness of breath or smothering sensation
- trembling

Panic disorder may or may not be associated with agoraphobia.

A study on the occurrence of panic disorder in 64 childbearing women found that 7 (10.9 %) of the women met the study criteria for postpartum onset of panic disorder (Sholomskas & Wickamaratne 1993). Postpartum onset was defined as the first panic attack occurring within 12 weeks post delivery, and the mean onset time was 7.3 weeks postpartum. The authors used probability statistics to conclude that onset was not a coincidental event.

No relevant literature was identified regarding specific observations needed for primary care clinicians to refer postpartum women for psychiatric evaluation. The recommended best practice guidance of the Scottish Intercollegiate Guideline Network, (Scottish Intercollegiate Guidelines Network (SIGN) 2002) is as follows:

1. Postpartum assessment of women's mood should encompass the understanding that normal emotional changes may mask depression symptoms or, conversely, emotional changes may be misinterpreted as depression.

2. Primary care teams should be aware that a shorter in-patient stay increases the likelihood of puerperal psychosis presenting following a mother's discharge.

Reference should also be made to other NICE guidance on mental health problems, details of which are given below.

5.5.2.2 Risk Factors

Postpartum depression

The risk factors for postpartum depression do not appear to differ to risk factors for non postpartum depression within the general population. The following have been consistently demonstrated to have an association with postpartum depression (Scottish Intercollegiate Guidelines Network (SIGN) 2002):

- past history of psychopathology and psychological disturbance during and after pregnancy
- low social support

- poor marital relationship
- recent life events
- postnatal blues

In addition, cohort and case control studies have identified the following as possible risk factors for postpartum depression (Scottish Intercollegiate Guidelines Network (SIGN) 2002):

- parents perceptions of their own upbringing
- unplanned pregnancy
- unemployment
- not breastfeeding
- antenatal parental stress
- antenatal thyroid dysfunction
- coping style
- longer time to conception
- depression in fathers
- emotional lability in maternal blues
- low quality social support
- having two or more children

Whilst individual factors may be associated with future depressive illness, health care professionals should ensure they are able to identify current illness, and are advised to refer to the NICE guideline ‘Antenatal and postnatal mental health: clinical management and service guidance’, for information on identification of symptoms.

Puerperal psychosis

Risk factors for puerperal psychosis are (Scottish Intercollegiate Guidelines Network (SIGN) 2002):

- past history of puerperal psychosis
- pre-existing psychotic illness
- family history of affective psychosis in first or second degree relatives

Post Traumatic Stress Disorder

Risk factors for PTSD following childbirth have only been explored relatively recently. There have been no large, prospective longitudinal studies conducted to date which could provide evidence of factors which may predict onset. Studies conducted to date have examined associations between a range of factors and PTSD, however due to methodological limitations, findings should be treated with caution. Czarnocka and Slade] (Czarnocka 2000) identified the following as risk factors for PTSD following delivery;

- unplanned pregnancy
- no partner present at birth
- past mental health problems,
- experiencing anxiety
- having an episiotomy during birth.

Wijma et al (1997) showed that nulliparity and a history of having received psychiatric/psychological counselling increased risk (1997), while Creedy et al (2000) identified the following obstetric complications with symptoms of PTSD;

- emergency caesarian section,
- forceps delivery,

- vacuum delivery
- high levels of pain.

Panic disorder

No specific literature was found on risk factors for panic disorder.

5.5.2.3 Debriefing interventions

Narrative Summary

Debriefing is an intervention which has been offered following traumatic events to prevent PTSD, however a Cochrane systematic review on psychological debriefing for preventing post-traumatic stress disorder in the general population (PTSD) found no evidence that single session debriefing prevented onset (Rose 2003).

A systematic review assessed the literature on debriefing or non-directive counselling specifically directed to prevent postpartum emotional distress (Gamble et al. 2002). Nine studies were identified. Of these, five were excluded because women's psychological morbidity was not measured and the women were seen at any stage postpartum, even years later. Another study used a cognitive-behavioural therapy intervention and therefore did not fulfil the criteria for a primary prevention (i.e. debriefing). Three randomised control trials fulfilled inclusion criteria. Two RCTs (Priest et al. 2003;Small et al. 2000) found that the debriefing intervention had no effect on depression while the third RCT (Lavender & Walkinshaw 1998) showed that the control group had higher levels of anxiety and depression. The studies by Small (2000) and Priest (2003) had relatively large sample sizes (1041 and 1745 women, respectively), while Lavender and Walkinshaw (1998) included 120 women. Small et al's (2000) intervention was an hour-long debriefing session during the postnatal stay conducted by a trained research midwife. The outcome measures were the EPDS, and the physical, mental and social health component scores of the SF-36. Priest et al's (2003) intervention was a single structured stress debriefing interview (lasting 15 minutes to 1 hour) conducted by a trained research

midwife within 96 hours of birth. The outcome measures used included the EPDS, Beck Depression inventory, General Health Questionnaire GQH-58 and an assessment by a psychologist. Lavender et al's (Lavender & Walkinshaw 1998) intervention was a 30-120 minute unstructured interview with a research midwife during the postnatal stay. The main outcome measure was the Hospital Anxiety and Depression Scale (HAD scale) which has not been validated for use on postpartum women. A commentary on the study suggested that the timing of the debriefing session and follow up at three weeks postpartum may have affected women's experience of the blues rather than postpartum depression (Wessely 1998).

In all three trials, women reported that the debriefing was helpful. It was therefore suggested that although debriefing may not reduce postpartum psychological morbidity (using 'caseness' criteria of research tools), a listening visit intervention may reduce emotional distress (Gamble et al. 2002) but further research is required.

5.5.3 Competencies

Competencies for referral in the literature are largely based on the use of screening tools. Validation of screening tools is beyond the remit of this Guideline and will be covered in the Antenatal and Postnatal Mental Health guideline to be published by NICE. Reference should also be made to the NICE guideline PTSD: The Management of PTSD in adults and children in primary and secondary care, and other NICE guidance for specific disorders which include Depression, Anxiety Disorders, PTSD, eating disorders, schizophrenia and bipolar disorders (www.nice.org.uk).

5.5.4 Referral pathways

For identification of, and referral pathways for, psychological and psychiatric problems after birth,, referral should be made to the NICE guidelines on Antenatal and Postnatal Mental Health or those for specific disorders which include Depression, Anxiety Disorders, PTSD, eating disorders, schizophrenia and bipolar disorders. (www.nice.org.uk).

5.6 Physical Health and Well being

Introduction

It is only within the last decade that studies have systematically documented the range of physical and psychological health problems experienced by women after childbirth (Brown & Lumley 1998;Glazener et al. 1991;MacArthur, Lewis & Knox 1991;Thompson & Alibhai 2003) many of which are unreported to or identified by healthcare professionals. A few studies have identified the incidence of symptoms occurring for the first time after giving birth, whilst others have documented all health problems, regardless of onset. It is clear that in many cases, symptoms persist beyond the postnatal period and in some cases can affect women's daily lives. The identification and management of ten common health problems are addressed here: perineal pain, dyspareunia, urinary incontinence, urinary retention, constipation, haemorrhoids, backache, headache, fatigue and faecal incontinence. Each of these morbidities, with the exception of faecal incontinence and urinary retention, has an incidence of 10% or greater in the literature which assesses postpartum wellness (Brown & Lumley 1998;Glazener et al. 1995;MacArthur, Lewis, & Knox 1991;Thompson & Alibhai 2003). Both faecal incontinence and urinary retention are potentially serious and disabling conditions which are under reported and under diagnosed and are therefore included in this review (MacArthur, Bick, & Keighley 1997). Breastfeeding issues are addressed in a separate chapter.

5.6.1 Perineal Care

Narrative Summary

5.6.1.1 How is perineal pain identified?

Perineal pain is commonly experienced by women who have had a vaginal birth, however much of the evidence available comes from studies of perineal management which have included this symptom as an outcome measure. The degree of pain experienced is a subjective assessment, made by the woman herself and the literature does not identify or recommend any standard method of perineal pain assessment. In the numerous studies, both quantitative and

qualitative, reviewed for this topic, pain intensity measures included visual scales, visual tools and questionnaires as well as healthcare provider observations. In many cases, assessments were made using tools developed for use in general populations. In some studies other indicators of pain severity included total dosage of analgesia used, weight of total amount of topical medication applied to relieve pain and/or frequency of treatments. Timing of assessment of perineal pain often differs between these studies and there is very limited information on long-term effects perineal pain..

5.6.1.2 How is perineal pain managed?

Strategies to relieve perineal pain can start with primary, secondary and tertiary prevention. The management of the perineum before and during birth (primary and secondary prevention) is not considered in detail here, as these will be addressed by other NICE guidance on intrapartum care.

Given the findings of the studies of maternal morbidity reported earlier which showed that women were reluctant to report symptoms, and healthcare professionals did not ask about them, it has been suggested that more attention should be given to asking women about their experiences. Salmon (Salmon 1999) in a study which presented data from unstructured interviews with 16 women about their experiences of childbirth suggested that improvements were needed in the interpersonal skills of healthcare professionals. Women felt that their concerns were not taken seriously. The practitioner's attitude toward their pain was identified as one of three themes emergent from the interviews. The researcher suggested that, "listening to women is the key to responsive care."

Dymond (Dymond 1999) found that among 59 midwives who worked in the maternity unit of a district hospital and were asked about their practice in relation to perineal management, 24% examined every woman's perineum; 65% examined women who had experienced perineal suturing; and 70% examined women who complained of perineal discomfort.

In addition to studies which have examined specific clinical interventions to prevent or minimise perineal trauma, other studies have examined the effectiveness of a variety of pain management modalities including, oral and

rectal analgesia, topical application of pharmacological and non-pharmacological preparations, bathing, complementary therapies and therapeutic ultrasound.

Local anaesthetics and non pharmacological preparations

Perineal pain is routinely treated by the application of local treatments to the perineum, including anaesthetic and non-pharmacological preparations. Some treatments, for example ice packs may be more commonly used than others as they are more readily available to women. Concerns that application of ice may delay healing due to vasoconstriction (Sleep 1995) were allayed in a meta-analysis of cold therapy undertaken by Steen (Steen & Cooper 1998). None of the studies on cold treatment of perineal trauma reported a delay in wound healing. Likewise, none of the papers reviewed for cold therapy in non perineal areas for surgical and non surgical procedures reported any delay in healing. Members of the same research team later conducted an RCT which included 120 women who had undergone an instrumental delivery to compare the effectiveness of icepack and Epifoam (an anti-inflammatory steroid-based foam applied directly to the trauma site), both commonly used at the study hospital, with cooling maternity gel pads specifically developed by the researchers (Steen et al. 2000). Treatments were administered whilst women were on the postnatal ward. No significant difference in pain was found but bruising and oedema were significantly lower in the gel pad group at 48 hours. A second RCT undertaken by Steen (Steen 2002) compared the effectiveness of the cooling gel pads with ice pack or no treatment. Both treatments were significantly better than placebo. There was no difference in healing between the three treatment groups. There was a trend toward less pain in the gel pad group. Women reported excellent (30% vs. 13%) or very good response (41% vs 25%) to gel pads compared with ice.

The effectiveness of three topical applications, Epifoam, hamamelis water (witch hazel) and ice were compared by Moore and James (Moore & James 1989) in an RCT which recruited 300 women who had an episiotomy for an instrumental delivery, were randomised to one of the three groups at delivery. The first application of the pain relieving agent was administered immediately following

repair of the perineal trauma, and women were told they could apply the agent at any time following this. Complete data were available for 205 women whose pain levels were assessed on the postnatal ward; 34 women were excluded as the trial protocol was not adhered to. Data were also obtained from the 126 women who attended their 6 week check at the hospital. No significant differences were found in pain levels on the first day post delivery or at six weeks postpartum, and no differences in wound healing, timing of resumption of first sexual intercourse or dyspareunia were found at 6 weeks.

A series of three small RCTs undertaken by Harrison and Brennan (1987;1987a;1987b) compared topical applications of alcoholic and aqueous lignocaine vs. cinchocain (a synthetic local anaesthetic used primarily in Germany) and mefenamic acid. Aqueous lignocaine appeared to be "slightly more effective" (p values were not provided) than the other three preparations, however as healthcare professionals were not blinded to group allocation it is possible that observer bias may have accounted for some of the differences. Corkill et al (2001) evaluated lignocaine gel versus placebo in 149 women with first or second degree perineal tears in a double-blind placebo controlled trial which was carried out in one maternity unit in the north-west of England. Women using the gel had lower average pain scores which reached significance on the second postpartum day, with no statistical difference in use of oral analgesia. As this was a secondary outcome (pain at 24 hours was the primary outcome), larger studies would be required to assess the effectiveness of gel in the immediate postnatal period. An RCT from Texas to assess the efficacy of 5% lidocaine ointment (n = 108) compared with placebo (n = 92) found this was not effective in relieving pain experienced following an episiotomy or perineal laceration (Minassian.V.A & Jazayeri 2002). A comparison of epifoam and lignocaine gel showed no difference between these preparations but both were more effective than placebo (Hutchins, Ferreira, & Norman-Taylor 1985).

In 2005 a Cochrane review of topically applied anaesthetics for treating perineal pain after childbirth was published (Hedayati, Parsons, & Crowther 2005). Eight trials which presented data on 976 women were included in the review. Three different topical anaesthetics were evaluated in the trials, including lignocaine,

cinchocaine and a topical preparation of 1% hydrocortisone acetate and 1% pramoxine hydrochloride. Different methods of measuring pain were used, which made trial comparisons difficult, and in some studies oral analgesia was used in addition to the topical application. From the limited data available, the authors concluded that the evidence to support the use of topically applied anaesthetics was not robust.

Oral Analgesia

One of the most commonly used analgesics to relieve mild perineal pain is paracetamol (Sleep & Grant 1988b), and studies which have assessed the effectiveness of oral analgesia have consistently shown an effect of treatment over placebo. Skovlund et al (1991) in a small RCT from Norway which included 33 women who had an episiotomy, data from whom were collected as part of a sub-group of a study of pain relief for uterine cramps, compared paracetamol with placebo and found paracetamol significantly superior to placebo.

A study of oral paracetamol versus hydrocodeine (Beaver & McMillan 1980) for pain relief among women who had either an episiotomy or uterine pain within 48 hours of giving birth showed comparable levels of pain relief between doses of 1000 mg paracetamol and 10 mg hydrocodeine. Treatment with naproxen (non-steroidal anti-inflammatory NSAID) versus paracetamol showed no significant difference in pain outcomes.

Ghosh et al (Ghosh et al. 2004) evaluated an analgesic protocol for the management of pain caused by perineal trauma within a four stage quality improvement project in one French maternity unit. In the first part of the study an audit of the morbidity and outcome of the existing medical management of perineal pain was undertaken. Only 51% of women who had perineal trauma sutured (n=126) had received analgesia. In the second phase of the study either ketoprofen 50mg and paracetamol 1g or if there were contraindications to NSAIDS, dextropropoxyphene 60 mg and paracetamol 800 mg, were provided to women with instructions on self-administration every 6 hours for the first 48 hours, then on an as needed basis for the third day. Pain levels were assessed at 6 hourly intervals using a numerical rating scale. Phases 3 and 4 repeated

the pain evaluation undertaken during Phase1. Significantly more women received analgesia using the self administered protocol ($p<.05$) than previously. However, results from this study must be carefully interpreted as the internal validity was poor.

Suppositories

A Cochrane review (Hedayati 2003) of non-steroidal anti-inflammatories given rectally after episiotomy which included three RCTs presenting data on a total of 249 women concluded that this method of pain relief was associated with less discomfort up to 24 hours after birth. None of the studies presented data on pain levels after three days of the birth, or effect on other outcomes. The route of administration may be unacceptable to some women.

Bathing

The effectiveness of bathing to relieve perineal pain has also been considered. Hill (Hill 1989) found no significant difference in the REEDA score (a tool used to asses wound redness, oedema, ecchymosis, or discharge and approximation of the skin edges) between postpartum women randomised to warm pack treatment, cold packs or warm sitz baths. Ramler and Robert's study (Ramler & Roberts 1986) of cold and warm sitz baths showed that cold sitz baths were significantly more effective in relieving perineal pain, however the effect was limited to the first 30 minutes after delivery. The fact that 119 of 159 women asked to take part in the study refused to do so suggests few women would opt for this method of pain relief. Bath additives were also assessed by Sleep and Grant (Sleep & Grant 1988a) in an RCT which randomised 1800 women who had a vaginal delivery to one of three groups. A 25ml sachet of 'Savlon' bath concentrate which has both antiseptic and cleansing properties was added to bath water each day for the first 10 days after delivery and compared to salt added to water and to plain water baths. No significant differences in pain or patterns of wound healing were noted at 10 days or at three months, and no differences in timing to resumption of intercourse nor problems experienced at three months. Women did report that bathing provided some relief from the discomfort they were experiencing.

Therapeutic ultrasound

A commonly used treatment used to promote healing of soft tissue injuries, particularly following sports injuries, is therapeutic ultrasound. Hay-Smith (Hay-Smith 1998) reviewed the use of ultrasound for postpartum perineal pain and dyspareunia for a Cochrane review. Four trials which were of variable quality were included, presenting data on 659 women. There was insufficient evidence to enable conclusions to be made about the use of ultrasound in treating perineal pain or dyspareunia, and evidence from large, high quality RCTS is now required.

Complementary Therapies

Dale and Cornwall (Dale & Cornwell 1994) investigated the role of lavender oil in relieving perineal discomfort and compared pure lavender oil, synthetic oil and one inert substance added to bathwater every day for the first 10 days after giving birth. 635 women were randomised to one of the three study groups. Post hospitalisation data were collected by community midwives who reinforced the procedure. No statistically significant differences were found between groups from daily perineal discomfort scores obtained using a visual analogue scale.

5.6.1.3 What competencies are needed to identify and manage perineal pain?

Specific competencies are not identified in the literature.

5.6.1.4 When and how often should women be assessed for perineal pain?

Frequency of assessment for common health problems is not specified in the literature.

5.6.1.5 What information about perineal pain does a woman need to maintain health and well being?

Informational needs of women regarding perineal pain have not been described in the literature.

5.6.2 Dyspareunia

Narrative Summary

5.6.2.1 How is dyspareunia identified?

Dyspareunia is a subjective experience of painful or difficult intercourse, and is likely to be associated with perineal pain (Glazener 1997). It is been a neglected area of maternal health, with data that are available usually obtained from studies of perineal management regimes. Due to the timing of questioning which differs between studies, there is likely to be recall bias with regard to onset, severity and duration of problems. Glazener conducted a longitudinal survey of health problems after childbirth among a 20% random sample of all women (n = 1249) who gave birth in the Grampian region of Scotland during a 12 month period. Women were asked to complete postal questionnaires at 8 weeks, and 12-18 months postnatally. Problems with intercourse were reported by 53% of women in the first eight weeks after delivery and 49% after the first two months. The need for help or advice with problems with intercourse was expressed by 13% of women at two months postpartum but a quarter of these did not seek assistance. The study found that many women resumed intercourse within 6 weeks of giving birth.

5.6.2.2 How is dyspareunia managed?

No studies were identified which evaluated management strategies for postpartum dyspareunia. A survey by Greenshields et al (1993) revealed that some women use oils or gels, or relaxation techniques.

5.6.2.3 What competencies are needed to identify and manage dyspareunia?

The literature does not identify specific competencies in this area. Barrett et al (1999) surveyed 85 women who attended their 6 week postnatal check. 31% were asked about problems with their perineum/vagina. Ten women (11%) said they wanted to ask something, including questions about sexual matters, but felt they could not. Glazener (Glazener 1997) suggested that postnatal sexual counselling and advice should be emphasised in postgraduate GP education.

5.6.2.4 When and how often should women be offered assessment of dyspareunia?

No research was located which addressed the frequency of sexual assessment.

5.6.2.5 What information about dyspareunia does a woman need to maintain health and well being?

The research literature does not address informational needs.

5.6.3 Headache

Narrative Summary

5.6.3.1 How is headache identified?

Headache is a commonly reported symptom among the general population. The literature identifies three common headache types: migraine, tension and cervicogenic (Bronfort et al. 2001;Scharff, Marcus, & Turk 1997), and it is not known if these are more likely to be experienced by women who have recently given birth. Information on experiences of headache during the postpartum period has been obtained from studies of maternal morbidity, some of which may be triggered by a particular event during labour. Headaches were reported by 14% of women whilst on the postnatal ward, 22% of women between discharge and 8 weeks postpartum and 15% at 12 – 18 months after the birth in the large prospective observational study of health problems after childbirth undertaken by Glazener and colleagues (1995).

A post dural puncture headache (PDPH) may occur following the administration of an epidural or spinal needle (Sudlow & Warlow 2001) and results from the puncture of the dura mater. Spinal anaesthesia necessitates the puncture of the dura, whilst an accidental puncture may occur with epidural anesthesia. The incidence of accidental dural puncture has been reported as between 0.5% and 1% by Stride et al (Stride & Cooper 1993); 1.5% by Choi and colleagues (Choi et al. 2003) and 1.7% by Chan et al (Chan et al. 2003). Choi et al reported that

approximately half of those who were punctured suffered a post dural headache. In one study of long-term health problems after childbirth (MacArthur, Lewis, & Knox 1993) 74 of 11,701 women were recorded as having an accidental dural puncture, 23% of whom reported headaches or migraine lasting for longer than six weeks. Stride and Cooper (Stride & Cooper 1993) undertook a case note analysis of women with accidental dural puncture from one maternity unit, which found an incidence of PDPH of 86%.

The identification of PDPH is by maternal symptoms or the diagnosis could be based on observation of cerebrospinal fluid (CSF) on insertion of an epidural and/or signs and symptoms characteristic of a dural puncture headache. These include a headache which worsens when the individual is upright, and relieved when assuming a supine position and is sometimes accompanied by nausea, vomiting and tinnitus.

Some studies have considered headache occurrence in the absence of a labour event. Stein et al (Stein et al. 1984) investigated the aetiology of postpartum headache in a small cohort study of 71 women with and without headache in their first postpartum week and found that there was a strong association with migraine history ($p<0.01$). Diagnosis is difficult as the nature of postpartum headache is uncertain. Headaches are not usually full-blown attacks of classical migraine and could be due to tension as well. However, 83% of the postnatal headache subjects in their study had a migraine predisposition. The authors concluded that the postpartum headaches experienced by the women in their study probably represent mild episodes of common migraine and were an example of the triggering effect that progesterone hormone withdrawal has among migraine subjects

5.6.3.2 Management of postpartum headache

As the literature does not evaluate specific postnatal management of headache unrelated to dural puncture, general population studies have been considered. Alternative therapy, in the form of spinal manipulation among the general population was reviewed by Bronfort et al (2001). Statistical pooling of the 9 studies in their review was not possible due to study differences, however using

their predefined criteria, the research team determined that there was "moderate" evidence that spinal manipulation had short term efficacy comparable with amitriptyline in the prophylactic treatment of chronic tension type headache and migraine. Vernon et al (1999) reviewed 24 RCTs in the categories of acupuncture, spinal manipulation, electrotherapy, physiotherapy, and homeopathy as treatment for non-migrainous headache. They concluded that electrotherapy to cranial muscles would appear to have enough evidence to support its use in treating tension headache. Homeopathy was not recommended. The evidence base for other treatment modalities was not sufficient to reach clear conclusions. In one small study, Scharff et al (1997) followed 30 women who were treated with physical therapy, relaxation training and biofeedback for headache during pregnancy. Twenty four (80%) women experienced immediate significant relief and 16 (67%) continued to report a reduction in symptoms during their pregnancy. There was no control for confounding in this study.

In a Cochrane review based on data from 24 RCTs, Sudlow and Warlow (2001) analysed standard preventive measures for post-dural puncture headache, including acupuncture, spinal manipulation, physiotherapy and homeopathy. They reviewed studies involving patients undergoing any type of dural puncture for any reason and found that there was no good evidence to suggest that routine bed rest after dural pucture was beneficial. The role of fluid supplementation was uncertain based on available evidence which was only presented in one of the included trials.

5.6.3.3 What competencies are needed to identify and manage postpartum headache?

Competencies are not described in the literature. Given early postnatal discharge, there may be a need to ensure community based healthcare professionals ask about signs and symptoms of PDPH among women who had spinal or epidural anaesthesia at delivery.

5.6.3.4 When and how often should women be offered assessment of postpartum headache?

Frequency of assessment is not described in the literature.

5.6.3.5 What Information about postpartum headache does a woman need to maintain health and well being?

The educational needs of women are not described in the literature.

5.6.4 Fatigue

Narrative Summary

5.6.4.1 How is fatigue identified?

Fatigue is also a commonly reported symptom amongst the general population, and one likely to be experienced by many women after childbirth. Cahill (Cahill 1999) proposed a definition of fatigue in women which differentiated it from the tiredness experienced at the end of the day: “Fatigue is defined as the sensation of profound tiredness that is not relieved by rest or sleep and is not associated with vigorous or prolonged activity.” Cahill also differentiated between physiologic fatigue and psychogenic fatigue and noted that different treatment modalities would be required. In their study of long-term health problems after childbirth, MacArthur and colleagues (1991) linked information on health problems experienced for the first time after the birth with women’s obstetric case notes and found that independent risk factors for extreme fatigue were associated with long first stage of labour, postpartum haemorrhage and associated anaemia, older mothers, especially having their first baby, twins, small babies and breastfeeding. For many women, symptoms of fatigue persist well beyond the 6 – 8 week postnatal period (Bick & MacArthur 1995;MacArthur, Lewis, & Knox 1991).

The identification of fatigue is through maternal self report.

5.6.4.2 How is fatigue managed?

One study was identified in the literature which evaluated the effectiveness of a self-care intervention, the “Tiredness Management Guide,” for the management

of postpartum fatigue (Troy & Dalgas 2003). There was a statistically significant decline in morning fatigue only by the fourth week postpartum.

No other management research was identified.

5.6.4.3 What competencies are needed to identify and manage postpartum fatigue?

No literature on competencies for management of postpartum fatigue was identified.

5.6.4.4 When and how often should women be offered assessment for postpartum fatigue?

No research on frequency of assessment was identified.

5.6.4.5 What information about postpartum fatigue does a woman need to maintain health and well being?

Research on women's educational needs was not identified.

5.6.5 Backache

Narrative Summary

5.6.5.1 How is back pain identified?

Backache may be experienced by up to half or more women during pregnancy, with varying degrees of severity, however women's experiences of this symptom postpartum have only recently been investigated, with some studies including backache as an outcome measure to assess the association with epidural analgesia during labour. MacArthur et al (1991) in a retrospective study of 11,701 postnatal women questioned 1 – 9 years after giving birth, found that 1634 (14%) reported new backache after the index birth, which lasted for longer than 6 weeks. The use of epidural analgesia was significantly associated with backache. Russell et al (Russell et al. 1993) investigated the factors associated with long term backache after childbirth (defined as new backache occurring within 3 months of the delivery and lasting for over 6 weeks). A postal

questionnaire surveyed 1015 primiparous women 12-15 months after their delivery. Six hundred and twelve of these women received an epidural and 403 did not. According to this survey, epidural analgesia during labour was a strong predictive factor for the onset of long term backache ($p<0.01$). Antenatal headache and abdominal pain were also associated with the development of long term backache. Thirty six women with symptoms of persistent back pain were seen in an outpatient clinic where it was observed that most backache was postural and not severe. Backache as a problem at some time since giving birth was reported by 547 (44%) of 1336 women included in an Australian study of postnatal health at 6 – 7 months after the birth, with use of epidural analgesia identified as a risk factor.

However, several subsequent studies have not found an association with backache and use of epidural analgesia. Two prospective randomised controlled trials evaluated the association between epidural analgesia and backpain. Howell et al (Howell et al, 2001) randomised 369 women to epidural or non epidural analgesia and assessed backache at three and twelve months after delivery by postal questionnaire. There was no significant difference in reported backache between groups at either time interval.

In another prospective RCT 611 women were randomized to receive either epidural analgesia or meperidine (Loughnan et al. 2002). A questionnaire on postnatal symptoms was sent to them at six months postpartum. There was an 83% response rate. There was no significant different between groups in the prevalence of symptoms of backache at 6 months postpartum, nor was there any signifificant difference in the incidence of new symptoms.

In a small Canadian study, Macarthur et al (1997) evaluated back pain among 164 women who chose epidural and 165 who did not at 1 and 7 days and 6 weeks after delivery. After excluding women who had pregnancy backache, the only statistically significant difference in new postpartum backache was found at day 1(52% epidural vs 39% no epidural). At six weeks there was a twofold epidural excess (15% vs. 7%), and at 1year 10% had backache in the epidural group and 14% in the non epidural group. Moir and Davidson (Moir & Davidson

1972) showed in a small study of 100 women that there was no significant difference in the incidence of postpartum headache, frequency of micturition or backache between women with epidural versus pudendal block.

The introduction of mobile epidural techniques, which use lower concentrations of local anaesthetic, together with an opiate, which produces a less dense block and allows women to mobilise during labour, may reduce adverse effects of traditional epidurals (Bick, MacArthur, Knowles, & Winter 2002) however further research is required.

Backache is identified by maternal self report.

5.6.5.2 How is back pain managed?

No studies were identified which identified effective interventions for backache in the postpartum period.

An RCT was carried out in Oxfordshire and Reading, Berkshire amongst a general population of adults with physiotherapy referrals for back pain (Frost et al, 2004). This study compared advice for low back pain with a standard course of physical therapy. The primary outcome was evaluated using the Oswestry disability index at 12 months. Seventy percent of patients provided follow up information at 12 months. There was no significant change in Oswestry scores at 12 months and the researchers concluded that routine physiotherapy seemed to be no more effective than one session of assessment and advice from a physiotherapist.

A Cochrane review (van Tulder et al. 2000) analysed studies of lumbar supports for the prevention and treatment of low-back pain among the general population. No evidence was found on the effectiveness of lumbar supports for secondary prevention. The review of therapeutic trials showed that there is limited evidence that lumbar supports are more effective than no treatment. It is still unclear if lumbar supports are more effective than other treatment for low back pain.

There were no studies identified which addressed the effectiveness of oral analgesia for back pain in the postpartum woman.

5.6.5.3 What competencies are needed to identify and manage back pain?

No studies were found which addressed the competencies required to manage postpartum back pain.

5.6.5.4 When and how often should women be offered assessment for back pain?

No research was found regarding the frequency of assessment of back pain.

5.6.5.5 What information about back pain does woman need to maintain health and well being?

Research literature regarding women's educational needs concerning back pain in the postnatal period was not identified.

5.6.6 Constipation

Narrative Summary

5.6.6.1 How is constipation identified?

Constipation is a deviation from normal bowel habits resulting in decreased frequency and regularity of defecation and alteration in the composition of stool (Tiran 2003). Constipation is identified by maternal self-report.

5.6.6.2 How is constipation managed?

A Cochrane review by Jewell and Young (Jewell 2001) concluded that dietary supplements of fibre in the form of bran or wheat fibre are likely to help women experiencing constipation in pregnancy. If the problem fails to resolve, stimulant laxatives are likely to prove more effective.

Research specific to constipation in the postpartum period was not identified.

5.6.6.3 What competencies are needed to identify and manage constipation?

No research was found which addresses the competencies in this area.

5.6.6.4 When and how often should women be offered assessment for constipation?

Research literature was not identified which addressed frequency of assessments.

5.6.6.5 What information about constipation does a woman need to maintain health and well being?

Research on the educational needs of women experiencing postpartum constipation was not identified.

5.6.7 Haemorrhoids

Narrative Summary

5.6.7.1 How are haemorrhoids identified?

Haemorrhoids result from swollen veins around the anus and are associated with chronic straining due to either constipation or diarrhoea. They are common during pregnancy and childbirth but the pathophysiology is not understood.

Identification of haemorrhoids can occur through maternal report or through observation and/or examination of the anus which may occur during the postpartum period.

No research was identified which described methods of identification.

5.6.7.2 How are haemorrhoids managed?

No literature addressing specific postpartum haemorrhoid treatment was located. In the protocol written for a pending Cochrane review by Alonso et al (Alonso, Johanson, & Martinez 2003) it is noted that neither dietary factors nor the use of physical or pharmacological topical agents has been proven. Phlebotonic medications (heterogeneous group of medications mainly used to treat chronic venous insufficiency) have not been reviewed.

5.6.7.3 What competencies are needed to identify and manage haemorrhoids?

There was no research on competencies identified.

5.6.7.4 When and how often should women be offered assessment for haemorrhoids?

Frequency of assessment was not addressed in the research literature.

5.6.7.5 What information about haemorrhoids dies a woman need to maintain health and well being?

Maternal educational needs in this area were not found in the literature searched.

5.6.8 Faecal Incontinence

Narrative Summary

5.6.8.1 How is faecal incontinence identified?

Childbirth may induce either mechanical or neurologic injury to the anal sphincter. This may result in anal incontinence of feces or flatus.

In a study from the West Midlands (MacArthur, Bick, & Keighley 1997), 906 women who gave birth in one maternity unit between April and September 1992 and experienced one or more health problems within three months of delivery lasting longer than six weeks were interviewed a mean of 45 weeks after the birth. Thirty six women (4%) developed new faecal incontinence after the index birth, 22 of whom had unresolved symptoms at the time of the interview. Only 5 had consulted a doctor. Among vaginal deliveries, forceps and vacuum extraction were the only independent risk factors. Twelve (33%) of those with new incontinence had an instrumental delivery compared with 114 (14%) of the 847 women who had never had faecal incontinence.

In 1993 Sultan et al published a prospective study of women at two London hospitals before and after delivery to establish the incidence of occult anal sphincter trauma during childbirth. Two hundred and two women were examined during the last 6 weeks of pregnancy and were re-evaluated six to eight weeks after delivery. The assessments included anal endosonography,

manometry, studies of pudendal nerve terminal motor latency and perineometry as well as a detailed questionnaire to identify symptoms of faecal urgency or incontinence. Of the 127 women who returned for follow up and who delivered vaginally, 13 (10 percent) had one or both bowel symptoms. No sphincter defect was detected before delivery in any primiparous woman. At six weeks after delivery 28 women (35%) had defects. Nineteen (40%) multiparous women had a sphincter defect before delivery, and 21 (44%) after delivery. The internal sphincter was injured more frequently than the external sphincter and was sometimes damaged when the perineum remained intact. The terminal motor latency of each pudendal nerve was measured in 63 primiparous and 33 multiparous women. Latency was significantly increased in both nerves in women from both groups who underwent vaginal delivery ($p<0.001$ in primiparous and $p<0.002$ and $p<0.009$ in multiparous). None of the 13 women with disturbances of bowel function had spontaneously reported their symptoms or sought medical attention.

A study performed in Lyon France examined 52 primiparous women using transanal ultrasound and manometry (Damon et al. 2000). Thirty eight women were asymptomatic, 28 of whom had a sphincter defect. Ten of fourteen symptomatic women had a defect. Although anal sphincter defects were common after vaginal delivery, this study suggests that they were not necessarily associated with functional or clinical abnormalities.

A prospective study at St. George's Hospital, London investigated the effect of pregnancy and delivery on anal continence, sensation manometry and sphincter integrity (Chaliha et al. 2001). One hundred and sixty one primiparous women recruited consecutively, were evaluated at 34 weeks gestation and subsequently completed a symptom questionnaire and underwent anal manometric and sensation evaluations and anal endosonographic examinations. The prevalence of faecal urgency before, during and after pregnancy was 1%, 9.4%, and 10.5% respectively. The prevalence of anal incontinence before, during and after pregnancy was 1.4%, 7.0% and 8.7% respectively. Thirty eight percent of women had evidence of sphincter trauma. Despite the high prevalence of sphincter defects, fewer than half of the women with a defect had symptoms.

A meta-analysis to determine the incidence of obstetric anal sphincter damage was undertaken by Oberwalder et al (2003). A Medline search yielded five studies with more than 100 subjects who underwent anal ultrasound after childbirth for evaluation of anal sphincter defects and who were questioned about symptoms of faecal/anal incontinence as defined by impairment in flatus and stool control but not including urgency. The meta-analysis showed a 26.9% incidence of anal sphincter defect in primiparous women and an 8.5% defect in multiparous. Overall 29.7% of anal sphincter defects were symptomatic. The probability of faecal incontinence associated with an anal sphincter defect was 76.8-82.8%.

Anal incontinence is more likely to be associated with vaginal delivery and several studies have investigated additional risk factors in women delivered vaginally, however evidence to support a protective effect of caesarean section is not conclusive.

A French study (Abramowitz et al. 2000) surveyed 259 consecutively recruited women in Paris who were asked to complete a questionnaire assessing faecal incontinence prior to anal endosonography six weeks before giving birth and eight weeks after the birth. New sphincter defects were observed in 1.7% of women, but only after vaginal delivery. Independent risk factors for sphincter defects were forceps delivery (OR 12, CI 4-20), perineal tears (OR16, CI 9-25) episiotomy (OR 6.6, CI 5-17) and parity (OR 8.8, CI 4-19). The overall rate of anal incontinence was 9%. Among these women only 45% had sphincter defects. The researchers postulated that latency of the pudendal nerve may also contribute to symptoms of faecal incontinence.

MacArthur et al (MacArthur et al. 2001) sent postal questionnaires at three months postpartum to all women who were delivered during 1993-1994 in three maternity units in Dunedin New Zealand, Aberdeen Scotland and Birmingham England. A total of 7879 questionnaires were returned, a 71.7% response rate. The prevalence of faecal incontinence was 9.6%. In primiparous women (n=3261), a forceps delivery was significantly associated with faecal incontinence (OR 1.94, 1.30-2.89). Vacuum extraction was not associated with

faecal incontinence at three moths postpartum. No associations were found for induced labour, duration of second stage, episiotomy, laceration or birth weight.

Christianson et al (2003) conducted a retrospective case control study in which 2078 obstetric records were reviewed, and 91 cases of documented anal sphincter injury were identified. Delivery with forceps was associated with a 10 fold risk of perineal injury (OR 11.9, CI 4.7-30.4) and midline episiotomy was also a risk factor (OR 2.5, CI 1.0-6.0). These women represented only those with identified anal sphincter injury, with no data collected on bowel symptoms.

A German case control study Peschers et al (2003) compared 50 primiparous women delivered by vacuum extraction with 50 women who delivered spontaneously. Episiotomy and perineal tears were matching criteria. Anal incontinence symptoms included faecal urgency, flatus incontinence, incontinence to liquid stool or to solid stool or faecal soiling. New anal incontinence symptoms after childbirth were found in 30% of the vacuum group compared to 34% of the vaginal delivery group. These differences were not significant.

A study by Ryhammer et al (1995) from Denmark evaluated the risk of permanent flatus after repeated vaginal deliveries. A questionnaire sent to 304 women with an 80% response rate showed that the risk of incontinence was significantly increased after the third delivery (OR 6.6, CI 2.4-18.3) compared with the first and second (OR 3.2, CI 1.1-9.1).

A Norwegian study (Nazir, Carlsen, & Nesheim 2002) confirmed the high frequency of occult sphincter injuries and anal incontinence five months after vaginal delivery. Eighty six primigravida women were recruited for the study. Transanal ultrasonography and vector volume manometry were performed and bowel symptoms recorded at 25 weeks of pregnancy and 5 months after giving birth. Nineteen women (25%) experienced flatus incontinence postpartum. After 12 months only one third of them were still incontinent. Fourteen women (19%) were found to have anal sphincter trauma on ultrasound scan. Of the delivery variables, only fetal head circumference was significantly associated with flatus

incontinence (P=0.01). The relationship to delivery interventions (vacuum, forceps, episiotomy) was not assessed.

5.6.8.2 How is faecal incontinence managed?

The effect of pelvic floor muscle exercises on symptoms of faecal incontinence was assessed by Glazener et al (2001) as part of the three centre study reported earlier (MacArthur 2001). The effect of PFE among women who reported urinary or faecal incontinence in the study at three months after giving birth was examined in a RCT. Only 12 of 273 women in the intervention group and 25 of 245 control women had any faecal incontinence. Women in the intervention group received instructions in a basic pelvic floor exercise programme, with instructions reinforced at seven and nine months after delivery. There was a significant improvement at 12 months among women with any faecal incontinence, p=0.012.

The RCOG recommendations for incontinence in women (Royal College of Obstetricians and Gynaecologists. 2002b) state that:

"Most women with postpartum faecal incontinence should be managed conservatively (Grade C)." Conservative treatment is not defined in these recommendations.

5.6.8.3 What competencies are needed to identify and manage faecal incontinence?

Specific research literature which identified competencies was not found.

5.6.8.4 When and how often should women be offered assessment for faecal incontinence?

Frequency of assessment was not addressed in the literature searched.

5.6.8.5 What information do women need about faecal incontinence to maintain health and well being?

The educational needs of postpartum women were not found in the literature search on this topic.

5.6.9 Urinary Retention

Narrative Summary

Little evidence was found which related to postpartum urinary retention.

5.6.9.1 How is urinary retention identified?

In one literature review (Saultz, Toffler, & Shackles 1991), the definition of postpartum urinary retention was commonly reported as the absence of spontaneous micturition within 6 hours of vaginal delivery. However, this definition was not research based. Retention can be self reported or identified by health care personnel, or may be asymptomatic. Research literature which addresses methods of identification was not found.

5.6.9.2 How is urinary retention managed?

One small study (Dolman 1992) looked at the extent of documentation of urinary output, measured by midwives, during labour and in the immediate postpartum period when epidural anaesthesia had been administered. Twenty patient records were reviewed and only 4 (20%) women had urinary output recorded in the postnatal ward. Management principles based upon research evidence were not found.

Burkhart et al (1965) studied 1000 postpartum women and performed bladder catheterization only when women complained of discomfort and inability to void. Using these criteria, 4.9% of women required at least one catheterization during the postpartum period

5.6.9.3 What competencies are needed to identify and manage urinary retention?

No specific research addressing competencies was identified.

5.6.9.4 When and how often should a woman be offered assessment for urinary retention?

Research evidence for frequency of assessment was not found.

5.6.9.5 What information about urinary retention does a woman need to maintain health and well being?

The educational needs of women regarding urinary retention was not found in the literature searched.

5.6.10 Urinary Incontinence

Narrative Summary

5.6.10.1 How is urinary incontinence identified?

Abrams (2002) defines three categories of urinary incontinence as follows:

Stress incontinence - "…the involuntary leakage on effort or exertion, or on sneezing or coughing."

Urge incontinence - "…the complaint of involuntary leakage accompanied by or immediately preceded by urgency"
Mixed urinary incontinence – "the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing."

Incontinence is identified by maternal self report.

Lee et al (2000) undertook serial measurements of pudendal nerve terminal motor latency, perineal descent and anal pressure before and after delivery on 80 women, who had delivered vaginally with posterolateral episiotomy without forceps assistance. They found that pudendal nerve damage and functional impairment in the pelvic floor sphincter musculature occurs during vaginal delivery. Pudendal nerve terminal motor latency recovers after two months whereas functional disturbance in the pelvic floor persists at least until six months.

5.6.10.2 How is urinary incontinence managed?

In a survey of 224 women who had given birth in the preceding 18 months, Fitzpatrick et al (2002) found that 108 respondents (48%) had experienced accidental urine loss since having a baby and 45 of these women (41.6%) reported that they had taken no action to remedy the problem. Some of the

women reported self-management strategies such as going to the toilet more frequently (67%), using pads (44%), practicing pelvic floor exercises (25%) and reducing activities (10%).

A number of systematic reviews exist on the management of urinary incontinence. Where such a review is available, individual studies included in the review will not be presented; the review alone will be cited.

A Cochrane review (Hay-Smith et al. 2001) evaluated pelvic floor muscle training for urinary incontinence in women. The review included 43 studies. This treatment is commonly recommended for women who experience stress leakage of urine on exertion and for women with mixed incontinence, that is both stress and urge incontinence. The technique is used less commonly for urge incontinence. The reviewers concluded that pelvic floor muscle training was better than no treatment or placebo treatments for women with stress or mixed incontinence. “Intensive” (basic programme enhanced by additional individual teaching or clinic visits) appeared to be better than “standard” (defined as routine hospital instruction or basic home programme) pelvic floor muscle training. There is insufficient evidence to determine if pelvic floor muscle training is better or worse than other treatments.

One of the studies reviewed by Hay-Smith et al (2001) was an RCT of nurse-led pelvic floor muscle exercises supplemented by bladder retraining evaluated at one year postpartum (Glazener, Herbison, & Wilson 2001). At the time of evaluation, significantly fewer women in the intervention group had urinary incontinence ($p=0.037$). Subsequently this research group examined the long term outcomes at six years postpartum to determine if these differences persisted (Glazener, 2004). The significant improvements relative to controls in urinary and faecal incontinence at one year were not found at six year follow up for urinary or faecal incontinence, regardless of subsequent deliveries. The earlier difference in the effectiveness of performance of pelvic floor muscle exercises did not persist in the longer term.

Herbison et al (Herbison 2002) conducted a Cochrane review on weighted vaginal cones for urinary incontinence. These cones can be used to help women

to train their pelvic floor muscles. Cones are inserted into the vagina and the pelvic floor muscles are contracted to prevent them slipping out. This review provides some evidence that weighted vaginal cones are better than no active treatment in women with stress urinary incontinence and may be of similar effectiveness to pelvic floor muscle training and electrostimulation. However, the value of cones in puerperal women is not clear. The reviewers conclude that cones should be offered as one option; if women find them unacceptable they know there are other treatment options are available.

Randomised or quasi-randomised trials of bladder training for the treatment of any type of urinary incontinence were assessed in another Cochrane review (Wallace et al. 2004). The reviewers concluded that the limited evidence available suggests that bladder training may be helpful for the treatment of urinary incontinence, but this conclusion can only be tentative as the trials were of variable quality and of small size with wide confidence intervals.

In another Cochrane review, preventative therapy was assessed by Hay-Smith et al (2002). This review analyzed physical therapies, specifically pelvic floor muscle exercises, for the prevention of urinary and faecal incontinence in adults. Three of the seven trials which were undertaken in women who had recently given birth reported less urinary incontinence after pelvic floor muscle training (the intervention) compared to controls at three months postpartum. Two trials included women at higher risk of postnatal incontinence, and the third trial used an intensive training programme. The other four trials did not find any difference in primary outcomes among childbearing women.

Harvey (Harvey 2003) conducted a systematic review of pelvic floor muscle exercises and their role in preventing pelvic floor muscle dysfunction. The author concluded that postpartum pelvic floor muscle exercises, when performed with a vaginal device providing resistance or feedback, appeared to be effective in decreasing symptoms of postpartum urinary incontinence. Reminder and motivational systems to perform “Kegel” [Pelvic Floor Muscle] exercises appeared to be ineffective in preventing incontinence.

Morkved and Bo (Morkved & Bo 2000) conducted a study of two postpartum groups. One group received intensive pelvic floor exercise training with a weekly physical therapy session. The control group followed routine written hospital instructions. At baseline there was no difference in rates of stress incontinence between study groups. One year later when 81 matched pairs were evaluated, women who did not participate in an intensive postpartum pelvic floor muscle training programme had significantly more incontinence than those who did participate.

Pharmacotherapy for urinary incontinence was not addressed as it falls outside of the Guideline's core care remit.

5.6.10.3 What competencies are needed to identify and manage urinary incontinence?

Specific research literature which identified competencies was not found.

5.6.10.4 When and how often should women be offered assessment for urinary incontinence?

Frequency of assessment was not addressed in the literature searched.

5.6.10.5 What information about urinary incontinence does a woman need to maintain health and well being?

The educational needs of postpartum women were not found in the literature search on this topic.

5.6.11 Postpartum Contraception

The early postpartum period is an appropriate time for a woman to consider her contraceptive needs. Women require adequate information, support and advice to make informed decisions about methods and timing of birth control. Table 5-3 was compiled, using expert sources, to identify available methods of contraception and the recommended timing of each type of birth control. Contraception is needed from three weeks postpartum and condoms are safe until the chosen method can be started.

Table 5-2 Methods of contraception

METHODS	TIMING
Combined oral contraceptives (COC)	
Breastfeeding	Breastfeeding women should be advised to avoid COCs in the first 6 weeks pp. COCs are not recommended between 6 weeks and 6 months pp however, if breastfeeding is established COCs may be considered if other methods are unacceptable. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	In women who are not breastfeeding, start 21 days postpartum. Contraception not needed in first 3 weeks and there is an increased risk of VTE If started later than 3 weeks pp, additional contraception is required for 7 days (BNF, 2004) Prodigy (PRODIGY 2005).
Combined injectable contraceptives	*Not available in UK
Progestogen only pills (POP)	
Breastfeeding	A breastfeeding woman can start a POP up to Day 21 pp without the need for additional contraceptive protection. After day 21 additional contraceptive protection is required for 2 days. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	May start POPs at any time. If less than 21 days pp no additional contraception is needed. WHO, (World Health Organization 2004)
Progestogen only injectable contraceptives	
Breastfeeding	Breastfeeding women will not require the injection until Day 21 pp and it is not recommended before 6 weeks pp. Use of injection before 6 weeks pp is outside product license. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	First dose is best delayed until 6 weeks pp as heavy bleeding has been reported when given to women in the immediate puerperium. However, if not breastfeeding the injection may be given within 5 days pp if woman is informed of risk of bleeding. Prodigy (PRODIGY 2005).
Implant (Norplant or Jadelle in the WHO	

guidance and Implanon [etonorgestrel] in FFPR guidance)	
Breastfeeding	Breastfeeding women may use the implant before Day 28 without other contraception. Use of implant before Day 21 pp is outside product license. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	If not breastfeeding, a woman may have this implant at any time WHO(World Health Organization 2004))
Transdermal combination contraceptive patch	
Breastfeeding	See COC above
Non Breastfeeding	Users who are not breastfeeding should start contraceptive patch no sooner than 4 weeks pp. If starting later women should be advised to use a barrier method for the first 7 days. If sex has already occurred, wait until first period before starting patch. Prodigy (PRODIGY 2005).
Copper bearing IUD	
Breastfeeding	Breastfeeding women may have an IUD inserted within the first 48 hours pp. Otherwise insertion should be delayed until 4 weeks pp. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	For all women with vaginal delivery an IUD can be fitted within 48 hours of birth. Later than this it should be inserted safely 4 or more weeks pp. The risk of uterine perforation is increased if an IUD is inserted between 49 hours and up to 4 weeks pp. (PRODIGY 2005)
Levonorgestrel releasing IUS (intrauterine system)	
Breastfeeding	Breastfeeding women may have this IUS inserted from 4 weeks pp. with additional contraception or abstention for 7 days. (Faculty of Family Planning and Reproductive Health Care 2004)
Non Breastfeeding	Any woman 4 or more weeks pp can have this IUS inserted.with additional contraception or abstention for 7 days (World Health Organization 2004)
Male Condoms	Can be used immediately with no effect on breastfeeding. (PRODIGY 2005)
Female Condoms	May be used when ready to resume sexual relations. No adverse effect on breastfeeding. (Black, Francoeur, & Rowe 2004a;Black, Francoeur, & Rowe 2004b;Black, Francoeur, & Rowe 2004c)
Diaphragm or cervical cap	Breastfeeding women should be advised to wait until at least 6 weeks pp before attending for assessment of size required. Contraceptive Choices for Breastfeeding Women; (Faculty of Family Planning and Reproductive Health Care 2004)
Spermicide	May be used when ready to resume sexual relations. No adverse effect on breastfeeding. Canadian Contraception Consensus (2004) This method used alone is not usually considered in UK due to high failure rates.
Standard Days Method	Fertility awareness pp not reviewed
Lactational	The Bellagio Consensus concluded that full or nearly full breastfeeding

amenorrhoea	and is amenorrhoiec confers 98% protection against pregnancy in the first 6 months after childbirth. (PRODIGY 2005)
Sterilisation	Tubal occlusion should be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested in association with pregnancy (either postpartum or post abortion) the woman should be made aware of the increased regret rate and the possible increased failure rate. (Royal College of Obstetricians and Gynaecologists. 2004a)

5.6.12 Maternal immunisation

Narrative Summary

Three maternal immunisations have been included in this review. Anti-D is given to prevent alloimmunisation in RhD negative mothers who carry RhD positive babies. Prevention of rhesus haemolytic disease in subsequent pregnancies has resulted in a decrease in perinatal deaths from alloimmunization by 100 fold. (Fung Kee Fung et al. 2003;National Collaborating Centre for Women's and Children's Health. 2003). Rubella immunisation (now MMR) is given postpartum to prevent rubella infection in a future pregnancy. Maternal rubella infection in the first eight to ten weeks of pregnancy results in fetal damage in up to 90% of infants(Salisbury & Begg 1996). Hepatitis B is not particularly indicated for a postpartum woman but may be indicated for the neonate if the mother is a chronic carrier of hepatitis B or has had acute hepatitis B during pregnancy (Salisbury & Begg 1996)

5.6.12.1 Anti-D

RhD-negative women giving birth to RhD-positive infants may become sensitised to anti-D as a result of fetomaternal haemorrhages (FMH). In a subsequent pregnancy, this could lead to a RhD positive baby developing a haemolytic disorder.

Crowther and Middleton (Crowther & Middleton 1997) conducted a meta analysis of randomised and quasi-randomised trials of postpartum anti-D prophylaxis and observed that giving anti-D immunoglobin to RhD-negative women delivering RhD-positive infants within 72 hours (irrespective of the

antibody status of the mother and baby) reduced the risk of RhD alloimmunisation 6 months postpartum (RR 0.04 [95% CI 0.02-0.12]) and in a subsequent pregnancy (RR 0.14 [95% CI 0.06-0.35]).

The RCOG clinical green top guideline (Royal College of Obstetricians and Gynaecologists. 2002a)recommends the administration of anti-D Ig (Immunoglobulin) to every non-sensitised RhD-negative woman within 72 hours following the delivery of a RhD-positive infant.

5.6.12.2 Rubella

According to the Department of Health MMR vaccine should be offered to all sero negative women after delivery (NHS Immunisation Information. 2004). A controlled study (Black et al. 1983) that assessed the effects of two rubella vaccines (Cendehill and RA 27/3), one of which (RA 27/3) is used both in monovalent form and in combination (MMR), observed that RA 27/3 administered postpartum prior to discharge produced serological responses in 97.6% of women after 6 weeks.

The 1996 Department of Health (Salisbury & Begg 1996) recommendation was that women found to be seronegative on antenatal screening for rubella should receive rubella vaccination following delivery and prior to discharge from the maternity unit. Correspondence with Judith Moreton at the Department of Health (June 24, 2004) states the following, “We are aware that in some areas they are advising non-immune women to go to their GP at 6 weeks and be vaccinated then. This is not just incorrect; it could also be dangerous as the mother could be pregnant again within that time.” Rubella vaccine is contraindicated in early pregnancy although not in breastfeeding. Since Sept. 2003 MMR has replaced single rubella vaccine, as there are no more supplies of single rubella vaccine available.

The Department of Health advises that MMR can be administered simultaneously with anti-Rho (D) (antibody that is given to Rhesus negative

women after giving birth), provided that separate syringes are used. The low dose of anti-Rho (D) globulin has been shown not to interfere with rubella vaccine. If not given simultaneously, it should be given 3 months after anti-Rho (D) (NHS Immunisation Information. 2004).

5.6.12.3 Hepatitis B (Hep B)

The Green Book (Salisbury & Begg 1996) recommends immunisation against Hepatitis B for individuals who are at increased risk because of their lifestyle, occupation or other factors such as close contact with a case or carrier. There are no specific recommendations for postpartum vaccination of Hep B, but reports from the CDC (Centers for Disease Control and Prevention. 1991) and DOH (Salisbury & Begg 1996) state that neither pregnancy nor lactation (CDC only) should be considered contraindications for Hep B vaccination of susceptible women.

A prospective US study of postpartum women eligible for Hep B immunisation observed that a vaccination schedule (course of 3 injections) starting at the first postpartum visit (average time interval between delivery and the first injection was 3.4 weeks) provided protection against Hep B in 75% and 95.7% of women receiving 2 or 3 injections, respectively (Jurema, Polaneczky, & Ledger 2001)

The postnatal period may provide an opportunity for updating the immunisation status of women who are at risk.

5.6.13 Lifestyle

The literature on changing lifestyle for new mothers was not searched for this guideline. The Department of Health publishes helpful guidance for women in the puerperium in *Birth to Five* (Department of Health. 2005) which comprises expert opinion regarding postnatal exercise regimes, diet, sexual activity and relationships.

5.6.14 Domestic Abuse

5.6.14.1 What tools exist to identify the woman at risk for domestic violence in the postpartum period?

Narrative Summary

The evidence for screening for domestic abuse in the health service setting was evaluated by Ramsay et al for the United Kingdom National Screening Committee (Ramsay et al. 2002). This review is not specific to the postpartum time period. Three of the NSC criteria for a screening programme were utilized in this review:

The screening test should be acceptable to the population

The complete screening test should be acceptable to health professionals

There should be an effective treatment or intervention for the problem.

The review of women's attitudes included only American studies. This review found that about half to three quarters of women patients in primary care thought screening for domestic abuse was acceptable. In two surveys of health professionals only a minority of doctors and half of nurses favoured screening. Although screening programmes were found to increase rate of identification of women experiencing domestic violence in antenatal and primary clinics little evidence was found for the effectiveness of interventions in healthcare settings of women who were identified by screening. There were no randomised controlled trials. Only two studies measured rates of domestic violence as outcomes. One of these was based in an emergency department and the other assessed counselling and advocacy support for women identified in an antenatal clinic. Rates of shelter use and counselling in shelters was significantly higher in the intervention group ($p=0.003$ and $p<0.001$ respectively). The authors conclude that although violence against women is a common health problem, the implementation of screening programmes in healthcare settings cannot be justified.

Another systematic review from the U.S. (Nelson 2004) examined the evidence on the benefits and harms of screening women in general for domestic violence.

None of the studies reviewed evaluated the performance of a screening instrument or procedure by using measurable violence or health outcomes. No intervention studies were identified in the postpartum time period.

The U. S. Preventive Services Task Force (Nelson 2004) clinical guideline based upon the review cited above found insufficient evidence to recommend for or against routine screening of women for intimate partner violence. This was a Grade I recommendation (evidence lacking).

A Cochrane Review (Coulthard et al. 2004) of "Domestic violence screening and intervention programmes for adults with dental or facial injury" found no RCTs for addressing domestic screening and intervention programmes for adults presenting with dental and facial injuries. The authors conclude that without evidence for the effectiveness of an intervention, it seems inappropriate to introduce screening programmes.

A paper published in the Journal of the Canadian Medical Association in 2005 (Wathen & Macmillan 2005) also found that no study had examined in a comparative design the effectiveness of screening when the end point was improved outcomes for women. Only one intervention study involved a primary care based programme. Brief counselling, professional counselling and outreach were compared in a sample of predominantly Hispanic women who were pregnant and had experienced physical abuse. There were no statistically significant differences among the groups at 18 months.

A systematic review by the Canadian Task Force on Preventive Health Care (Macmillan & Wathen 2001) made the following recommendations:

- Due to the lack of a demonstrated link between screening and the reduction of violence outcomes, the Canadian Task Force concludes that there is insufficient evidence to recommend for or against routine screening for violence either pregnant or non-pregnant women . This is distinct from the need for clinicians to include questions about exposure to domestic violence as part of their diagnostic assessment of women.

This information is important in caring for the patient, and may influence assessment and treatment of other health problems.

- The Task Force concludes that there is insufficient evidence to recommend for or against counselling of abused women by primary care clinicians, although decisions to do so may be made by the clinician and patient on other grounds.

The Confidential Enquiries into Maternal Deaths (Confidential Enquiry into Maternal Deaths. 2002) endorsed the routine questioning about domestic violence in antenatal care but also emphasised the need for supporting protocols and strategies. In the Department of Health publication Domestic Violence: A Resource Manual for Health Care Professionals (2000)

Section 3.13 states:

Approaches to routine enquiry should employ validated screening questions and methodologies. Such tools have been developed in the United States, but have not generally been tested in the U.K.

The Health Department manual also reviewed routine questioning in health care setting other than antenatal care. Universal screening is likely to be superior rather than selective screening based on risk factors they conclude but once again, it is essential that supporting guidelines, protocols and necessary training in their use.

In the NICE Antenatal Care Guideline (National Collaborating Centre for Women's and Children's Health. 2003) the following recommendation is made regarding screening for domestic violence:

Healthcare professionals need to be alert to the symptoms or signs of domestic violence and women should be given the opportunity to disclose domestic violence in an environment in which they feel secure. (D)

5.6.15 The Six to Eight Week Maternal Postnatal Check

Narrative Summary

The routine review of women at 6 - 8 weeks postpartum has been practised since the early 1900s and was initiated to reduce maternal morbidity (Gunn 1998). The vaginal examination was carried out as a part of the postpartum check-up because of a long held assumption that vaginal birth led to injury and infection of the cervix which could progress to become carcinoma of the cervix. The timing of the consultation is often attributed to the timing of complete uterine involution. Recent research also shows that despite high levels of uptake, 90% of women in the U.K. attend a postpartum examination, high levels of maternal morbidity persist. (See narrative below).

Gunn et al (1998) surveyed GPs as to what physical examination and discussion should take place at the routine six week postpartum check. A total of 1022 questionnaires were sent to GPs throughout Victoria, Australia. The response rate was 70%. Over 65% of the doctors recommended routine examination of the abdomen, blood pressure, perineum, vagina, pelvic floor and breasts at the six week check-up. Fewer than half the sample believed that common health problems should routinely be discussed. The female GPS were three times more likely to believe that maternal feelings should be explored routinely and twice as likely to discuss social problems and infant behaviour.

A survey of 190 women and 55 GPs was carried out by Bowers (Bowers 1985) to determine attitudes of both groups about the postpartum examination. Forty five percent of women indicated that they would prefer to be examined by a female. In this study only one woman was found to have a retroverted uterus, although all women had a vaginal examination. As this is an insignificant problem at 6 weeks the value of the pelvic examination was questioned. Women indicated that contraception was often adequately discussed but infant feeding and their emotional state was not.

Gunn et al (1998) also conducted a randomised control trial to investigate whether a visit to a general practitioner (GP) one week after discharge results in better clinical outcomes and greater satisfaction with services than the traditional six week exam. Women were recruited from one urban and one

rural hospital in Australia. Six hundred and eighty three women participated in the trial. All women received a letter and an appointment date to see a GP for a postpartum check. The intervention group saw the GP at one week and the control group at 6 weeks, which was usual care. Postal surveys were sent at three and six months. The average response rate was 67.5%. No significant differences were found between the groups in EPDS and SF-36 scores; numbers of clinical problems; breastfeeding rates or satisfaction with general practitioner care. The authors conclude that to make clinically effective improvements in maternal health more is required than early postnatal review. As part of a wider study which investigated long term problems after childbirth Bick and MacArthur (Bick & MacArthur 1995) investigated the attendance and content of the postnatal examination. Data were obtained through postal questionnaire and linked to the obstetric case notes of 1278 women (80% response rate) who had delivered a baby at Birmingham Maternity Hospital between April and September 1992. The attendance rate for the postpartum examination was 91% in the study population. The researchers wanted to investigate whether the examination conducted at the six week check was related to relevant delivery factors or to symptoms reported by women at the time of the examination. Having an abdominal examination was not found to be related to any delivery factors. A vaginal examination was associated with having a vaginal delivery ($p<0.001$) and with perineal trauma ($p<0.02$). However, over two thirds of women with an intact perineum and half of women delivered by elective caesarean section had a pelvic examination. There were no associations between complaints of stress incontinence and having a urine test or a vaginal examination, which may have been undertaken if the woman had reported a urinary problem. Three quarters of women with a history of PPH, low third day HB or new onset postpartum fatigue did not have a blood test at their 6 week postpartum assessment. The authors suggest that the timing, relevance and content of the postpartum examination should be re-evaluated.

In a report of the RCGP Maternity Care Group published in 1995 it was noted that, “The content of the six week postnatal check has come under review; it

remains, however, an important occasion to review with the mother the significant event of childbirth and start of parenting."

6 Infant Feeding

6.1 Recommendations

Infant Feeding

Providing a supportive environment for breastfeeding

1 Breastfeeding support should be made available regardless of the location of care. **[A]**

2 All healthcare providers (hospitals and community) should have a written breastfeeding policy that is communicated to all staff and parents. Each provider should identify a lead health care professional responsible for implementing this policy. **[D(GPP)]**

3 All maternity care providers (whether working in hospital or in primary care) should implement an externally evaluated structured programme that encourages breastfeeding, using the Baby Friendly Initiative (www.babyfriendly.org.uk) as a minimum standard. **[A]**

4 Healthcare professionals should have sufficient time, as a priority, to give support to a woman and baby during initiation and continuation of breastfeeding. **[D(GPP)]**

5 Where postnatal care is provided in hospital, attention should be paid to facilitating an environment conducive to breastfeeding. This includes arrangements for:

- 24 hour rooming-in and continuing skin-to-skin contact when possible **[A]**
- privacy **[D(GPP)]**
- adequate rest for the woman without interruption due to hospital routine **[D(GPP)]**
- access to food and drink on demand. **[D(GPP)]**

6 Formula milk should not be given to breastfed babies in hospital unless medically indicated. **[B]**

7 Commercial packs, for example those given to women when they are discharged from hospital, containing formula milk or advertisements for formula should not be distributed... **[A]**

8 Women who leave hospital soon after birth should be reassured that this should not impact on breastfeeding duration. **[A]**

9 **Information and community support**

10 Written breastfeeding education materials as a stand alone intervention are not recommended. **[A]**

11 **Starting successful breastfeeding**

12 In the first 24 hours after birth, women should be given information on the benefits of breastfeeding, the benefits of colostrum and the timing of the first breastfeed. Support should be culturally appropriate. **[GPP]**

13 Initiation of breastfeeding should be encouraged as soon as possible after

birth, ideally within one hour. **[D(GPP)]**

14 Separation of a woman and her baby within the first hour of the birth for routine postnatal procedures, for example, weighing, measuring and bathing, should be avoided unless these measurements are requested by the woman, or are necessary for the immediate care of the baby. **[C]**

15 Women should be encouraged to have skin to skin contact with their babies as soon as possible after birth. **[A]**

16 It is not recommended that women are asked about their proposed method of feeding until after the first skin to skin contact. **[D(GPP)]**

17 From the first feed, women should be offered skilled breastfeeding support (from a healthcare professional, mother-to-mother or peer support) to enable comfortable positioning of mother and baby and to ensure that the baby attaches correctly to the breast to establish effective feeding and prevent concerns such as sore nipples. **[D(GPP)]**

18 Additional support with positioning and attachment should be offered to women who have had:

- narcotic or a general anaesthetic, as the baby may not initially be responsive to feeding **[C]**
- a caesarean section, particularly to assist with handling and positioning the baby to protect the woman's abdominal wound **[D(GPP)]**
- initial contact with their baby delayed. **[D(GPP)]**

19 **Continuing successful breastfeeding**

20 Unrestricted breastfeeding frequency and duration should be encouraged. **[A]**

21 Women should be advised that babies generally stop feeding when they are satisfied, which may follow a feed from only one breast. Babies should be offered the second breast if they do not appear to be satisfied following a feed from one breast. **[D(GPP)]**

22 Women should be reassured that brief discomfort at the start of feeds in the first few days is not uncommon, but this should not persist. **[D(GPP)]**

23 Women should be advised that if their baby is not attaching effectively he or she may be encouraged, for example by the woman teasing the baby's lips with the nipple to get him or her to open their mouth. **[D(GPP)]**

24 Women should be advised of the indicators of good attachment, positioning and successful feeding.

Indicators of good attachment and positioning

- mouth wide open
- less areola visible underneath the chin than above the nipple
- chin touching the breast, lower lip rolled down, and nose free
- no pain

Indicators of successful feeding in babies

- audible and visible swallowing
- sustained rhythmic suck
- relaxed arms and hands
- moist mouth
- regular soaked/heavy nappies.

Indicators of successful breastfeeding in women

- breast softening
- no compression of the nipple at the end of the feed
- woman feels relaxed and sleepy **[GPP]**

25 Women should be given information about local breastfeeding support groups. **[C]**

Assessing successful breastfeeding

26 A woman's experience with breastfeeding should be discussed at each contact to assess if she is on course to breastfeed effectively and identify any need for additional support. Breastfeeding progress should then be assessed and documented in the postnatal care plan at each contact. **[D(GPP)]**

27 If an insufficiency of milk is perceived by the woman, her breastfeeding technique and her baby's health should be evaluated. Reassurance should be offered to support the woman to gain confidence in her ability to produce enough milk for her baby **[C]**

28 If the baby is not taking sufficient milk directly from the breast and supplementary feeds are necessary, expressed breast milk should be given by a cup or bottle. **[B]**

29 Supplementation with fluids other than breast milk is not recommended. **[C]**

Expression and storage of breast milk

30 All breastfeeding women should be shown how to hand express their colostrum or breast milk and advised on how to correctly store and freeze it. **[D(GPP)]**

31 Breast pumps should be available in hospital, particularly for women who have been separated from their babies, to establish lactation. All women

who use a breast pump should be offered instructions on how to use it. **[D(GPP)]**

Preventing, identifying and treating breastfeeding concerns

Nipple pain

32 Women should be advised that if their nipples are painful or cracked, it is probably due to incorrect attachment. **[D(GPP)]**

33 If nipple pain persists after repositioning and re-attachment, assessment for thrush should be considered. **[D(GPP)]**

Engorgement

34 Women should be advised that their breasts may feel tender, firm and painful when milk 'comes in' at or around 3 days after birth. **[GPP]**

35 A woman should be advised to wear a well-fitting bra which does not restrict her breasts. **[D(GPP)]**

36 Breast engorgement should be treated with:

- frequent unlimited breast feeding including prolonged breastfeeding from the affected breast
- breast massage and if necessary, hand expression
- analgesia **[A]**

Mastitis

37 Women should be advised to report any signs and symptoms of mastitis including flu like symptoms, red, tender and painful breasts to their healthcare professional urgently. **[C]**

38 Women who report the signs and symptoms of mastitis should be offered assistance with positioning and attachment and advised to:

- continue breastfeeding and/or hand expression to ensure effective milk removal and, if necessary, this should be with gentle massaging of the breast to overcome any blockage **[A]**
- take analgesia compatible with breastfeeding, for example paracetamol **[D(GPP)]**
- increase fluid intake **[D(GPP)]**

39 If signs and symptoms of mastitis continue for more than a few hours of self management, a woman should be advised to contact her healthcare professional again (urgent action). **[D(GPP)]**

40 If the signs and symptoms of mastitis have not eased, the woman should be evaluated as she may need antibiotic therapy (urgent action). **[B]**

Inverted nipples

41 Women with inverted nipples should receive extra support and care to ensure successful breastfeeding. **[D(GPP)]**

Ankyloglossia (tongue tie)

42 Evaluation for ankyloglossia should be made if breastfeeding concerns persist after a review of positioning and attachment by a skilled health care professional or peer counsellor. **[D(GPP)]**

43 Babies who appear to have ankyloglossia should be evaluated further (non-urgent action; refer to NICE Interventional Procedure on Tongue Tie (National Institute for Health & Clinical Excellence, 2005). **[D(GPP)]**

Sleepy baby

44 Women should be advised that skin-to-skin contact or massaging a baby's feet should be used to wake the baby. The baby's general health should be assessed if there is no improvement. **[D(GPP)]**

Formula feeding

45 All parents and carers who are giving their babies formula feed should be offered appropriate and tailored advice on formula feeding to ensure this is undertaken as safely as possible, in order to enhance infant development and health and fulfil nutritional needs. **[D(GPP)]**

46 A woman who wishes to feed her baby formula milk should be taught how to make feeds using correct, measured quantities of formula, as based on the manufacturers instructions, and how to cleanse and sterilise feeding bottles and teats and how to store formula milk. [Refer to DH advice on bottle feeding (Department of Health. 2005) **D(GPP)]**

Parents and family members should be advised that milk, either expressed milk or formula should not be warmed in a microwave. **[D]**

47 Breastfeeding woman who want information on how to prepare formula feeds should be advised on how to do this. **[D(GPP)]**

Table 6-1 Infant feeding information and advice	
Time band 1: First 24 hours	
	Women should be offered information and reassurance on: • colostrum – which will meet the needs of the baby in the first few days after birth **[D(GPP)]** • timing of the initial breastfeed and the protective effect of colostrums. This advice should be culturally sensitive **[C]** • The nurturing benefits of putting the baby to the breast in addition to the nutritional benefits of breastfeeding. **[D(GPP)]**
Time band 2: 2–7 days	
	A woman should be offered information and reassurance on: Feeding patterns: • that her baby may have a variable feeding pattern, at least over the first few days, as the baby takes small amounts of colostrum and then takes increasingly larger feeds as the milk supply comes in **[D(GPP)]** • that when the milk supply is established, a baby will generally feed every 2–3 hours, but this will vary between babies and, if her baby is healthy, the baby's individual pattern should be respected. **[A]** Position and attachment: • that being pain free during the feed is an indicator of good position and attachment **[D]** Other indicators of good attachment include: • chin touching the breast, with the lower lip rolled down, with the nose free **[D]** • mouth is wide open **[D]** • less areola visible below the baby's mouth than above the nipple **[D]** • The baby is swallowing. **[D]** Signs of successful milk transfer:

Table 6-1 Infant feeding information and advice	
	The baby has: • audible swallowing **[D]** • sustained rhythmic suck and swallowing with occasional pauses **[D]** • relaxed arms and hands **[D]** • moist mouth **[D]** • satisfaction after feeding **[D]** • Regular soaked/heavy nappies. **[D]** The woman: • feels no breast or nipple pain **[D]** • experiences her breast softening **[D]** • may experience uterine discomfort **[D]** • observes no compression of the nipple at the end of the feed **[D]** • feels relaxed and sleepy **[D]** **Engorgement** – full breasts are common on day 3 but engorged breasts (hard, hot, inflamed) are a sign of inadequate milk drainage requiring treatment **[D]** **Safety** – milk, either formula or expressed breast milk, should not be heated in a microwave as there is a danger of scalding (Advise Family/Partner as appropriate). **[C]** **Benefits of breastfeeding** – that babies who are exclusively breastfed for 6 months will accrue the greatest health benefits and disease prevention. **[B]** **Local breastfeeding support groups** – how to access and what services and support they provide. **[A]**
	Women should be advised to report to their healthcare professional: **Urgently;** the signs and symptoms of mastitis including flu like symptoms, red, tender and painful breasts. **[A]**

6.2 Evidence Statements for Infant Feeding

What factors immediately after the birth contribute to successful breastfeeding?

Core Care

48 Most healthy full term babies will demonstrate pre-feeding behaviours within the first hour of life. [Level 1++]

49 The Baby Friendly initiative (WHO/UNICEF 1989) Step 4 recommendation is that a first breastfeed should be offered 'soon after the birth'. [Level 4]

50 Early separation of mother and baby may disrupt pre-feeding behaviours. [Level 3+]

51 Early skin-to-skin contact appeared to have some clinical benefit especially regarding breastfeeding outcomes and infant crying and had no apparent short or long-term negative effects [Level 1++]

52 Early skin to skin contact with suckling is associated with increased duration of breastfeeding. [Level 1+]

Raised concern

53 Narcotic pain medication appears to have a detrimental effect on pre-feeding behaviour. [Level 2+]

54 Women who have had a general anaesthetic are less likely to commence breastfeeding. [Level 3+]

55 Women who deliver by CS are less likely to commence breastfeeding, but no more likely to discontinue breastfeeding than women who have a vaginal birth. [Level 1++]

What practices encourage breastfeeding?

Core Care

56 Unrestricted breastfeeding helps prevent engorgement, increases milk supply, stabilises neonatal serum glucose levels and increases initial weight gain. [Level 4.]

57 Milk composition will change during a feed, with low calorie 'fore' milk released at the beginning of a feed and high calorie hind milk produced as the feed progresses. [Level 4]

58 Correct positioning and attachment of the infant on the breast prevent sore nipples and ineffective feeding. Attachment may be facilitated if the baby is held at the level of the breast, with his/her body turned toward the breast and his/her head and body aligned. [Level 4]

59 Breastfeeding may be facilitated if the mother is comfortable, with her body well supported and the baby is brought to the breast. [Level 4].

60 Existing evidence points to no effect of dummy use on breastfeeding duration. [Level 1++].

61 Baby Friendly recommends no artificial teats. [Level 4]

Do environmental factors (hospital practice; Baby Friendly Initiatives; rooming-in) facilitate effective breastfeeding?

Core Care

62 The 3 day WHO/Unicef Breastfeeding Training programmes may improve the knowledge of midwives and nurses and increase breastfeeding rates. [Level 2+]

63 There is a beneficial effect on the duration of any breastfeeding with all forms of extra support. [Level 1++]

64 Extra professional support appears beneficial for any breastfeeding but did not reach statistical significance for exclusive breastfeeding. [Level 1++]

65 Peer support is effective in reducing the cessation of exclusive breastfeeding but its effect on any breastfeeding did not reach statistical significance. [Level 1++]

66 Institutional changes in hospital practices to promote breastfeeding, either as part of or independent to the Baby Friendly Hospital Initiative, are effective at increasing both the initiation and duration of breastfeeding, particularly in developing countries. These may include stand-alone interventions such as rooming-in or a package of interventions, such as rooming-in, early skin-to-skin contact and health education. [Level 1++]

67 Peer support as a stand alone intervention when delivered to women in low-income groups is an effective intervention to increase initiation and duration rates among women who expressed a wish to breastfeed. [Level 1++]

68 The distribution of commercial hospital discharge packs, with or without formula appears to reduce the number of women exclusively breastfeeding. [Level 1++].

69 Short postnatal stay (<,48 hours) does not appear to affect breastfeeding rates. [Level 1++].

Information and Community Support

Core Care

70 Evidence statements reflect the HTA of 2000 which evaluated interventions to promote the initiation of breastfeeding:

Social support interventions did not produce significantly increased rates of initiation compared with standard care. [Level 1++]

Peer support as a stand alone intervention when delivered to women in low-income groups is an effective intervention to increase initiation and duration rates among women who expressed a wish to breastfeed [Level 1++]

71 Media campaigns as a stand alone intervention, and particularly television commercials, may improve attitudes towards, and increase initiation rates of breastfeeding. [Level 1++]

72 The use of literature alone had a limited impact and was not recommended. [Level 1++]

How should successful breastfeeding be assessed?

Core Care

73 Perceived milk insufficiency is a common reason for early cessation of breastfeeding. [Level 4]

Signs of successful milk transfer include:

- Baby has plenty of wet nappies each day and is having nothing but breast milk;
- Baby is growing and generally gaining weight
- Baby is awake and alert for some of the time. [Level 4]

74 Delayed onset of milk production (>72 hours) may be a risk factor for baby weight loss >10% of birth weight and formula

supplementation. [Level 3]

75 Supplements are required only if medically necessary. [Level 4]

76 Supplementation with fluids other than breast milk negatively impacts breastfeeding duration [Level 2].

77 If supplements are necessary cup feeding may improve breastfeeding duration, however this may only be of benefit among babies born by CS. [Level 1+]

What should be done to prevent, identify and treat breastfeeding problems?

Breastfeeding Problems: Nipple Pain

Raised Concern

78 Correct positioning and attachment of the infant may prevent nipple trauma. [Level 4]

79 Topical treatments for nipple pain, breast shells and nipple shields have not been shown to be effective [Level 1++]

Breastfeeding Problems: Engorgement

Core Care

80 The symptoms of breast engorgement include firm, tender, and/or painful breasts. [Level 4]

Raised Concern

81 Treatment of engorgement includes breast drainage, breast massage and analgesia. Cabbage leaves or cold gel packs may be helpful, but the observed effects may be as a result of placebo and need to be examined in larger studies. [Level 1+]

Breastfeeding Problems: Mastitis

Raised Concern

82 The signs and symptoms of mastitis range from focal inflammation with minimal systemic symptoms, to abscess and septicaemia. The woman may have flu-like symptoms and pyrexia, and c/o hot, tender breasts [Level 1++]

83 Non infective mastitis should be treated conservatively with moist heat and continuation of breastfeeding to ensure effective drainage. [Level 1++]

Action/Referral

84 Treatment of infective mastitis includes the use of a beta lactamase resistant antibiotic along with moist heat and continued breastfeeding. [Level 2]

Breastfeeding Problems: Inverted Nipples

Raised Concern

No literature was identified which addressed the problem of inverted nipples in the postnatal period.

Infant Breastfeeding Problems: Tongue Tie

Raised Concern

85 Conservative treatment for suspected tongue-tie includes breastfeeding support to maximize positioning and attachment, and parent education and reassurance as appropriate. [Level 4]

Treatment/Referral

86 If there is no improvement in feeding in babies with severe tongue

tie, frenulotomy is likely to help mothers and their babies continue to breastfeed. [Level 4]

Culture and Breastfeeding

87 Cultural differences in timing of the initial breastfeed and beliefs about colostrum are common. [Level 3]

88 Culturally specific education can be effective in increasing duration rates of breastfeeding. [Level 1++]

Expression and storage of breast milk

Core Care

89 Babies should be exclusively breast fed for as long as possible.[Level 4]

90 Breast milk may be expressed manually, by hand pump or by mechanical pump. [Level 4]

91 Proper methods of expression and storage may limit bacterial contamination of breast milk. [Level 4]

92 Recommended storage methods and duration include:

Breast milk may be kept no longer than 24 hours. It can also be frozen for one week in a freezer or up to three months in a deep freezer. Thawed breast milk should be used within 24 hours, and breast milk should never be re-frozen. [Level 4]

Feeding formula milk

Core Care

93 Information about formula-feeding techniques such as cleaning of equipment, making feeds and unhurried, demand feeding will

enable a carer to feed effectively. [Level 3]

94 Equipment used for infant feeding should be sterilized. [Level 4]

95 Formula heated in microwave ovens heats unevenly. [Level 3]

6.3 Breastfeeding

Introduction

Breastfeeding provides many short and long-term health advantages for a woman and her baby. Benefits of breastfeeding for the infant include protection against gastrointestinal, urinary, respiratory and middle ear infection (Aniansson et al. 1994;Howie et al. 1990;Pisacane et al. 1992) and atopic disease, especially if there is a family history of this (Burr et al. 1989;Oddy et al. 1999). There is also increasing evidence of long-term protection against cardio-vascular disease (Wilson et al. 1998), Singhal, 2000 4283 /id}. For the woman, breastfeeding can reduce the risk of certain forms of cancer, including all breast cancer (Department of Health. 1996). Other advantages associated with breastfeeding include promotion of attachment between the mother and her infant, and ready availability of nourishment for the baby (Bick, MacArthur, Knowles, & Winter 2002)

Breastfeeding for a minimum of six months and continued breastfeeding up to two years of age or beyond is recommended by the World Health Organization (World Health Organization 2003a). Despite these important advantages, many women in the UK who commence breastfeeding will change to formula feeding, often within the first few weeks of giving birth, and rates of exclusive breastfeeding remain low, especially amongst younger women and women from low-income groups (Hamlyn, Brooker, & Oleinikova 2002).

6.3.1 What factors immediately after the birth contribute to successful breastfeeding?

6.3.1.1 When should the first breastfeed commence?

The timing of when a baby receives a first breastfeed has not been explicitly evaluated, although there is evidence to suggest that earlier feeding may be associated with some advantages, including enhanced relationship between mother and baby, and maintenance of the baby's temperature (Dyson et al. 2006). The UK Baby Friendly Initiative Step 4 recommendation is that health care professionals should 'help mothers initiate breastfeeding soon after the birth' (UNICEF 2006). The most recent UK wide Infant Feeding Survey (Hamlyn, Brooker, & Oleinikova 2002) reported that 72% of women who wished to breastfeed commenced a first feed within one hour of giving birth.

Studies have shown that babies exhibit specific pre-feeding behaviours soon after birth, if restrictions to maternal contact are not in place. A Cochrane review of the effects of early skin-to-skin contact on breastfeeding exclusivity and duration also considered effects on infant breastfeeding behaviour (Anderson et al. 2003). It included studies, some of which were thirty years old, which showed that most healthy full term infants would spontaneously grasp the nipple and begin to suckle by approximately 55 minutes post birth, but for the first 30 minutes following the birth may only lick the nipple. Findings also showed that after the first two hours post birth, babies often became sleepy and difficult to arouse. Further details of this review are included in section 6.3.1.3.

Jansson et al (1995) documented pre-feeding behaviours among 46 newborn babies in a cohort study undertaken in Pakistan, which included observing behaviours such as hand to mouth and rooting activities in newborns. When infants were bathed in accordance with the local hospital routine, those bathed a median of 17 minutes after birth did not demonstrate these behaviours, whilst infants bathed a median of 28.5 minutes post birth demonstrated a full range of pre-feeding behaviours. Potential confounders which could have affected infant behaviour, such as maternal pain relief during labour, were not described.

A randomised controlled trial by Taylor et al (1985) which compared additional early physical contact between 50 primiparous mothers and their babies, including skin-to-skin contact, found that skin-to-skin contact alone had no significant effect on breastfeeding duration. However, when suckling occurred with early skin-to-skin contact, that is feeding within the first 30 to 70 minutes, women were more likely to still be breastfeeding at 2 months postpartum ($p<0.001$) compared to those who did not suckle during extra contact.

6.3.1.2 Are there factors arising from the birth which are detrimental to breastfeeding which would be responsive to intervention?

The evaluation of factors detrimental to breastfeeding involves an assessment of the impact of interventions during labour on the infant's pre-feeding behaviours and on the timing of initiation and duration of breastfeeding. Anaesthesia and analgesia during labour have been the focus of a number of studies, because of the potential for pain-relieving medication to cross the placental barrier and affect infant behaviour. Maternal analgesia may be administered IV or IM as a centrally acting narcotic agent, or peripherally in the form of epidural or spinal analgesia. It is uncommon now for general anaesthesia to be administered for delivery, even for emergency caesarean section, because of the increased safety of regional anaesthesia (National Collaborating Centre for Women's and Children's Health. 2004).

Interventions during labour

A study by Ransjö-Arvidson et al (2001) aimed to examine the impact of maternal analgesia for labour pain relief on infant behaviour. Pre-feeding infant behaviour during the first two hours of life was the focus of this study. A convenience sample of 28 infants whose mothers had uncomplicated pregnancies and births were videoed to observe for pre-feeding gestures including movement of eyes, hands and mouth, touching the nipple before suckling, rooting and licking movements. Women were grouped according to type of analgesia they had received during labour. One group had received mepivacaine via pudendal block (n=6), a second group had received pethidine

or bupivacaine (n=12), and a third group received no analgesia during labour (n=10). A significantly lower proportion of babies whose mothers had received any medication touched the nipple with their hands before suckling ($p<0.01$), made licking movements (<p0.01) and fed ($p<0.01$).

Baumgarder et al (2003) looked at the effects of epidural analgesia on the first and subsequent breastfeeds during the first 24 hours of life among infants born to 231 women who had a vaginal delivery with or without an epidural. They found that although there was a trend for more women who had an epidural to feed within the first hour of giving birth, this was not statistically significant (OR 1.66, $p<0.06$). Successful breastfeeding was defined by a LATCH breastfeeding assessment score of 7/10, including 2/2 for the actual latching on portion of the scoring system. Two successful breast feeds within 24 hours were achieved by 69.6% of mothers who had an epidural during labour compared with 81% of women who did not have an epidural, a statistically significant finding (OR 0.53; $p=0.04$).

Volmanen et al (2004) in a qualitative study undertaken in Lapland contacted 164 women to ask about problems with breastfeeding, and mixed breast and formula feeding, a median of 2.4 years after delivery. Ninety-nine women returned completed questionnaires. Fifty six of these women received an epidural during labour. Although the study was limited by size and potential recall bias, those who had epidural analgesia in labour reported a higher incidence of partial breastfeeding or formula feeding (67% vs. 29%; $p=0.003$). The researchers speculated that infants depressed by bupivacaine crossing the placental barrier (via epidural) might be less capable of stimulating lactation during the neonatal period, however these findings should be treated with caution given the study limitations.

In a well designed cohort study, Radzyminski (2003) looked at the effect of ultra low dose epidural analgesia on breastfeeding among 56 mother infant dyads. Twenty-eight women had epidural analgesia, with pain relief provided by low dose fentanyl and bupivacaine, and 28 did not use any analgesia. Several methods of evaluation were employed to assess drug effects on infant

feeding up to 24 hours post delivery, including the Preterm Infant Breastfeeding Behaviour Scale (Nygvist et al 1996) and a neuro-behaviour scale (Amiel-Tison et al 1982). No significant difference was demonstrated between breastfeeding behaviours of babies born to mothers who had an epidural and those who had no method of analgesia

Factors arising from the birth affecting initiation and duration of breastfeeding

A cohort study conducted by Righard and Alade (1990) compared sucking behaviours in healthy babies immediately following birth and the effect on these babies of different postpartum routines and administration of pethidine for maternal labour pain relief. Babies whose mothers had prolonged post birth maternal contact (greater than 1 hour, n = 38) were compared to those with routine hospital care which consisted of 15-20 minutes of contact, followed by a 20 minute separation of mother and baby for infant weighing, measuring, bathing and dressing (n = 34). Those infants who had longer maternal contact were significantly more likely to breastfeed within the hour than infants who were separated from their mothers ($p<0.001$). Among babies whose mothers received pethidine during labour breastfeeding within one hour was also significantly higher ($p<0.001$) if they were not separated from their mothers.

Dewey et al (2003) examined the incidence of and risk factors for suboptimal infant breastfeeding behaviour, delayed onset of lactation and excess neonatal weight loss among the healthy, term infants of 280 women in California who wanted to exclusively breastfeed for at least one month. Women received guidance on lactation, and data on breastfeeding were collected on days 0, 3, 5, 7 and 14. Trained lactation consultants evaluated infant breastfeeding behaviour using the Infant Breastfeeding Assessment Tool (Mathews 1988), which includes ratings for arousal, rooting, time to latch and sucking effectiveness. Scores ranged from 0 to 3 points (0 = did not exhibit target behaviour, 3 = readily exhibited target behaviour). Logistic regression analysis showed several factors were associated with suboptimal feeding behaviour

(defined as a score < 10 on the Infant Breastfeeding Assessment Tool), including primiparity (days 0 and 3), and caesarean delivery (among multiparous women on day 0). Other factors associated with suboptimal feeding behaviour included use of non breast milk feeds during the first 48 hours, and maternal flat or inverted nipples.

Bick et al (1998) interviewed 906 of 1278 women who responded to a postal questionnaire to obtain information on the characteristics of long-term health problems after childbirth, a mean of 45 weeks after their delivery. All women had delivered at one maternity unit in the West Midlands. Women were asked about their health and well-being and about infant feeding, and a number of social factors, such as support with childcare. Data were linked with their maternity record, and several obstetric and socio-demographic factors were found to be significantly associated with non-initiation of breastfeeding; general anaesthesia during or shortly after labour; multiparity; younger maternal age; and unmarried status. Three predictors for early cessation of breastfeeding were found: return to work within three months of birth (p=0.0001: OR =3.16, 1.5-6.67); regular child care support from female family members (p=0.0006: OR = 1.42, 1.09-1.85) and a score of 12 or over on the EPDS (p=0.0021: OR 1.93, 1.11-3.35). .

6.3.1.3 Does skin-to-skin contact contribute to successful breastfeeding?

Early skin-to-skin contact, where the naked baby is placed prone onto the mother's bare chest immediately following birth or within 24 hours of birth (Anderson et al. 2003), is a practice based on acknowledgement that specific innate behaviours may prime reciprocal, interactive behaviour between a mother and her infant. A Cochrane review by Anderson et al (2003) included 17 studies which presented data on 806 mother-infant dyads. The methodological quality of most of the studies was poor and intervention characteristics, such as duration of skin-to-skin contact, varied greatly. Data were obtained from diverse populations from a range of countries. Fifteen studies only included women who had given birth vaginally, and all but one study included only healthy, full-term babies. More skin to skin dyads were still

breastfeeding one to three months (30 to 90 days) postbirth (OR 2.15; CI 1.10 to 4.22). The reviewers concluded that early skin-to-skin contact appeared to have some clinical benefit especially regarding breastfeeding outcomes and infant crying and had no apparent short or long-term negative effects. Study data showed that most of the infants suckled during the skin to skin intervention which may be a critical component of this intervention with regard to long term breastfeeding success. Although further research is required, it appears mothers and babies should not be separated following the birth without an unavoidable medical reason.

A recently published paper presented findings from an RCT undertaken in the north of England, which examined the effects of skin to skin care on breastfeeding outcomes (Carfoot, Williamson, & Dickson 2005). Two hundred and four mother infant dyads were randomised to routine care or skin- to-skin care. The infants in the usual care group were dried and wrapped in a towel before being handed to their mother or father. In the skin–to-skin group infants were placed prone against their mother's skin and between her breasts as soon as possible after birth. The primary outcome was success of the first breastfeed. Secondary outcomes included breastfeeding at 4 months and baby body temperature 1 hour after delivery. There were no significant differences between the two groups on successful first feed or breastfeeding at 4 months. The Cochrane Library review by Anderson et al described previously indicated that some skin to skin studies involved the separation of mothers and infants allocated to control groups after birth. In contrast, in this study there was immediate contact between mothers and babies in both intervention and control groups. Pooling the results from this trial with those in the Cochrane review by Anderson et al (2003) gives a combined odds ratio of 1.89 (1.06-3.34) a slightly smaller but more precise effect estimate, which is still statistically significant.

Mikiel–Kostyra et al (2002) also looked at the effect of early skin to skin contact after birth on duration of breastfeeding. The study was based on national survey data. Skin to skin contact was implemented for 1020 mothers and babies out of 1250 women surveyed at 3 years postpartum. In 586 cases

(57.5%) skin to skin lasted for less than 5 minutes. A small group of 53 mothers who had contact for 30 minutes or longer exclusively breastfed for 1.55 months longer and weaned 3.10 months later than than those with no contact. The actual duration of exclusive breastfeeding in this group was 4.02 + 2.72 months and for overall breastfeeding 10.07 +8.85 months. Although this survey found an association between mothers and infants with prolonged skin to skin contact and the duration of breastfeeding ($p<0.001$), recall bias and small sample size must be considered in the analysis.

6.3.2 What practices encourage breastfeeding?

A range of practices were assessed to address this question, including optimal frequency and duration of feeding, attachment technique, and factors within the hospital environment which affect successful initiation of breastfeeding.

6.3.2.1 Is there an optimal (or minimum) frequency and duration of a breastfeed?

During the last century, women were advised that each breastfeed should be limited in frequency and duration, as this was considered to protect against a range of potential problems, including sore nipples. Recent evidence has shown that restrictive feeding practices can be more harmful (Dyson et al. 2006). It is now generally accepted that breastfeeding should be unrestricted, and should be facilitated whenever the baby shows signs of hunger, such as increased alertness, activity, mouthing, rooting or crying, or when the mother wishes to feed (World Health Organization Division of Child Health and Development. 1998).

In a systematic review entitled *The Effectiveness of Public Health Interventions to Promote the Duration of Breastfeeding* (Dyson et al. 2006) the authors report that there is substantial evidence from old trials that the timing and duration of breastfeeds should be responsive to the needs of the baby. No recent trials have been conducted and it is postulated that it would now be considered unethical to restrict the timing and duration of breastfeeding.

6.3.2.2 How should the baby be positioned for effective attachment of the baby to the breast?

It is likely that almost all postnatal breastfeeding problems could be prevented if a baby is able to breastfeed effectively and efficiently from the outset. In order to prevent sore nipples and ineffective feeding it is important that a new mother receives support to learn how to position and attach her baby correctly at the breast. A number of alternative positions can be adopted by the mother to facilitate her baby's feeding. Common advice is that the mother should hold the baby at the level of her breast, with the baby's body turned towards her, and his or her head and body aligned (International Lactation Consultant Association. 1999).

6.3.2.3 How can the mother successfully attach the baby on the breast?

Studies of attaching (latching) babies on to initiate breastfeeding were not identified in the literature search. The Department of Health publication *Birth to Five* (Department of Health. 2005) provides a step by step guide to beastfeeding in text and in pictures. This guidance recommends appropriate maternal and infant positoning and advises that breastfeeding should feel comfortable and audible swallowing should be heard. The mother and baby should be relaxed. If breastfeeding is not comfortable it is recommended that mothers slide one of their fingers into the baby's mouth and gently break the suction and try again.

6.3.2.4 How should the mother position herself to facilitate effective breastfeeding?

Little evidence was identified regarding maternal position during breastfeeding. One cohort intervention study (Ingram, Johnson, & Greenwood 2002) used a 'breastfeeding technique' taught in a 'hands off' way by hospital midwives to improve breastfeeding rates. A component of the technique included giving advice to the mother to make herself comfortable, to support her back with cushions and to place her feet flat on the floor/stool/book to keep her lap level. A narrative review recommended that the mother should sit upright, with her

back well supported, and her feet flat on the floor or on a footstool (Shaw 2002). A second narrative review stated that the importance of the mother's position during breastfeeding is inadequately addressed in the literature. Feeding may be unsuccessful if the mother's breast and the infant's body are at an awkward angle. The mother should be encouraged to find a position that is comfortable for her, where her body is well supported and the baby is brought to the breast (Renfrew 1989).

6.3.3 Do environmental factors (hospital practice; Baby Friendly Initiatives; rooming-in) facilitate effective breastfeeding?

6.3.3.1 Evidence Surrounding the Clinical-Effectiveness

The impact of organisation of the routine hospital postnatal environment on the uptake and duration of breastfeeding has been the focus of some studies, particularly in relation to the Baby Friendly Hospital Initiative.

In 1991 a global movement was launched by the World Health Organization and the United Nations Children's Fund to ensure a health care environment at birth where breastfeeding was the norm (Saadeh & Akré 1996). The Baby Friendly Hospital Initiative promotes *Ten Steps to Successful Breastfeeding*, which are presented below:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.

2. Train all health care staff in skills necessary to implement this policy

3. Inform all pregnant women about the benefits and management of breastfeeding

4. Help mothers initiate breastfeeding soon after birth.

5. Show mothers how to breastfeed and how to maintain lactation, even if they should be separated from their infants.

6. Give newborn infants no food or drink other than breast milk, unless medically indicated

7. Practice rooming-in by allowing mothers and infants to remain together 24 hours a day

8. Encourage breastfeeding on demand

9. Give no artificial teats, pacifiers, dummies, or soothers to breastfeeding infants

10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

A Seven Point Plan for the Protection, Promotion and Support of Breastfeeding in Community Health Care Settings was also developed in consultation with UK health and medical professionals and was designed to complement the Ten Steps so that work could be carried out collaboratively and consistently in maternity and primary care settings(UNICEF UK 2004). The Plan covers issues such as breastfeeding policies, support for mothers, staff training needs, in order to enable providers of community healthcare to protect and promote breastfeeding.

The effect of the Baby Friendly Hospital Initiative on breast feeding rates in Scotland was recently evaluated in an observational study using an annual survey of progress towards the Baby Friendly Hospital Initiative and annual breastfeeding rates (Broadfoot et al. 2005). Breastfeeding statistics were collected at the time of the Guthrie screening at 7 days postpartum. Data were collected from maternity units which had over 50 births a year in Scotland between 1995 to 2002 (n = 33), which provided data on 464,246 births. Women giving birth during this time period were 28% (OR 1.28, 1.24-1.31) more likely to be breast feeding at 7 days if they gave birth in a hospital with the UK Baby Friendly Hospital Initiative standard award. These results were adjusted for mother's age, deprivation score, hospital size and year of birth.

From 1995 breastfeeding rates increased significantly faster in hospitals with Baby Friendly status, 11.39% vs 7.97% (p value not provided).

Several systematic reviews have evaluated the effect of various hospital practices on the initiation and successful continuation of breastfeeding, including the impact of the Baby Friendly Initiative. Fairbank et al (2000) evaluated the effectiveness of interventions to promote the initiation of breastfeeding in a systematic review funded by the UK Health Technology Assessment programme. A total of 59 studies were reviewed, comprising 14 RCTs, 16 non RCTs and 29 before and after studies. The review found that:

- Institutional changes in hospital practices to promote breastfeeding, either as part of or independent of the Baby Friendly Hospital Initiative, can be effective at increasing both the initiation and duration of breastfeeding, particularly in developing countries. These may include stand-alone interventions such as rooming-in or a package of interventions, such as rooming-in, early contact and health education.

- Training programmes may be useful in improving the knowledge of midwives and nurses but there was no significant change in attitude of health professionals or in breastfeeding rates.

- Social support interventions did not produce significantly increased rates of initiation compared with standard care.

- Peer support as a stand alone intervention when delivered to women in low-income groups is an effective intervention to increase initiation and duration rates among women who expressed a wish to breastfeed.

- Media campaigns as a stand alone intervention, and particularly television commercials, may improve attitudes towards, and increase initiation rates of breastfeeding.

- The use of literature alone appeared to have limited impact and was not recommended.

Following publication of the HTA review (Fairbank et al. 2000) a controlled, non randomised study was published by Cattaneo and Buzetti, on behalf of the Breastfeeding Research and Training Working Group (2001), which presented outcomes on breastfeeding rates before and after staff training for the Baby Friendly Initiative (BFI). The study was undertaken in eight Italian hospitals (no Italian hospitals at the time had achieved BFI status), with data on breastfeeding rates collected at hospital discharge and at three and six months after the birth. Hospitals were allocated to one of two groups. Following an initial period of assessment in both groups of hospitals, local trainers in group 1 were trained following an adapted programme based on the Baby Friendly Initiative, who in turn cascaded training to the health professionals at their unit. A second assessment phase was undertaken, and the intervention replicated in group 2. A third and final period of assessment was undertaken in both groups 5 months after training had been completed. A range of data collection tools were used, including the self assessment tool of the BFI for each of the 10 steps, an assessment of usual hospital practice at each point in time, a self administered questionnaire to health professionals, and interviews with mothers at discharge and a telephone interview at 3 and 6 months. All hospitals showed an improvement in compliance with the 10 steps, from 1 to 3 steps, to 6 to 10 steps. Interestingly, the study showed that steps 4 – 9 were easier to achieve in Italy. Healthcare professionals' knowledge of breastfeeding improved, although response rates from both groups were low. Following training there was a significant increase in mothers reporting exclusive breastfeeding at discharge, full breastfeeding at three months, and any breastfeeding at six months, although the proportion of women breastfeeding at these points in time were below recommended rates, and could have reflected a lack of support in the community. Despite problems with data collection and loss to follow up the intervention appeared to be successful, however the sustainability and cost of the intervention were not assessed.

Labarere et al (2003) found that a 3 day training programme for health professionals implemented in a French maternity hospital resulted in an increased rate of exclusive breastfeeding at discharge ($p<0.01$). It is unclear if

the training programme was based on steps to achieve BFI accreditation. Data on 323 mothers and babies were obtained before training commenced and data on 324 mothers and babies after training had been implemented. Babies in the before sample were less likely to be breastfed within 1 hour of birth ($p=0.01$), to room-in 24 hour/day ($p<0.01$), and were more likely to receive formula supplementation ($p<0.01$). Impact on the duration of breastfeeding was not an outcome.

DiGirolamo and colleagues (2001) carried out a longitudinal cohort study to assess the impact of the type and number of BFI practices experienced by mothers on breastfeeding outcomes. Data were collected from the 1993/1994 Infant Feeding Practices Survey, a longitudinal survey of pregnant and new mothers up to 12 months after their delivery from across the USA, conducted by the United States Food and Drug Administration. The main outcome measure was breastfeeding cessation within six weeks of giving birth.

Of 2610 women deemed eligible for the study, 1737 (67%) returned the antenatal and subsequent postnatal questionnaires. There were imbalances in the characteristics of responders who were more likely to be white, over 30 years of age, married and to have a higher income and educational achievements. The focus of the study was the 1085 women who reported an intention to breastfeed for more than 2 months after their delivery. The impact of 5 of the 10 BFI steps were assessed; breastfeeding initiation within one hour of the birth; feeding only breast milk; rooming-in; breastfeeding on demand; no use of pacifiers [dummies]. Seventeen percent of women had given up breastfeeding within 6 weeks. Only 7% of the mothers had experienced all 5 steps, with strongest risk factors for early cessation found to be late commencement of a first breastfeed and supplementation of the infant. When compared to women who experienced all 5 steps, mothers who experienced none were eight times more likely to stop breastfeeding within 6 weeks (adjusted odds ratio 7.7, 95% CI 2.3 to 25.8).

Philipp et al (2001) compared breastfeeding initiation rates at Boston Medical Centre, USA, prior to (1995), during (1998) and after (1999) the BFI was

implemented. Two hundred complete medical records randomly selected by computer were reviewed for each of the three years. Data collected from the records enabled infants to be categorised into four groups; exclusively breastfed; mostly breast milk; mostly formula; and exclusive formula. The maternal and infant demographics for all three years were comparable. Full implementation of the 10 Steps leading to Baby-Friendly designation resulted in significant increases in breastfeeding initiation rates from 58% in 1995 to 77.5% in 1998 to 86.5% in 1999, ($p<.001$) leading the authors to conclude that full implementation of BFI was an effective strategy to increase breastfeeding initiation rates in the US hospital setting.

A Cochrane review undertaken by Donnelly et al (2000) evaluated another hospital practice, the distribution of commercial hospital discharge packs containing artificial formula or promotional material for artificial formula. Nine RCTs providing data on a total of 3730 women were analysed. The reviewers concluded that the giving of commercial hospital discharge packs, with or without formula appears to reduce the number of women exclusively breastfeeding at 0-2 weeks (OR 1.99, CI 1.04-3.79), 3-6 weeks (OR 1.23, CI 1.05-1.43) and 8-10 weeks (OR 1.73 1.13-2.64) but had no significant effect upon the earlier termination of non-exclusive breastfeeding.

The length of stay on the postnatal ward has reduced considerably in the UK, as a consequence of a number of drivers, including cost containment (Dyson et al. 2006). The impact of reduced in-patient care on maternal and infant health outcomes and feeding practices have been considered in several studies, although as referred to earlier, changes in service provision have tended to only include breastfeeding as a secondary outcome. The effect on the duration of breastfeeding was evaluated by Brown and Lumley (Brown & Lumley 1997), in a study from Australia. The researchers assessed the impact of early discharge on maternal health outcomes including duration of breastfeeding in women who gave birth 6 – 7 months previously at hospitals in Victoria. At six weeks, three months, and six months small, nonsignificant differences were observed in the pattern of infant feeding of women who were discharged within 48 hours and

those who stayed five or more days after birth. Women who left hospital on day three or four had significantly lower rates of breastfeeding at six weeks (OR 0.58, 0.4-0.8), three months (OR 0.6, 0.5-0.8) and six months (OR 0.74, 0.6-0.96).

A Cochrane review by Brown and colleagues (2002) which considered the safety, impact and effectiveness of a policy of early postnatal discharge for healthy women and their term babies, where 'early discharge' referred to discharge that was earlier than standard care in the setting in which the intervention was implemented. Eight randomised controlled trials were identified which presented data on 3,600 women. Reports of problems with breastfeeding and conflicting advice on breastfeeding within the first four weeks of the birth were included as secondary maternal outcomes. The pooled estimate from six trials which reported data on partial or exclusive breastfeeding at one or two months postpartum suggested no significant difference between women who had early hospital discharge and the control group who received standard care (pooled RR = 0.96, 95% CI 0.78 to 01.18), however there was significant heterogeneity between the trials included in this analysis (for example, cultural differences in duration of breastfeeding, and different measures used to assess breastfeeding).

A large longitudinal cohort study from Sweden (Waldenström & Aarts 2004) was undertaken to investigate the duration of breastfeeding and number of breastfeeding problems, with a focus on the length of postpartum stay. Women attending for their first antenatal clinic appointment were recruited from all clinics in Sweden over three weeks evenly spread over a 1 year period. Data on any breastfeeding were collected by postal questionnaire at two months and 1 year post delivery. Data on 2709 women (82% of the 3293 who originally agreed to participate) who completed questions on length of stay included in the 2 month questionnaire were presented in this paper. Women were divided into six groups according to length of postnatal stay (day 1 <24hrs to day 6 ≥ 120hrs). A number of statistical tests were undertaken to examine the effect of length of stay and potential confounding factors on duration of breastfeeding. A

number of maternal characteristics were associated with length of stay, for example, early discharge (day 1) was associated with being older, having a lower level of education and lack of support from a partner. In terms of breastfeeding, a more positive experience of breastfeeding was associated with a shorter in-patient stay. Kaplan Meier analysis showed the unadjusted median duration of any breastfeeding was 7 months in women discharged from the postnatal ward on day 1 post-delivery and 8 months in women discharged on any of the following days, a non-significant difference (p=0.66). The effect of several maternal characteristics on breastfeeding duration which were statistically significant in the Kaplan Meier analysis were investigated further in a multivariate model, however no statistical differences were found between the six groups and relative risk of discontinuing to breastfeed. The authors concluded that maternal characteristics and their experience of their first breastfeed may be more important predictors of breastfeeding duration than length of in-patient care.

The Canadian Task Force for Preventive Medicine (Palda et al. 2003) updated their review published in 2000 of the literature and guidelines for interventions to promote breastfeeding. The guideline included recommendations against providing commercial discharge packages to new mother and recommended roomin-in and early maternal contact to promote breastfeeding.

Implications for the provision and organisation of effective community-based postnatal care following early discharge of women who wish to breastfeed have not been considered. It is possible that early discharge could prevent exposure to detrimental hospital practices (Dyson et al. 2006), however lack of support and follow-up, and potential for conflicting advice, could also serve to encourage a woman to give up.

6.3.3.2 Evidence Surrounding the Cost-Effectiveness of the Baby Friendly Hospital Initiative

There are no suitable cost-effectiveness studies that deal with the Baby Friendly Hospital Initiative (BFI) in England and Wales. Data from eight

maternity units regarding experience of BFI, initiation rates both prior to and after implementation and relevant demographics were collected and modelled to ascertain the effects of a recommendation that BFI be pursued in all units. The units were chosen to investigate units serving a wide range of demographic and geographic groups. In addition to data from 6 English units, data were included from one unit in Glasgow and one in Antrim, Northern Ireland. This was considered as secondary information and was used to build up a broader picture of BFI implementation. Both provided similar data to English units.

Costs of BFI

Different costs applied to units depending on their current position relative to the BFI. At the time of analysis, the Baby Friendly website (http://www.babyfriendly.org.uk/home.asp) revealed that England and Wales had 34 fully accredited units, 58 units with a certificate of commitment and 183 unaccredited units. Therefore, when groups of costs apply to different degrees because of this, this was represented in the model.

The first cost, presented in Table 6-2, is the planning, accreditation and follow-up payments to the BFI organisation. The costs were supplied independently by a number of units and are represented in the model. A summary is shown here.

Table 6-2 Cost Components of BFI Accreditation

Possible Cost	Cost(£current)	When do these occur relative to initial accreditation?
Initial BFHI Work plan	720	1 year before
Initial Assessment	5000	-
Initial Assessment	1720	During the first year after

Follow-Up		
Reaccreditation	4900	2 years after
Later Assessment	2100	At three year intervals after reaccreditation

These figures include subsistence costs and accommodation for the BFI staff when relevant.

The next issue is the cost of the Baby Feeding coordinator. The recent DoH Good Practice and Innovation guide suggests each unit has a full-time member of staff for this role but practice varies between units. Therefore, the model developed costed a grade G nurse for 25 hours per week (this figure excludes time actually spent training staff in BFI methodology). Note that this figure refers to the extra time demands of Baby Friendly. This may mean employing a coordinator solely for Baby Friendly or increasing the contract of a currently employed coordinator by 25 hours (moving from part-time to full-time).

The third concern is the cost of cascading the training through the unit. The costs that emerge from this are those of replacing unit staff while training, the cost of the co-ordinator for this time and a health visitor assisting in the sessions. This structure was suggested through the survey of units (specifically the Infant Feeding Coordinator for East Lancashire Hospitals NHS Trust). The assumption was that the sessions ran for two days, four times a year in accredited units and weighted the salaries of these two members of staff to reflect this. During accreditation, these costs were calculated based on 150 midwives all being trained immediately prior to initial assessment. On top of these, the model assumed a cost of replacing staff at £125 per person per day while they are being trained.

Over fifteen years, these costs are calculated assuming that all units move immediately to implement the strategy. Future events are discounted at the NICE recommended 3.5% per annum, reflecting the greater weight placed by society on events that happen in the present. The cost of the scheme per

annum over fifteen years is £7.825 Million at present value. It should be noted that there is a greater level of costs in the earlier years.

Cost Savings Associated with BFI

If the BFI leads to significantly altered levels of breastfeeding rates, it is important to investigate how these different rates will affect costs in other parts of the NHS. The first stage is to consider the effect of BFI on breastfeeding initiation rates. Evidence presented in the clinical narrative suggested a strong dose-response relationship – as the number of components of the Baby Friendly Initiative was increased, the early termination rates amongst women who had indicated antenatally a preference to breast-feed fell (DiGirolamo, Grummer-Strawn, & Fein 2001). The cost-effectiveness study requires some indication of the extent of the improvement amongst all women since the scheme applies across the unit.

The data for the units are presented here.

Hospital Name	Pre-BFI Initiation Rate	BFI initiation rate
Oldham	29% (1994)	64% (2004)
Blackburn	27% (1997)	68% (2004)
Bradford	53% (1999)	62 % (2004)
Glasgow	51% (1997)	67% (2004)
Antrim	43% (1997)	55-60% (2004)
Derby	50% (1996)	72% (2004)
Guildford	Not supplied	Not supplied
Halifax	65% (1995-6)	74% (2004)

Clearly, there are problems extrapolating these figures to a typical BFI-attributable improvement rate. There is first the question of the counterfactual: What would have happened had BFI not been implemented? 2001 information from the Baby Friendly Initiative (Radford 2001) suggested an average rise of 10.6% over a four-year period compared to a steady level national breast feeding rate trend between 1980 and 1995. Figures from the Office of National Statistics (Hamlyn, Brooker, & Oleinikova 2002) show a small increase in breastfeeding rates in England and Wales between 1995 and 2000. They suggest an increase of 3% over the period, attributable largely to demographic

changes in the new mother population. Since the raw figures in Baby Friendly Units show an increase above that level, the non-BFI units must have had a rate below 3%. Scottish evidence (Tappin et al. 2001) covering the 1990's suggests an improvement in breastfeeding rates of 8.1% over the period for Baby-Friendly Units. This compared with 2.2% for those without.

The second issue is that the improvement in initiation rates reported from BFI units is by no means uniform. It ranges from 9% in Bradford and Halifax to 41% in Blackburn. An average of 21% for these units suggests they are the best-performers among the BFI units (since their rates are higher than other BFI evidence). The analysis undertaken here assumed 10% to be a realistic target.

Due to this uncertainty, sensitivity to the improvement rate was undertaken to evaluate whether the recommendation(s) remained constant across a range of improvement rates. If this is demonstrated then the result is robust irrespective of this level of uncertainty about the effect.

The incidence of a number of childhood diseases is affected by breastfeeding rates. In this model, the focus was on gastroenteritis and otitis media. Much of the literature also includes necrotizing enterocolitis. Indeed, the serious consequences of this, coupled with an incidence rate of 0.5 to 1 per 1000 live births, suggest this is of importance in the decision making process. However, since its occurrence is largely confined to premature babies, it cannot be included in the primary analysis for a guideline based on core care for healthy babies (excluding those born before 37 weeks).

The model also included an estimate of cost-saving on formula milk and teats due to greater breast-feeding. In the model, this saving is relatively small compared to those of the included diseases. Macro-level costing data from Antrim estimates the cost saving per breastfed infant (limited to immediate neonatal spending) at £1.69 per baby (£1.42 for formula milk and 27p on teats).

Using a Department of Health 1995 figure on gastroenteritis (Department of Health. 1996) updated to 2005 using a 3% inflation rate, a 1% increase in breastfeeding rate will save approximately £672 000 annually across the

country. This is in terms of both the time of doctors and treatment for the condition.

Evidence on the spending undertaken by the system on otitis media is limited. However, US evidence suggests an incidence rate in the first six months of 25% for breastfed infants and 53% for bottle-fed infants. Thus, a 1% increase in breastfeeding among the 640 000 live births annually will reduce the number of cases by

(0.53-0.25) x 640 000 x 0.01 = 1792

If the average cost of treating otitis media is set at £30 (covering HCP time in assessment and follow-up and treatment options), this sums to £53 760 per annum saved per 1% increase in breastfeeding rate. A suitable cost per patient was not found in the literature. Therefore, an approximate figure of £30 was suggested, covering two practice nurse contacts and £10 on treatment and further follow-up. This figure may be open to change since there is a trend towards a 'watch and wait' strategy, which will reduce the cost of treatment (Glasziou et al. 2004)

If we were to assume a breastfeeding improvement rate attributable to the Baby Friendly Initiative of 10%, the model predicts a net annual financial cost to the system of £459 700. It is highly likely that the Initiative is cost-effective. This is for three major reasons.Firstly; the model only looked at cost-savings in formula, teats and the diagnosis and management of otitis media and gastroenteritis. It is almost certain that other cost savings would be achieved in other disease areas. The literature ranges in certainty on other areas but mooted cost savings could lie in, amongst others, diabetes mellitus, respiratory tract infections, eczema, urinary tract infections, heart disease, bowel disease such as Crohn's, asthma and ovarian cancer and breast cancer in the mother. The reason for exclusion was due to the uncertainty regarding the magnitude of effect of breastfeeding on these various conditions.

The second reason is that non-financial advantages of breastfeeding have been ignored in the model. The diseases included in the model have a

significant disutility beyond the financial implication. Furthermore, there seems to be a wide consensus on the bonding and emotional benefits of breastfeeding. While these are impossible to reliably quantify, they should be considered in the decision making process.

Thirdly, the model assumes that recruitment of an infant feeding co-ordinator is necessary in all units not currently accredited. If this overstates the need for recruitment, the net cost of universal implementation will fall. Similarly, as educational facilities become accredited under the scheme, the need for all staff to be trained at the start of employment will reduce.

6.3.4 How should successful breastfeeding be assessed?

Breastfeeding success cannot be determined by one quantifiable outcome, but should reflect aspects of an individual infant's feeding activities and a woman's satisfaction with her method of infant feeding. Several assessment tools (Table 6-3) have been developed in an attempt to enable health professionals and women to assess the establishment of lactation, breastfeeding competencies and problems that may occur in an objective way (See Table 4) (Hamelin & McLennan 2000;Schlomer, Kemmerer, & Twiss 1999).

Table 6-3
Breastfeeding Assessment Tools

Tool	Focus	Scored by	Measures
BAPT:Breastfeeding Attrition Prediction Tool	Mother's knowledge of and attitudes toward breastfeeding that may predict early weaning	Mother	Attitude;subjective norm;control
IBFAT:Infant Breastfeeding Assessment Tool	Infant	Mother or nurse	Signaling;rooting;sucking
LATCH: Breastfeeding Charting System	Infant and mother	Mother or nurse	Latch on; audible swallowing; type of nipple; comfort of breasts; hold: amount of assistance required
MBA: Mother-Baby Assessment	Infant and mother	Nurse	Readiness; position;latch on; milk transfer; outcome
SAIB: Systematic Assessment of the Infant at the Breast	Infant	Mother or nurse	Alignment; areolar grasp; areolar compression; audible swallowing

MBFES: Maternal Breastfeeding Evaluation Scale	Mother and infant	Mother	Maternal enjoyment/role attainment; infant satisfaction/growth; lifestyle/maternal body image.
PEBPT; Potential Early Breastfeeding Problem Tool	Mother	Mother	Breastfeeding problems among postpartum women

Two studies were identified which evaluated the relationship between breastfeeding assessment tools and breastfeeding outcomes. Hamelin and McLennan (Hamelin & McLennan 2000) in a study from Canada assessed the relationship between the use of the LATCH Breastfeeding Charting System by nursing staff during postpartum hospitalisation and breastfeeding outcomes. A post test control group design with non random groups collected data from a convenience sample of 180 breastfeeding women who gave birth in an urban perinatal centre, and consented to take part in the study. Ninety women received the LATCH tool intervention, which assigned a numerical score of 0, 1 or 2 to five key components of breastfeeding, as listed in Table 1 above. Six week postpartum telephone interviews demonstrated no significant differences in breastfeeding outcomes between the two groups in exclusive breastfeeding. Although women in the post-test group reported increased confidence in their assessment of infant breastfeeding and when to ask for help with breastfeeding problems, the use of the LATCH assessment did not reduce the incidence of early breastfeeding problems, particularly concern relating to insufficient milk, which was reported by a similar proportion of women in both groups (50% of 46%).

A pilot study by (Schlomer, Kemmerer, & Twiss 1999) evaluated how the scores on the LATCH and IBFAT correlated with scores on breastfeeding satisfaction (MBFES tool) and breastfeeding problems (PEBPT tool). A small convenience sample of 30 breastfeeding mothers and babies were studied, with 15 in each group. As scores on the LATCH and IBFAT increased, maternal satisfaction scores tended to increase, and breastfeeding problem scores decreased, but neither reached significance which may be due to the

small sample size and other study limitations, including the subjectivity of the assessment.

The Breastfeeding Clinic, Hospital for Sick Children, in Toronto (Newman 1996), developed a decision tree and management protocol based on expert opinion and clinical experience, to assess breastfeeding in order to prevent problems with dehydration and poor weight gain in breastfed infants. The initial assessment of breastfeeding included proper attachment, positioning, suckling as well as observation of frequent mustard coloured bowel movements and 8 soaked (not damp) nappies per day.

A systematic review (Dyson et al. 2006) published by the HDA reviewed a postnatal self monitoring daily log described by Pollard, 1998. Although successful among American women of high socio-economic status, it was felt that widespread implementation of this strategy would increase health inequities.

6.3.4.1 What information can be given to the mother to help her decide if her baby is getting enough milk?

Concerns about insufficient milk supply (IMS) are frequently cited as a reason for early termination of breastfeeding or for supplementation with formula. Breast milk production is a function of both maternal capacity for milk synthesis and infant demand for milk (Dewey et al. 2002). Any situation which contributes to infrequent stimulation and removal of milk from the breasts can result in a diminished milk supply. Hill (Hill 1992) in a narrative review of the literature relating to potential clinical and non clinical factors associated with IMS suggested that rigid feeding schedules, supplementation, and nipple problems were common maternal factors. Infant sucking difficulties and irritability constitute infant-related factors.

Hillervik-Lindquist (1992) studied 51 mother infant dyads and compared those who experienced a “lactation crisis” because of perceived breast milk insufficiency and those who did not. Twenty eight of 51 women perceived they had breast milk insufficiency. Differences between the two groups, which were

assessed by home visits and telephone contacts during the first 6 months postpartum, revealed differences in breastfeeding attitudes. The crisis group tended to initiate breastfeeding for infant related reasons more frequently than the non crisis group, which more frequently gave mother related reasons. During the course of breastfeeding, attitude changes in a negative direction were significantly more common in the crisis group.

In a series of ten in-depth interviews with primiparous women (Dykes & Williams 1999) six women expressed concern about breast milk sufficiency. Among the themes which emerged in this study were the quest to quantify and visualise breast milk which included weighing the baby and comparing breast milk appearance to formula and anxiety regarding the adequacy of their diets. Conflicting advice from health professionals regarding appropriate feeding practices and the need for support were also identified as prominent themes.

Dewey and colleagues (2002) presented preliminary findings from a community-based prospective study of the incidence of and risk factors for insufficient milk intake in a study undertaken in California, USA. Two hundred and eighty mother-infant pairs were recruited within 24 hours of the birth. Lactation guidance was provided by trained health professionals during the in-patient stay and at the woman's home on days 3, 4 and 14 as required. The reported preliminary results were as follows:

- Delayed onset of milk production (>72 hours pp) was common (24%) especially in primiparous women (34%)
- Weight loss > 10% of birth weight occurred in 12% of infants by day 3, and was 6 times more likely if there was a delayed onset of milk production (35 vs. 5.6%).
- Delayed onset of milk production was a key risk factor for subsequent formula use
- About half of infants scored < 10 on the IBFAT on day 1 but this decreased to 22% on day 3 and 14% on day 7

- The vast majority (81%) of women reported breastfeeding problems on day 3

The need to ensure women were followed at around the third day postpartum was highlighted, particularly primiparous women and women delivered by caesarean section. Caution should be applied when interpreting results, as the study population had high educational attainment and high levels of social support, both factors associated with increased uptake and longer duration of breastfeeding.

McCarter-Spaulding and Kearney (Carter-Spaulding & Kearney 2001) postulated that low confidence in parenting ability might be associated with perceived insufficient milk supply. Sixty breastfeeding mothers of infants ages 1-11 weeks were recruited at paediatric visits and asked to complete a Perceived Insufficient Milk questionnaire. There was a significant correlation ($p<0.01$) between self-efficacy and perceived insufficient milk scores leading the researchers to suggest that interventions to enhance parenting self-efficacy may improve women's confidence in the adequacy of their milk supply.

Birth to Five (Department of Health. 2005) advises that women can be sure their babies are getting sufficient milk and is not dehydrated if he or she:

- Has plenty of wet nappies each day and is having nothing but breast milk;
- Is growing and generally gaining weight
- Is awake and alert for some of the time.

6.3.4.2 If the baby is not getting enough milk, what can the health professional suggest for the mother to do?

Expert opinion forms the basis of evidence in this area. No research studies were identified which evaluated various methods of feeding enhancement.

Birth to Five (Department of Health. 2005) advises that women feed as frequently and for as long as the baby wants. Frequent feeds, including night feeds, stimulate milk production.

The Breastfeeding Clinic in Toronto (Newman 1996) utilises several techniques to improve infant feeding. Initially, infants are repositioned, and mother-infant pairs are assisted with proper attachment and breast compression if necessary. Finger feeding using a lactation aid or cup feeding is used in the rare cases when intervention is required. Women are given guidance regarding signs of normal feeding and danger signs of dehydration.

6.3.4.3 What effect do supplements have on the success of breastfeeding?

Step six of the WHO/UNICEF Ten Steps to Successful Breastfeeding states, "Give newborn infants no food or drink other than breast milk, unless medically indicated" (Hunt 2002). A number of studies have reviewed the effect of supplementation on the duration of breastfeeding.

Blomquist et al (1994) studied feeding patterns in a maternity ward in Sweden. Five hundred and twenty one newborns were followed prospectively for four months. One quarter of the babies received supplementary feeds on the third day of life. At three months the adjusted odds ratio of not being breastfed was 3.9 for those who received supplements.

A Spanish study (Martin-Calama 1997) evaluated the effect of feeding glucose water to breastfeeding newborns. One hundred and eighty newborns were randomly assigned to two groups. One group were allowed to receive 5% glucose water ad libitum from a bottle for the first 3 days of life. The second group received no supplements to human milk during the same period. There was a significantly greater weight loss in the non glucose water group during the first 48 hours but no difference at 72 hours. Weight loss did not exceed 7% in either group. The percentage of infants receiving formula in the first month postpartum was significantly greater in the supplemented group ($p<.05$). Breastfeeding duration was followed until 20 weeks postpartum and found to be significantly longer in the non glucose water babies ($p<0.01$). The researchers

speculated that administration of glucose water may contribute to deficient lactogenesis. This has not been routine practice in the U.K. for many years.

The effect of formula discharge packs on breastfeeding duration has been reviewed in the narrative for question 2-2 d (Donnelly et al. 2000).

Dyson et al (2006) reviewed five RCTs and two non RCTs and based on the evidence reviewed, concluded that supplements in the neonatal period should be given only when there are sound medical indications, which supports the WHO/UNICEF recommendation included in the BFI 10 steps. If supplements are given for medical reasons or mothers' choice the duration of breastfeeding is less likely to be affected if only a small number of supplements are given in the first five days.

6.3.4.4 In what circumstances should a baby receive supplementary feeds? AND how should breast-milk or substitutes be given to a baby who is not actively breastfeeding?

The WHO/UNICEF recommendation for supplementation only when medically necessary is noted in Section 6.3.4.3 above. No research was identified which specifically addressed circumstances for supplementation. A paper by Newman (Newman 1996) which was reviewed in the narrative for question 6.3.4.2 on breast milk sufficiency described a decision tree for assessment of adequate feeding. Based on experience gained at the Breastfeeding Clinic of the Hospital for Sick Children, Toronto, the author maintained that dehydration and poor weight were potentially preventable problems. The serious consequences of poor feeding are severe hypernatraemic dehydration, severe weight loss and severe hyperbilirubinemia with possible irreversible damage to a baby's brain or other vital organs. The preferred method at the clinic for supplementing a dehydrated baby who can be repositioned and reattached on the breast but is still not feeding well is through a lactation aid at the breast. A feeding tube attached to a source of supplemental breast milk is positioned at the nipple so as the infant sucks, he/she receives breastmilk both directly and via the supplement. If repositioning, re-attachment and breast compression are

not effective and the baby is truly not attaching, finger feeding or cup feeding is recommended. Finger feeding is a technique which utilises a lactation aid feeding tube along side the carer's index finger. This allows feeding without the use of an artificial nipple (teat). It is believed by these clinicians that finger feeding helps train the baby to take the breast, whereas using an artificial nipple interferes with breastfeeding, although evidence to support this was not identified.

Howard et al (1999) examined the effects of two methods of delivery of supplementary fluids on breastfeeding duration; cup feeding or bottle feeding for supplements during the postnatal stay; and early (2 – 5 days) versus late (> 4 weeks) introduction of an infant dummy. Recruitment took place antenatally among women who intended to breastfeed and were undecided or wanted their babies to have a dummy. Randomisation was performed using opaque envelopes in blocks of 20. Seven hundred of 807 infants whose mothers fulfilled inclusion criteria were randomised to receive bottle/early dummy (n = 169); bottle/late dummy (n = 167); cup/early dummy (n = 185); or cup/late dummy (n = 179). Data were collected at birth and throughout the infant's first year of life by investigators blinded to group interventions. Effects on breastfeeding duration were evaluated using survival analysis and logistic regression. Supplemental feeds regardless of method had a detrimental effect on breastfeeding duration, when assessed at 1 year postpartum ($p<.0001$), with no differences in cup versus bottle groups and breastfeeding duration. Effects were modified by the number of supplements; exclusive and full breastfeeding duration was prolonged in cup fed infants given more than two supplements. The researchers concluded that findings supported recommendations to avoid exposing breastfed babies to artificial teats in the neonatal period.

Dyson et al (2006) in their systematic review undertaken for the HDA, reviewed two studies which presented data on a total of 1302 infants. The only conclusion drawn from the evidence was that cup feeding may have better outcomes in relation to breastfeeding duration compared to bottle feeding in infants delivered by caesarean section.

The Singapore Ministry of Health evidence based guideline (2002) recommends that mother's own colostrum or milk should be the first choice for supplementation.

6.3.5 What should be done to prevent, identify and treat breastfeeding problems?

6.3.5.1 Sore nipples, painful nipples and nipple trauma

Identification

No specific studies on identification of nipple pain, sore nipples or nipple trauma were identified in the literature.

Prevention and Treatment

Sore and/or painful nipples are common problems associated with associated with poor information and support. They frequently occur due to suction trauma that is secondary to incorrect positioning. Paramount to prevention is therefore the correct attachment of the infant to feed.

A systematic review on management of nipple pain and /or trauma associated with breastfeeding (Page, Lockwood, & Guest 2003) identified eight studies of interventions aimed at preventing nipple pain/trauma (five other included studies examined interventions to manage pain). Meta-analyses could not be performed due to study heterogeneity, however a narrative summary of each study and comparison of interventions between studies was undertaken. Six prevention studies only included primiparous women. The studies are detailed below.

Standard antenatal education for primiparous women (n = 79) was compared with an additional half hour one – to – one education session within 24 hours postpartum (n = 79)(Henderson et al, 2001). There was statistically less nipple pain in the intervention group at day 2 ($p \leq 0.005$) and day 3 postpartum ($p \leq 0.04$), however this difference did not persist at 6 weeks, 3 months and 6 months.

One small RCT (Buchko et al, 1994) compared interventions to prevent pain among 73 primiparous breastfeeding women: instruction only (n = 15), warm moist tea bags (n = 21), warm water compress (n = 18), and milk massaged into the nipple and air dried (n = 19). The researchers found that the expressed milk group had the highest mean scores for pain effect and intensity, as assessed using a visual analogue scale (VAS). The warm water compress group had the lowest mean VAS scores, although statistical significance was not reported.

A second RCT from the USA (Pugh et al, 1996) compared four interventions amongst 177 primiparous women: instruction only (n = 44), warm water compress (n = 44), milk massaged into the nipple and air dried (n = 45) and, USP modified lanolin (n = 44). The warm water compress group reported the lowest nipple pain intensity and effect (assessed using a numeric rating scale) on days 7 and 14 postpartum. The interventions assessed in an RCT from Turkey which recruited 90 women included the application of warm wet compresses on or around the nipples after breastfeeding four times a day; application of expressed milk on the nipples after each feed; and no treatment. More women in the expressed milk group had cracked nipples on day 1, but on days 2 to 10 fewer women in this group had this symptom. There was no statistical difference in nipple pain scores, although it is unclear how scores were assessed. A pilot study of 23 women which compared lanolin versus breast milk found no difference in nipple pain or trauma. Women acted as their own controls. Pain was self assessed using a four-point scale, completed after every feed for 10 days postpartum, and trauma assessed by a researcher blinded to study allocation on days 0,1,2,3,5,7 and 10. It should be noted that hydrous lanolin has been discontinued due to concerns about pesticide residue. Only highly purified, anhydrous lanolin is suitable.

A study from the UK evaluated outcomes in 200 women randomised to use one of two aerosol sprays: placebo of distilled water versus chlorhexidine (0.2%)/alcohol (Herd & Feeney, 1986). Outcomes in relation to the condition of the nipples were assessed using a Likert scale. Both groups showed a

significant reduction in breast pain and trauma from week 1 to week 4. The chlorhexidine group experienced less pain and significantly more mothers in the chlorhexidine group were breastfeeding at 4 weeks. A second RCT from Italy included 219 primiparous and multiparous women and compared aerosol sprays and/or ointments with the avoidance of treatment. The results of the study suggested that the use of aerosol sprays may be no better than doing nothing.

An RCT involving 50 primiparous and multiparous women evaluated the effectiveness of a film dressing compared to no treatment (Ziemer et al, 1995). Women acted as their own controls, with breasts randomly allocated to each group. The dressing was made from polyethylene and was specifically designed for the study. Although there was a statistically significant decrease in total pain score, assessed using a six-point verbal descriptor scale, for the film dressing group, there was a high drop-out rate (16%) probably due to the painful removal of the dressing which may counteract the reduced pain scale result.

The reviewers concluded that due to the small sample sizes, inadequate reporting of data, and inclusion of only primiparous women in several studies, findings could not be generalised. The limited evidence available showed that no single intervention offered conclusive benefit in terms of the prevention of nipple pain.

Dyson et al (2006) reviewed 3 studies on the use of topical agents to treat sore nipples and concluded that no one treatment was more effective than another. Their review also identified one study which assessed the benefit of breast shells, evidence from which did not support their use as an effective intervention for the management of sore nipples. An earlier review by Renfrew et al (2000) included evidence from three studies of nipple shields, which found no beneficial effect from their use on breastfeeding duration, milk transfer or milk volume. If problems with attachment are suspected the mother should detach the infant by inserting a finger into the corner of the baby's mouth to break the seal and release the nipple/areola. Correct positioning and

attachment are crucial, and there is no evidence to suggest that limiting breastfeeding duration or applying topical agents, such as breast milk or lanolin has an effect on nipple soreness. Use of nipple shields will not enable incorrect attachment and positioning to be resolved.

Nipple pain may also be related to thrush, information and guidance on which is included in the chapter on infant management.

6.3.5.2 .Breast pain

No literature was found in the search strategy that specifically related to management of breast pain other than pain related to the nipple or to breast engorgement.

6.3.5.3 Breast engorgement

Breast engorgement is a common complication of the early postnatal period and usually occurs between 2-5 days after delivery (Kulshi et al, 1978, (Roberts, Reiter, & Schuster 1995) peaking on day 3 (Roberts 1995). It can also occur in women who are not breastfeeding, however the evidence presented here is only relevant to women who are breastfeeding. Engorgement arises either as a result of venous and lymphatic stasis prior to the onset of milk secretion, or by the obstruction of the lactiferous ducts following the onset of lactation. If the excess milk is not removed the alveolar space (where cells excrete milk) may become over-distended resulting in the breasts feeling hot, tender, swollen and painful. If left untreated, the over-distension will cause pressure on the surrounding tissue and will occlude the capillaries. This may result in increased arterial pressure to the breasts and compression of the connective tissue. The drainage of the lymph nodes may be impeded with consequent development of oedema. It is important to treat breast engorgement because it may lead to physiological changes including decreased milk output, which could potentially create an insufficient milk supply.

<u>Identification</u>

Symptoms of breast engorgement include firm, tender, and/or painful breasts. One small cohort study followed 120 women for 14 days after delivery, during which they were asked to complete a validated six-point engorgement scale previously developed by the authors (Humenick, Hill, & Anderson 1994). Of these women, 114 provided 'adequate engorgement' data as defined by the authors. Four distinct patterns of engorgement were identified; bell-shaped, multimodel, intense and minimal. Mothers who experienced a bell shaped engorgement pattern (46/40%) reported one experience of very firm and tender breasts as early as day 3 and as late as day 14, following which their symptoms declined. Mothers who reported multimodal engorgement experienced peak engorgement and resolution of symptoms for at least 24 hours followed by peak(s) thereafter (18/16%). Mothers with intense engorgement reported symptoms were present for the entire 14 day study period (23/20%). Minimal engorgement mothers experienced firm but non-tender breasts or only slight breast changes from those occurring during pregnancy (27/24%). The findings of this small study are not generalisable, nevertheless, suggest symptoms of engorgement differ between individual women, with no association with maternal or infant characteristics or breastfeeding pattern. Further research in this area is required.

Prevention

The following preventive measures were identified by Renfrew et al in their introduction to a systematic review on the treatment of engorgment (Dyson et al. 2006):

- Early breastfeeding
- Correct positioning and attachment of the infant on the breast
- Spontaneous breastfeeding.

Treatment

A Cochrane review was identified on interventions to relieve symptoms of breast engorgement among breastfeeding women (Snowden, Renfrew, &

Woolridge 2001). Eight trials were included in the review, providing data on a total of 424 women. Five trials compared treatment versus placebo (Serrapeptase (anti-inflammatory proteolytic enzyme drug), bromelain/trypsin protease complex, oxytocin, cabbage leaf extract and ultrasound). Two trials compared two treatments against each other (room temperature cabbage leaves versus chilled cabbage leaves and chilled cabbage leaves versus gel packs). One trial compared intervention (gel packs) versus no treatment.

Only two RCTs showed a direct effect of the intervention tested on symptoms of engorgement. The first was a study using a bromelain/trypsin protease complex (Murata, Hanzawa, & Nomura 1965). The drug significantly decreased symptoms of engorgement namely pain and swelling (OR 8.02, 95% CI 2.76-23.3). The second study used Serrapeptase (Kee et al, 1989). The drug treatment resulted in a significant improvement in total improvement rate compiled from the following symptoms; breast pain, breast swelling and induration of lactation (OR 3.6, 95% CI 1.27-10.26). Analysis of individual symptoms showed that Serrapeptase did not have a significant effect compared with placebo. Serrapeptase and the bromelain/trypsin protease complex are only licensed for use in Italy and Japan for the treatment of breast engorgement postpartum.

None of the studies utilising cabbage leaves were able to exclude the possibility of a placebo effect. Roberts et al 1995a used a self administered questionnaire of pain perception (Bourbonnais pain ruler, analogue scales of breast hardness and engorgement scales: (Bourbonnais 1981)). The tool was used pre and post treatment with either chilled or room temperature cabbage leaves. There was no difference in outcome between chilled or room temperature cabbage leaves; both treatments resulted in a significant reduction in the post-pain scale rating (chilled cabbage leaves: 38% decrease in pain; room temperature cabbage leaves: 38% decrease in pain). Roberts et al (Roberts 1995) used the same methodology to compare chilled cabbage leaves with chilled gel packs. There was no significant difference between the two interventions, although there was a preference for use of cabbage leaves. Chilled cabbage leaves caused a

decrease in the post-test pain scale compared with the pre-test by 30%, while chilled gel packs caused a 39% reduction.

The use of oxytocin (Ingelman et al, 1953), ultrasound (McLachlan 1987;McLachlan et al. 1993) , cabbage leaf extract (Roberts, Reiter, & Schuster 1998) or cold packs (Robson 1990) had no effect on symptoms of breast engorgement. The Cochrane reviewers noted that the cold pack study had different base-line measures between the intervention and control groups. As outcomes were assessed following breastfeeding, this may explain the lack of difference because the effect of feeding might have over-ridden the potential effect of the intervention. The Cochrane reviewers also noted that the statistical power of the cabbage leaf extract study (Roberts, Reiter, & Schuster 1998) must be questioned because the trial was stopped on ethical grounds before the planned study size was recruited.

The systematic review undertaken for a breastfeeding guideline developed by the Singapore Ministry of Health (2002) stated that central to management of breast engorgement is the need to ensure that the mother is comfortable, so that she can continue to nurse and maintain her milk supply. Breast milk drainage should also be maintained to prevent the development of back pressure in the ducts, which would cause decreased milk production. To this end, demand feeding is the most appropriate management because suckling by the infant is the most effective mechanism for removal of milk. Additionally, breast massage effectively increases milk supply and relieves plugged ducts. Pain may be reduced with the application of cabbage leaves, which can be used with breast massage, milk expression and analgesia. Warm packs/hot compresses should be avoided because although they improve vascular flow, they may aggravate swelling if the ducts are blocked. Warm packs can be used if breasts are leaking.

Breast massage and hand expression of breast milk may also be used to stimulate the milk ejection process, increase milk supply and relieve blocked ducts. *Birth to Five* (Department of Health. 2005) provides both written and pictorial instructions for the expression of breast milk.

6.3.5.4 Mastitis

Lactation mastitis is defined as, "…a cellulitis of the interlobular connective tissue within the mammary gland that usually occurs in the first 6 weeks postpartum. The clinical spectrum ranges from focal inflammation with minimal systematic symptoms to abscess and septicaemia (Foxman et al. 2002). Some clinicians make a distinction between infective and non-infective mastitis (Osterman & Rahm 2000). Identification of causative organisms and appropriate treatment of lactation mastitis has not however been well researched.

Birth to Five (Department of Health. 2005) expert opinion recommends that a woman with a red, hot, painful area on the breast should continue to feed, making sure that the baby is correctly attached. Feeding on demand is encouraged. Women are also advised to rest and not to wear a bra, especially at night. If symptoms do not resolve, treatment with antibiotics may be required.

Thomsen et al (Thomsen, Espersen, & Maigaard 1984) suggested that inflammatory breast symptoms could be classified according to leukocyte counts of milk and quantitative cultivation for bacteria into milk stasis, non-infectious inflammation and infectious mastitis. The criterion set for infectious mastitis was the occurrence of any bacteria in numbers greater than 103 cfu/ml milk. However there is a bacterial content in breast milk representing normal skin flora and Osterman & Rahm (Osterman & Rahm 2000) refer to studies which indicate that the predominant potential pathogenic bacterium isolated in milk from women with lactation mastitis is Staphylococcus aureus and rarely beta-haemolytic streptococci. In their study cultures were taken from 40 women with lactation mastitis. Women with positive cultures for normal skin flora (61%) were treated conservatively with rest and frequent emptying of the breast and had no complications and no antibiotic therapy. Nine of sixteen women with cultures which indicated a potentially pathogenic bacteria received antibiotics. Eighty one percent of these women had symptoms longer than one week and 31% chose to wean their children.

In an observational study from Denmark of 339 cases of mastitis occurring in 213 women, Thomsen et al (Thomsen, Espersen, & Maigaard 1984) also showed that emptying the breast resulted in a significant decrease in the duration of symptoms and a significantly improved outcome ($p<0.001$). The duration and outcome of cases were compared among women who received no interventions and women who received treatment, comprising systematic emptying of the breast, supplemented in some cases with antibiotics based on culture of their breast milk. If symptoms resolved, followed by resumption of normal lactation for the next two weeks, the outcome was defined by the authors as 'good'. A defined 'bad' outcome included symptoms persisting for more than two weeks, impaired milk secretion, recurrence of infection or development of sepsis or a breast abscess. Infectious mastitis without treatment was followed by a good outcome in only 15%, and 11% of women developed abscesses. Emptying the breast increased the rate of a good outcome to 50% and significantly decreased the duration of symptoms. The addition of antibiotic (penicillin/erythromycin) therapy resulted in a good outcome in 96% of cases and further reduced duration of symptoms ($p<0.001$).

In a small RCT by Hager and Barton (Hager & Barton 1996) the breast milk of 25 women with mastitis was cultured. The cultures were predominantly Staphylococcus aureus, characteristic of normal skin flora and were resistant to penicillin. Half of the women were treated with amoxicillin and half with cephradine (a cephalosporin). All recurrences were due to the presence of pathogenic staphylococcus aureus and required treatment with a beta lactamase resistant antibiotic. On the basis of this investigation, the researchers suggest the use of a beta lactamase resistant antibiotic for mastitis along with moist heat and continued breastfeeding.

The literature is not robust in this area and the two remaining studies were methodologically flawed but both demonstrated a response to antibiotic therapy. Both Devereux (Devereux 1970) and Niebyl et al (Niebyl, Spence, & Parmley 1978) recommend early treatment of mastitis with antibiotics and continued feeding to prevent abscess formation.

6.3.5.5 When should a woman be asked about problems?

Literature was not identified which addressed the timing of inquiry about breastfeeding problems.

6.3.5.6 Under what circumstances should a woman be referred?

Literature was not identified which addressed the timing of inquiry about breastfeeding problems.

6.3.5.7 Inverted nipples

Identification

No literature was found in the search strategy that specifically related to the identification of inverted nipples

Treatment

No literature was found in the search strategy for treatment of inverted or non protractile nipples in postpartum women.

6.3.5.8 Are there interventions to facilitate continued breastfeeding when the baby is:

a. Jaundice (reference infant management)

b. Tongue tied

c. Sleepy

d. Failure to gain weight

Research studies which address infant problems with breastfeeding are rare.

Tongue Tie

The condition of tongue-tie (ankyloglossia or short lingual frenulum) is controversial. There is no agreement among professionals on the definition, diagnosis or treatment of this condition (Berg 1990). It is thought that this

condition may cause difficulty in attaching on to the nipple and inadequate feeding and nipple pain may result. However, without a standardized definition the actual prevalence of this condition is unknown and the degree to which ankyloglossia results in maternal discomfort is also uncertain (Dyson et al. 2006).

Ballard et al (Ballard, Auer, & Khoury 2002) utilized a tool for the assessment of ankyloglossia called the Hazelbaker Assessment Tool for Lingual Frenulum Function which assesses attaching and nipple pain. The researchers examined 2763 breastfeeding inpatient infants and 273 outpatient infants for possible ankyloglossia using the tool. Each dyad was observed breastfeeding, and mothers asked to describe the quality and sensation of the suck at the breast. If pain was reported, the mother was asked to grade this on a scale of 1 to 10. Ankyloglossia was diagnosed in 88 (3.2%) inpatients, and 35 (12.8%) outpatients. The mean scores of the tool were similar to the presenting symptoms of nipple pain and poor attachment. Median infant age at presentation was lower for poor attachment than for nipple pain (1.2 days cf 2.0 days). Frenulotomy was performed in 123 infants. Attachment improved in all cases and mean maternal nipple pain levels fell significantly (p=.0001). As the study did not include a control group, or collect data on the duration of breastfeeding, findings may not be generalisable.

Conservative treatment for suspected tongue-tie may involve breastfeeding support to maximize attachment to the breast, parent education and reassurance. According to the Canadian Paediatric Society guidance, if there is no improvement in feeding, referral for a frenulotomy/frenulectomy should be considered (Canadian Paediatric Society 2002),

An RCT was undertaken to determine if conservative management (referral to a lactation consultant) of infants with tongue tie and a feeding problem, or immediate division of the frenulum was more effective and enabled infants to feed normally (Hogan, Westcott, & Griffiths 2005). Between March and July 2002 all babies born in the district of Southampton were inspected for tongue tie. If feeding problems developed and the infant's mother consented, the

babies were randomized to either intensive support from the lactation consultant or to immediate division of the tongue tie. A total of 57 babies were randomized. Of the 29 controls one improved and breastfed for 8 months (3%). Of the 28 babies who had immediate division, 27 improved and fed normally but one remained on a nipple shield ($p<0.001$). Twenty four women breastfed their babies for 4 months (60%). Overall, division of the tongue tie babies resulted in improved feeding in 95% of babies.

A study by Griffiths (Griffiths 2004) assessed indications for and safety and outcome of simple division of tongue tie without an anaesthetic. The study group comprised 215 infants younger than 3 months who experienced difficulty breastfeeding. The mean age was 19 days. During the procedure 183 infants (85%) cried for 20 seconds or less. Feeding was assessed by the mothers immediately, at 24 hours and 3 months after division. Prior to division,189 (88%) had difficulty latching, 166 (77%) of mothers experienced nipple trauma and 155 (72%) had a continuous feeding cycle. Within 24 hours, 172 (80%) were feeding better. Overall, 138 (64%) breastfed for at least 3 months (UK national average is 30%).

An audit of frenulotomy was carried out on 21 infants referred between January and June 2002 at Southampton General Hospital and on 21 babies referred over a 3 month period in 2003 (Blenkinsop 2003). The outcome in 95% of cases showed that division of the tongue-tie improved feeding and early diagnosis and treatment appeared to be beneficial to successful breastfeeding.

NICE has recently issued guidance on division of ankyloglossia (tongue tie) for breastfeeding babies (National Institute for Health & Clinical Excellence. 2005). NICE's review showed that the procedure was safe enough and worked well enough to improve breastfeeding in affected babies that guidance in performing this procedure was warranted.

Sleepy babies

There was no research literature located in relation to sleepy babies and breastfeeding. Glover (Glover 1995) developed a flow chart designed to assist

nursing staff with decision making regarding supplementation. A good practice point on this chart involves interventions when an infant does not wake and feed effectively within 3-5 hours of the last feed. The mother is instructed to wake the baby, use gentle stimulation, unwrap the baby, change the nappy, rock and massage. If the infant still does not feed then assessment should be done for signs and symptoms of hypoglycaemia, sepsis and dehydration.

Weight loss

No research on breastfeeding interventions for infants who are losing weight were located. Previous reviews of supplementation addressed methods of supplementation, particularly those employed at the Breastfeeding Clinic in Toronto.

6.3.6 Information and Community Support

6.3.6.1 What information and support offered to the woman and her partner and family members is more likely to enable women to successfully commence and continue breastfeeding?

6.3.6.2 What information and support do women want/value to help them successfully breastfeed?

6.3.6.3 What advice and support can give a mother confidence in her ability to breastfeed her baby?

6.3.6.4 How best is information and support provided?

The research literature does not provide studies which indicate the specific information women should or want to receive in relation to breastfeeding. Several excellent systematic reviews address the topic of support for breastfeeding mothers. A Cochrane review by Sikorski et al (Sikorski et al. 2002), "Support for Breastfeeding Mothers," analysed 20 eligible randomised or quasi randomised controlled trials involving 23,712 mother-infant pairs. There was a beneficial effect on the duration of any breastfeeding in the meta-analysis of all forms of extra support (RR for stopping any breastfeeding before

six months 0.88, CI 0.81-0.95). Extra professional support appeared beneficial for any breastfeeding (RR 0.89, CI 0.81-0.97) but did not reach statistical significance for exclusive breastfeeding (RR 0.90, CI 0.81-0=1.01). On the other hand the effect of lay support was the opposite. Peer support was effective in reducing the cessation of exclusive breastfeeding (RR 0.66, CI 0.49-0.89) but its effect on any breastfeeding did not reach statistical significance (RR 0.69-1.02).

Dyson et al (2006) found high quality evidence that both health professional support and peer support can be effective in supporting both exclusive and any breastfeeding among relatively advantaged women. Evidence of lesser quality suggests that "… effective support can come from peers and from professionals, working separately or together, if it is specific breastfeeding support rather than general postnatal support and if it is offered to women who actively want breastfeeding support or have decided to breastfeed" (Dyson et al. 2006). The review findings supported the conclusions of an earlier systematic review by Fairbank et al (2000) undertaken for the HTA programme to assess the effectiveness of interventions to promote the initiation of breastfeeding, which showed that written education materials were not effective at increasing the duration of breastfeeding among women in different income groups from developed countries. This review also found that the combination of antenatal education and limited postnatal telephone support was not effective among high income women and women who intended to breastfeed. This research featured a combination of antenatal education and postnatal telephone support among highly educated and highly motivated women. Conclusions should not be drawn about other groups of women..

In contrast, Fairbank et al (2000) did find that breastfeeding literature alone or combined with a more formal, non interactive method of delivering health education had a limited effectiveness on the commencement of breastfeeding. Small informal group health education classes seem to increase both initiation and duration rates of breastfeeding. Two studies reviewed demonstrated the effectiveness of peer support programmes. The reviewer's recommendations

for breastfeeding support to promote the initiation and duration of breastfeeding included:

- Good practice peer support programmes
- Good practice breastfeeding education programmes
- Previously reviewed changes in maternity ward practices to promote mother-infant contact and autonomy.

6.3.6.5 Are there cultural differences that need to be considered in delivering information and support on breast or bottle-feeding?

Cultural differences in feeding practices were highlighted in a survey of "Human Relations Area Files" (a compendium of cross-cultural data, Murdock et al 1982) and ethnographic infant feeding literature on the timing of infant feeding (Morse, Jehle, & Gamble 1990). Data obtained from 120 cultures showed that in 50 cultures there was a practice of withholding colostrum from the infant for 48 hours or more. The authors suggest it is important to determine a mother's belief about colostrum if she is refusing to nurse the infant immediately. It may be that she would like to breastfeed in a day or two and that culturally acceptable prelacteal substitutes should be given to the infant.

Dyson et al (2006) evaluated two trials involving culture-specific education sessions. Both trials suggest that such education can be effective at increasing duration rates of breastfeeding but the poor quality of these trials does not provide robust evidence.

A qualitative study using focus groups was conducted with a group of Turkish and Kurdish women about child feeding issues (England, Doughty, & Genc 2003). Breastfeeding or mixed breast/bottle feeding were the normal methods of feeding in this group. Concern about adequacy of feeds was the primary reason for supplementation. The role of the health visitor was understood by women in these groups and mothers were more positive about their experiences of health visitors than doctors.

Interviews conducted by Bailey and colleagues collected qualitative data to examine the cultural expectations and experiences of breastfeeding among low income first time mothers (Bailey, Pain, & Aarvold 2004). Sixteen women were interviewed in their own homes in an area of North Tyneside, England. Non breastfeeding cultures permeated this area with little support for breastfeeding, an expectation of failure and expertise and confidence with bottle feeding more widespread among family and friends.

A quasi experimental pilot study which recruited 20 women explored whether breastfeeding support for women provided by a community health nurse and peer counsellor who made visits in hospital and the woman's home, and provided telephone support improved outcomes in low income breastfeeding women (Pugh 2001). The women who received the intervention had higher breastfeeding rates at five months. Although the study was not powered to demonstrate statistical differences, social support from a nurse and peer counsellor may be an approach for further research on breastfeeding duration among low income women.

6.3.7 Expression and storage of breast milk

6.3.7.1 Should all mothers who wish to breastfeed be taught to express breast-milk?

No research studies were identified which addressed these issues. The systematic review undertaken for the breastfeeding guidelines published by the Singapore Ministry of Health (Singapore Ministry of Health 2002) supported the International Lactation Consultant Association recommendation that mothers should be taught expression, collection and storage of breast milk.

6.3.7.2 What are the best methods of expressing and storing breast-milk?

A guideline published by the National Association of Neonatal Nurses (1999) entitled "Early discharge of the term newborn," provides good practice recommendations for two methods of removal of milk from the breast:

- Manual expression which is inexpensive and allows for skin to skin contact that may increase milk supply

- Mechanical pumping which can increase hormonal stimulation and can extract milk from both breasts simultaneously.

A study by Pittard et al (Pittard, III et al. 1991) measured the number of colony forming units (CFU) /ml in expressed milk from 16 women. Each woman employed both sterile and clean containers for collection and used both manual and mechanical pumping for milk expression. There was no statistically significant difference in colony count >104 CFU/ml between the clean and sterile containers or between those collected manually versus through pumping.

Breast milk expression and storage is described in the Department of Health publication for new parents entitled *Birth to Five* (Department of Health. 2005). It is recommended that milk be expressed into a sterilised bottle and then refrigerated. Breast milk may be kept no longer than 24 hours in the refrigerator. It can also be frozen for one week in a freezer or up to three months in a deep freezer. Thawed breast milk should be used within 24 hours, and breast milk should never be re-frozen.

6.4 Feeding formula milk

6.4.1.1 What information offered to the woman and her partner is more likely to enable women to formula feed?

Formula feeding refers to the use of bottles for feeding commercial formula milk to infants rather than breastfeeding. A survey of Scottish primiparous women (Cairney & Alder 2001) reviewed data from postal questionnaires and found that fewer than 50% of 365 postpartum women studied reported being given information before the birth of their babies on safe formula feeding techniques such as sterilising bottles and teats, making feeds and offering the right quantities. Of the women who began breast feeding and later introduced

formula feeds, a large percentage of women (60-65%) did not recall being given any information by professionals.

Several studies were located which evaluated formula preparation procedures. Data presented in a conference paper (Jacob 1985) were obtained from a cross sectional survey of 30 bottle-feeding mothers who were interviewed at home, which found that 11 (37%) mothers were not preparing feeds according to manufacturers directions. Only 14 (47%) mothers were sterilising bottles and teats according to health visitor recommendations and there was a statistically significant association between how a mother prepared a feed and how she sterilised; 86% of those who did not sterilise correctly also did not follow manufacturer's directions for formula preparation. Feed preparation and sterilisation were related to social class and to parity. Lower social classes and multiparous women were more likely to use incorrect techniques. The study also showed that instructions on bottle feeding techniques were received by 71% of primiparous women but only 25% of multiparous mothers.

Birth to Five (Department of Health. 2005) recommends sterilising all equipment used for formula feeding. The Department of Health leaflet on formula feeding also provides specific instructions for sterilizing and preparing formula milk (Department of Health. 2005).

Microwave heating of infant formula was studied by (Sigman-Grant, Bush, & Anantheswaran 1992). Bottles of refrigerated infant formula were heated in a microwave oven and temperatures throughout the bottle were assessed. Ascorbic acid and riboflavin contents were also determined by established methods. Significantly higher temperatures at the topmost portions of all bottle types were present. There was no significant reduction in riboflavin or vitamin C content following microwave heating. The non-uniformity of heating in the microwave led the researcher to recommend inverting bottles of formula heated in a microwave 10 times before feeding in order to mix formula temperatures.

An American study (Sigman-Grant, Bush, & Anantheswaran 1992) examined a cohort of more than 1000 subjects at each infant age in order to describe

practices related to infant formula feeding. These included diluting and concentrating the formula, mixing formula with warm tap water, sterilizing, storing prepared formula, heating in a microwave oven, putting the baby to bed with a bottle and adding cereal and sweeteners to formula. Compliance with recommended practices and events of infant diarrhoea were analysed. Data were reported for months 2, 5 and 7. All practices were self reported by postal questionnaire. Failure to comply with recommendations was high for several practices. Thirty three percent of mothers mixed formula with warm tap water rather than sterilized water and up to 48% heated bottles in a microwave. Thirty five percent of mothers added other food to bottles of formula of 2 and 5 month old infants. Receiving instruction from a health care professional on formula use had a positive effect on these practices for mothers of infants at 2 months of age. Diarrhoea was not related to sterilising teats and bottles or boiling tap water used to reconstitute the formula.

The National Association of Neonatal Nurses guideline for "Early Discharge of the term newborn" (1999) offers good practice points for feeding formula milk:

- Formula-feeding should not be hurried. Each feed should take at least 20 minutes to provide oral gratification.
- Infants can be fed on demand
- The newborn learns to bottle-feed.
- Infants require winding after each ounce of formula
- Infants should be held for the feed
- Do not prop the bottle

6.4.1.2 Should a breastfeeding mother be shown how to prepare a bottle? And if so in what context?

No literature was identified which addressed this question. However, Baby Friendly Initiative reccommends that breastfeeding women – or those planning

to breastfeed – should not be shown how to make up a formula feed. There is no information regarding breastfeeding mothers preparing bottles of breastmilk.

6.4.1.3 Is there a risk of overfeeding breast or formula fed babies?

One small study addressed the possibility of overfeeding in infancy. Sievers et al (International Lactation Consultant Association. 1999) refer to research which has shown a positive association between minimal or non-breast-feeding and adolescent obesity in a low socio economic status study group. This research group evaluated the diurnal distribution and size of feeds in 10 breast fed and14 formula fed infants during the first 4 months of life. A day-night asymmetry of feeding became more pronounced over time. The researchers hypothesize that this may reflect early weaning practices of western mothers. There was also a continuous increase in the median feeding volume in the formula feeding group and from the 6th week of life onwards, formula fed infants had significantly higher feeding volumes ($p<0.05$).

7 Maintaining Infant Health

7.1 Recommendations

1 Healthy babies should have normal colour for their ethnicity, maintain a stable body temperature, and pass urine and stools at regular intervals. They initiate feeds, suck well on the breast (or bottle) and settle between feeds. They are not excessively irritable, tense, sleepy or floppy. The vital signs of a healthy baby should fall within the following ranges:

- respiratory rate normally 30−60 breaths per minute
- heart rate normally between 100 and 160 beats per minute in a newborn
- temperature in a normal room environment of around 37°C (if measured).
- [D(GPP)]

2 At each postnatal contact parents should be offered information and guidance to enable them to:

- assess their baby's general condition
- identify signs and symptoms of common health problems seen in babies
- contact a healthcare professional or emergency service if required. **[D(GPP)]**

3 Parents, family members and carers should be offered information and reassurance on:

- their baby's social capabilities as this can promote parent–baby attachment (in the first 24 hours)
- the availability, access and aims of all postnatal peer, statutory and voluntary groups and organisations in their local community (within 2–8 weeks) **[D(GPP)]**

4 Both parents should be encouraged to be present during any physical examination of their baby to promote participation of both parents in the care of their baby and enable them to learn more about their baby's needs.

. **[D(GPP)]**

Parenting and emotional attachment

5 Assessment for emotional attachment should be carried out at each postnatal contact. **[D(GPP)]**

6 Home visits should be used as an opportunity to promote parent or mother-to -baby emotional attachment. **[B]**

7 Women should be encouraged to develop social networks as this promotes positive maternal-baby interaction. **[B]**

8 Group based parent-training programmes designed to promote emotional attachment and improve parenting skills should be available to parents who wish to access them. [**A]**

9 Health care providers should offer fathers information and support in adjusting to their new role and responsibilities within the family unit. **[GPP]**

Physical examination and screening

10 The aims of any physical examination should be fully explained and the results shared with the parents and recorded in the postnatal plan and the personal child health record. **[D(GPP)]**

11 A complete examination of the baby should take place within 72 hours of birth. This examination should incorporate a review of parental concerns and the baby's medical history should also be reviewed including: family, maternal, antenatal and perinatal history; fetal, neonatal and infant history including any previously plotted birth-weight and head circumference; whether the baby has passed meconium and urine (and urine stream in a boy). Appropriate recommendations made by the NHS National Screening Committee should also be carried out. (www.nsc.nhs.uk/ch_screen/child_ind.htm).

A physical examination should also be carried out. This should include checking the baby's:

- appearance including colour, breathing, behaviour, activity and posture
- head (including fontanelles), face, nose, mouth including palate, ears, neck and general symmetry of head and facial features. Measure and plot head circumference
- eyes; check opacities and red reflex
- neck and clavicles, limbs, hands, feet and digits; assessing proportions and symmetry
- heart; check position, heart rate, rhythm and sounds, murmurs and femoral pulse volume

- lungs; check effort, rate and lung sounds
- abdomen; check shape and palpate to identify any organomegaly; also check condition of umbilical cord
- genitalia and anus; check for completeness and patency and undescended testes in males
- spine; inspect and palpate bony structures and check integrity of the skin
- skin; note colour and texture as well as any birthmarks or rashes
- central nervous system; observe tone, behaviour, movements and posture. Elicit newborn reflexes only if concerned
- hips; check symmetry of the limbs and skin folds (perform Barlow and Ortolani's manoeuvres)
- cry; note sound
- weight; measure and plot.
- [D(GPP)]

12 The newborn blood spot test should be offered to parents when their infants are 5-8 days of age. **[D(GPP)]**

13 At 6–8 weeks, an examination, comprising the items listed in item 11, should be carried out. In addition, an assessment of social smiling and visual fixing and following should also be carried out. **[D(GPP)]**

14 A hearing screen should be completed before discharge from hospital or by week 4 in the hospital programme or by week 5 in the

community programme. **[D(GPP)]**

15 Parents should be offered routine immunisations for their baby according to the schedule recommended by the Department of Health. **[D(GPP)]**

Physical health and well being

Jaundice

16 Parents should be advised to contact their healthcare professional if their baby is jaundiced, their jaundice is worsening, or their baby is passing pale stools. **[D(GPP)]**

17 Babies who develop jaundice within the first 24 hours after birth should be evaluated. (emergency action). **[D(GPP)]**

18 If jaundice develops in babies aged 24 hours and older, its intensity should be monitored and systematically recorded along with the baby's overall well-being with particular regard to hydration and alertness. **[D(GPP)]**

19 The mother of a breastfed baby who has signs of jaundice should be actively encouraged to breastfeed frequently, and the baby awakened to feed if necessary. **[D(GPP)]**

20 Breastfed babies should not be routinely supplemented with formula, water or dextrose water. **[D(GPP)]**

21 If a baby is significantly jaundiced or appears unwell, evaluation of the serum bilirubin level should be carried out. **[D(GPP)]**

22 If jaundice first develops after 7 days or a baby remains jaundiced after 14 days in an otherwise healthy baby and a cause has not already been identified, it should be evaluated (urgent action).

[D(GPP)]

Skin

23 Parents should be advised that cleansing agents should not be added to a baby's bath water nor should lotions or medicated wipes be used. The only cleansing agent suggested, where it is needed, is a mild non-perfumed soap. **[D(GPP)]**

24 Parents should be advised how to keep the umbilical cord clean and dry and that antiseptics should not be used. **[A]**

Thrush

25 If thrush is identified in the baby, the breastfeeding woman should be offered information and guidance about relevant hygiene practices. **[D(GPP)]**

26 Thrush should be treated with an appropriate antifungal medication if the symptoms are causing pain to the woman or the baby or feeding concerns to either. **[D(GPP)]**

27 If thrush is non-symptomatic, the woman should be advised that anti-fungal treatment is not required. **[D(GPP)]**

Nappy rash

28 For babies with nappy rash the following possible causes should be considered:

- hygiene and skin care
- sensitivity to detergents, fabric softeners or external products that have contact to the skin

- presence of infection. **[D(GPP)]**

29 If painful nappy rash persists it is usually caused by thrush and treatment with anti fungal treatment should be considered. **[C]**

30 If after a course of treatment the rash does not resolve, it should be evaluated further (non-urgent action). **D(GPP)]**

Constipation

31 If a baby has not passed meconium within 24 hours, the baby should be evaluated to determine the cause which may be related to feeding patterns or underlying pathology (emergency action). **[D(GPP)]**

32 If a baby is constipated and is formula fed the following should be evaluated (urgent action) **[D(GPP)]**

- feed preparation technique
- quantity of fluid taken
- frequency of feeding
- composition of feed.

Diarrhoea

33 A baby who is experiencing increased frequency and/or looser stools than usual should be evaluated (urgent action). **[D(GPP)]**

Colic

34 A baby who is crying excessively and inconsolably, most often during the evening, either drawing its knees up to its abdomen or arching its back, should be assessed for an underlying cause, including infant colic (urgent action). **[D(GPP)]**

35 Assessment of excessive and inconsolable crying should include: [D(GPP)]

- general health of the baby
- antenatal and perinatal history
- onset and length of crying
- nature of the stools
- feeding assessment
- woman's diet if breastfeeding
- family history of allergy
- parent's response to the baby's crying
- any factors which lessen or worsen the crying.

36 Health care professionals should reassure parents of a healthy baby with colic, that the baby is not rejecting them and that colic is usually a phase that will pass. Parents should be advised that holding the baby through the crying episode, and accessing peer support may be helpful. **[D(GPP)]**

37 Use of hypoallergenic formula in bottle fed babies should be considered for treating colic, but only under medical guidance. **[A]**

38 Dicycloverine (dicyclomine) should not be used in the treatment of colic due to side effects such as breathing difficulties and coma. **[A]**

Fever

39 The temperature of a baby does not need to be taken, unless there are specific risk factors, for example maternal pyrexia during labour.

[D(GPP)]

40 When a baby is suspected of being unwell, the temperature should be measured using electronic devices which have been properly calibrated and are used appropriately. (Cross refer to Fever in Children guideline) **[C]**

41 A temperature of 38°C or more is abnormal and the cause should be evaluated urgently (emergency action). A full assessment, including physical examination should be undertaken. **[D(GPP)]**

Vitamin K

42 All parents should be offered vitamin K prophylaxis for their babies to prevent the rare but serious and sometimes fatal disorder of vitamin K deficiency bleeding. **[A]**

43 Vitamin K should be administered as a single dose of 1 mg intramuscularly as this is the most clinically and cost effective method of administration. **[A]**

44 If parents decline intramuscular Vitamin K for their baby, oral Vitamin K should be offered as second line option. Parents should be advised that oral Vitamin K must be given according to the manufacturers instructions for clinical efficacy and will require multiple doses. **[D(GPP)]**

Safety

45 All home visits should be used as an opportunity to assess relevant safety issues for all family members in the home and environment and promote safety education. **[A]**

46 The healthcare professional should promote the correct use of basic safety equipment, including, for example, infant seats and smoke

alarms and facilitate access to local schemes for provision of safety equipment. **[A]**

47 Parents should be given information in line with the Department of Health guidance about sudden infant death syndrome (SIDS) and co-sleeping (Reduce the risk of cot death, November 2005) which states that “The safest place for your baby to sleep is in a cot in your room for the first six months. While it’s lovely to have your baby with you for a cuddle or a feed, it’s safest to put your baby back in their cot before you go to sleep. There is also a risk that you might roll over in your sleep and suffocate your baby, or that your baby could get caught between the wall and the bed, or could roll out of an adult bed and be injured.” **[B]**

48 Parents should be advised never to sleep on a sofa or armchair with their babies. **[B]**

49 If parents choose to share a bed with their infant, they should be advised that there is an increased risk of SIDS, especially when the baby is less than 11 weeks old, if either parent: [B]

- is a smoker
- has recently drunk any alcohol
- has taken medication or drugs that make them sleep more heavily
- is very tired.

50 If a baby has become accustomed to using a pacifier (dummy) while sleeping, it should not be stopped suddenly during the first 26 weeks. **[B]**

Child abuse

51 Health professionals should be alert to risk factors and signs and symptoms of child abuse. **[D(GPP)]**

52 If there is raised concern, the healthcare professional should follow local child protection policies. **[D(GPP)]**

Table 7-1

Infant health core information and advice

Time Band 1: First 24 hours

Parents should be offered information on*:* • vitamin K – in order to make an informed decision about its use **[GPP]** physiological jaundice including: • that it normally occurs around 3–4 days after birth **[C]** • Reasons for monitoring and how to monitor **[D(GPP)]**.
Parents should be advised to report to their healthcare professional: • **urgently,** development of jaundice. **[D(GPP)]**

Time Band 2: 2–7 days

All women and their families should be given information about availability, access and aims of all postnatal peer, statutory and voluntary groups and organisations in their local community. **[D(GPP)]**
Parents should be offered information and reassurance on: • ***their infant's social capabilities* –** as this can promote parent–infant attachment **[B]** • ***nappy rash* –** frequent nappy changes and cleansing and exposure of the perianal area reduces babies' contact with faeces and urine **[D(GPP)]** • ***cord care* –** how to keep the umbilical cord clean and dry **[A]** • **safety** – how to reduce accidents, particularly scalds and falls **[A]** • **sudden infant death** – how to reduce risk, including co-sleeping. **[B]**
Parents should be advised to report to their healthcare professional: • changes in the baby's established bowel pattern (which will take up to 7 days to establish), including hard stools that are difficult to pass or increased frequency of loose stools. **[D(GPP)]**

Time Band 3: 2–8 weeks (Day 8 onward)
All women and their families should be given information about availability, access and aims of

Table 7-1

Infant health core information and advice

all postnatal peer, statutory and voluntary groups and organisations in their local community.

7.2 Evidence Statements for Infant Health

Note: The title of each section is linked to the relevant narrative for ease of reference

Emotional Attachment and Parenting

1 Providing information to new parents appears to enhance attachment and parenting knowledge and interaction with their infants. [Level 2+]

2 A variety of strategies may be effective in providing parenting information. These include group based training programmes, home visiting programmes, videos shown in hospital, and one-to-one interventions. [Level 2+]

3 Close physical contact through use of soft infant carriers or kangaroo techniques may promote maternal infant attachment. [Level 2+]

4

Physical Examinations and Screening

5 There is no high level evidence base for the conduct and content of the physical examination of the newborn. Therefore the recommendations for this exam are based upon expert opinion and good practice. They incorporate the screening measures recommended by the National Screening Committee.

6 There is no robust evidence regarding the optimal frequency of

growth monitoring in newborns

7 **Physical Health and Well being**

8 Routine supplementation of nondehydrated breastfed infants with mild jaundice with water or dextrose water is not recommended. [Level 4]

9 Jaundice before 24 hours of age is always considered pathological and requires further evaluation. [Level 4]

10 Late breast milk jaundice develops much less commonly at around, 4-7 days after birth and peaks day 7-15. [Level 4]

11 No evidence was identified for general care of infant skin conditions.

12 Keeping the cord clean and dry is as effective as treatment with antiseptics and antiseptics appear to prolong time to cord separation. [Level 1+]

13 Optimal antifungal treatment of thrush remains to be determined.

14 *Candida albicans* appears to be associated with severe napkin dermatitis. [Level 2+]

15 No research studies were identified which addressed constipation in the newborn.

16 The Paediatric Accident and Emergency Research Group based at the University of Nottingham have defined diarrhoea as, "…a change in bowel habit for the individual child resulting in substantially more frequent and/or looser stools." [Level 4]

17 Hypoallergenic formula appears to be an effective treatment for

colic in formula fed babies. [Level 1++]

18 Dicycloverine (dicyclomine) may be effective for colic but can cause breathing difficulties and coma and is not recommended for infants. [Level 1++]

19 Several studies demonstrate that tympanic thermometry is not as accurate as axillary or rectal temperatures. [Level 2+]

20 For the purposes of vaccine research fever in infants has been defined as a rectal temperature of > 38^0 C. [Level 4]

Vitamin K

21 In light of available evidence it does not appear that there is a link between childhood cancer and IM Vitamin K prophylaxis. [Level 1+]

22 A single IM dose of 1mg Vitamin K appears to be effective prophylaxis for both early and late VKDB. [Level 1+]

23 If oral Vitamin K is given, multiple doses are required for adequate protection of breastfed infants against late VKDB. [Level 1+]

24 The exact dosage and timing of oral Vitamin K administration after the delivery dose has not been determined. [Level 2+]

25 The intramuscular route of Vitamin K administration appears to be more clinically effective and more cost effective. [Level 1+]

Safety

26 Parent education appears to lead to behaviour change. [Level 1]

27 Home visiting appears to have a positive effect on prevention of childhood injury. [Level 1]

28 Most accidents involving babies occur in the home. Fires and falls are the most common causes of accidents in this age group.[Level 2]

29 Social deprivation is a risk factor for childhood accidents.[Level 2]

30 Supplemental strategies may be needed in deprived areas to ensure safer homes. [Level 4]

31 Child car restraint legislation and education appear to change behaviour and reduce injury.[Level 1]

32 Well designed smoke detector programmes which include implementation appear to reduce injury and promote behaviour change.[Level 1]

33 General community prevention initiatives may lead to both injury prevention and behaviour change.[Level 1]

Reducing the risk of SIDS

34 Prone sleeping position, head covering, and maternal smoking appear to be the most consistent risk factors for SIDS. [Level 2++]

35 Co-sleeping is a risk for SIDS if infants are less than 11 weeks old [Level 2++]

36 A change in behaviour from the habitual use of a pacifier may be a risk factor for SIDS. [Level 2+]

Child Abuse

37 There do not appear to be any screening tools for child abuse with adequate sensitivity, specificity and positive predictive value to assess for risk of maltreatment with sufficient accuracy. [Level 2++]

Table 7-2

Infant health core information and advice

Time Band 1: First 24 hours

Parents should be offered information on*:* o vitamin K – in order to make an informed decision about its use o physiological jaundice including: that it normally occurs around 3–4 days after birth reasons for monitoring and how to monitor.
Parents should be advised to report to their healthcare professional: **urgently,** development of jaundice within 24 hours of the birth.

Time Band 2: 2–7 days

All women and their families should be given information about availability, access and aims of all postnatal peer, statutory and voluntary groups and organisations in their local community.
Parents should be offered information and reassurance on: o ***their infant's social capabilities* –** as this can promote parent–infant attachment o ***nappy rash* –** frequent nappy changes and cleansing and exposure of the perianal area reduces babies' contact with faeces and urine o ***cord care* –** how to keep the umbilical cord clean and dry o **safety** – how to reduce accidents, particularly scalds and falls o **sudden infant death** – how to reduce risk, including co-sleeping.
Parents should be advised to report to their healthcare professional: o changes in the baby's established bowel pattern (which will take up to 7 days to establish), including hard stools that are difficult to pass or increased frequency of loose stools.

Time Band 3: 2–8 weeks (Day 8 onward)

All women and their families should be given information about availability, access and aims of all postnatal peer, statutory and voluntary groups and organisations in their local community.

7.3 The healthy baby

A healthy baby should have normal colour for his/her ethnicity, maintain a stable body temperature, pass urine and open his/her bowels at regular intervals. A healthy baby initiates feeds, sucks well on the breast (or bottle) and settles between feeds. A healthy baby is not excessively irritable or tense and is not excessively sleepy or floppy. The vital signs of a healthy baby should fall within the following ranges:

- Respiratory rate normally 30-60 breaths per minute
- Pulse rate, normally between 100-160 in a newborn
- Temperature in a normal room environment of around 37 degrees C (if measured)

7.4 Emotional Attachment and Parenting

7.4.1.1 Are there interventions which promote attachment/bonding in the postpartum period?

Attachment theory postulates that the formation of secure attachment depends upon the mother's sensitive responsiveness to the infant's signals to provide the context in which the infant's experiences and feeling of security are organized. The relationship is bi-directional however and the infant's behaviour is not only influenced by the mother but it may also affect the mother's behaviour. More distal factors may also affect the quality of the development of attachment, including maternal personality and social support. The quality of parental attachment is believed to be a major predictor of long-term outcomes including childhood psychopathology, behavioural difficulties or developmental delay (Armstrong et al. 2000).

An early meta-analysis (Turley 1985) was undertaken to assess experimental controlled studies which provided information to mothers regarding the sensory and perceptual capabilities of their newborns in an effort to determine whether the intervention influenced maternal-infant interaction. A second purpose was to

assess the effect of location where the information was provided. The results showed that providing information to mothers produced positive mean effect sizes for all outcome categories, maternal and infant responsiveness, maternal knowledge, confidence, attitude and sensitivity (no p values provided). The effect of location was significant (p=0.009). Those studies in which the information was presented in the home setting tended to produce the largest mean effect size in terms of maternal-infant interaction. Thus, according to this study, the post discharge period would appear to be the most effective time for health professionals to support mothers in discovering their infant's feelings, responses and abilities.

A meta-analysis undertaken by a research team from The Netherlands evaluated 70 published studies presenting 88 intervention effects (Bakermans-Kranenburg, Van Ijzendoorn, & Juffer 2003). Studies were not limited to RCTs. As study analyses used various statistical tests, outcomes were recomputed and transformed into Cohen's d. A core set of 51 randomized control studies was identified, presenting data on 6282 mothers and infants. This core set of studies appeared to be significantly effective in enhancing maternal sensitivity (p<.001). Non randomised studies seemed to run the risk of inflated effects. Interventions focusing on sensitivity only were more effective than other types of interventions (p=0.03). Unexpectedly, the four studies that did not use personal contact as a means of intervening tended to show the largest effect size. These studies relied on the provision of soft baby carriers or introducing the kangaroo method, a workbook on responsiveness or a videotape. The effect of interventions conducted at parents' homes was not significantly different from the effect of interventions conducted elsewhere. In studies on attachment (n=23) the effect size was small but significant (p<.05). Sensitivity focused interventions significantly affected infant attachment security (<.01). The most effective interventions did not always use a large number of sessions nor did they necessarily start early in life or even before birth.

The Anisfeld et al study (Anisfeld et al. 1990) was included in the Bakermans-Kranenburg et al meta-analysis described above. This small American study (n=49) randomised mothers to soft baby carriers or to infant seats. Follow up

was by questionnaire at 2 months and by video tape, Bayley Scales of Infant Development, the Carey Infant Temperament Scale and Product Use Questionnaire. A final assessment at 13 months consisted of the Ainsworth Strange Situation, the Lifestyle Questionnaire II and the Product Evaluation Questionnaire. There were significantly more securely attached infants in the baby carrier group ($p=0.019$). Fifteen of 16 high users of the carriers had infants who were securely attached. Of the seven moderate/low users, four were securely attached.

An intervention designed to influence mothers' sensitive responsiveness toward their infant was carried out in Brazil, in collaboration with London Guildhall University (Wendland-Carro, Piccinini, & Millar 1999). Thirty eight mothers and their newborns were randomly assigned either intervention group one or group two. On day 2 or 3 postpartum the intervention group one viewed an "enhancement video" on newborn competence to interact, affectionate handling of the infant and which encouraged mothers to explore and interact with their infants. Group two saw an alternative video on basic care giving skills and infant health issues. One month later, observations were undertaken in the homes of study participants. Free play and bathing were observed and videotaped. The observations were examined for the frequency of synchronous and asynchronous co-occurrences, that is, reciprocal exchanges between mother and infant. Overall synchrony-asynchrony scores were higher for the enhancement group compared to the basic skill control group ($p<0.01$). For the enhancement group there were more co-occurrences involving infant vocalization with mother's reciprocal vocalization, smiling, soothing, and stimulation compared to the control group.

A study to assess the effect of maternal social support on attachment was carried out among low income primiparas in Michigan (Jacobson & Frye 1991). Forty six women were recruited and randomly assigned to intervention or control. The intervention group was assigned a "volunteer coach" who visited them in the home periodically until 12 months postpartum to talk about their pregnancy and delivery and early infant care. At the fourteen month

assessment infants of mothers in the experimental group were rated as more securely attached than control on the Attachment Ratings measure (Waters and Deane's Q sort procedure, 1985), $p<0.005$.

A meta-analysis of studies that evaluated the relationship between social support and maternal behaviours toward the baby was carried out in 1992 in the U.S. (Andresen & Telleen 1992). They included 66 studies. The study designs were not reported. The majority of the studies sampled white, middle income, married mothers. A wide variety of measures were used to operationalize social support. The types of social support most frequently measured were emotional and material support. Emotional support indicated supportive actions that conveyed empathy, caring, love, and trust. Material support included the physical resources needed to cope with the demands of parenting such as financial assistance and help with child care. Six meta-analyses of these studies showed significant relationships to exist between emotional support and maternal behaviours (CI .03-.60) and material support and maternal behaviours (CI .05-.61). However, some statisticians would argue that the use of meta analysis for any studies except RCTs is inappropriate and that it is not possible to adjust for the bias inherent in less robust study designs. The variability of interventions and outcome measures as well as the homogeneity of the sample make generalisability of this analysis questionable.

Another meta-analysis of studies investigated the relationship between social support and adolescent mothers' interaction with their infants. This analysis included 13 studies, most of which were cross sectional in design (Clemmens 2001). As noted above, the use of meta-analysis for any studies except RCTs is statistically inappropriate as adjustment for bias in the study design is not possible. This meta- analysis showed a significant relationship between social support of adolescent mothers and their interactions with their infant ($r=.30$, CI .239-.379). However, these results should be cautiously interpreted.

Are there interventions which promote parenting in the postpartum period?

A “review of reviews” was carried out by the Health Development Agency (HAD) in 2004 (American College of Obstetricians and Gynecologists 1998). In systematic reviews which looked at a number of measures of parenting or mother-child interaction the evidence suggests that home visiting can produce positive effects on various dimensions of parent child interaction. The HAD reviewers recommended further work in evaluating which types of programmes are likely to replicate these impacts.

A recently published study (Puura et al. 2005) evaluated the outcome of the European Early Promotion Project. This study was conducted in five countries: Cyprus, Finland, Greece, Serbia and the UK. In this study a group of primary health care nurses were trained to support mothers with newborn babies and to intervene early if there were problems that might interfere with the babies’ care. A comparison group was seen by a different group of nurses who had no additional training. These mothers received standard care. An initial assessment using the HOME inventory, a detailed interview and observational methods was done at 6-8 weeks. Outcomes were measured at 24 months for each country. In the UK no significant differences in change scores were found on the interview ratings. On the HOME inventory there were significant changes with mothers in the intervention group showing positive gains in verbal and emotion responsiveness (p=0.02), organisation of the child’s environment (p=0.004), provision of appropriate play material and in the total HOME score (p=0.003).

A Cochrane review of group based parent training programmes aimed to establish the efficacy of such programmes and to assess the role of parent education in the primary prevention of emotional and behavioural problems (Barlow & Coren 2003). Five RCTs were included in the review and a meta-analysis was conducted. The meta-analysis of the independent observations of children’s emotional and behavioural adjustment showed a significant result favouring the intervention group (ES -0.54, CI -0.84—0.23). The limited evidence available concerning the extent to which these results are maintained over time is equivocal.

A systematic review to assess the effectiveness of home visiting programmes on parenting and the quality of the home environment was carried out by Kendrick et al (Kendrick et al. 2000) of the University of Nottingham. Thirty four studies met inclusion criteria. Twenty six used participants considered at risk of adverse maternal or child health outcomes; two used preterm or low birth weight infants and two used infants with failure to thrive. Only eight used participants not considered to be at risk of adverse child health outcomes. Parenting and the quality of the home environment were measured in a variety of ways in these studies. The most commonly used measure was the Home Observation for Measurement of the Environment (HOME) used in 17 of the studies. The infant-toddler version of the inventory consists of six subscales measuring aspects of the quality of the home environment in relation to parenting. Twenty seven studies reported other measures of parenting and 10 studies reported both HOME scores and other measures of parenting. Twelve of 17 studies reporting HOME scores were included in a meta analysis. Fourteen effect sizes were extracted from the 12 studies and entered into the meta analysis. A highly significant result was obtained suggesting home visiting was effective in improving the quality of the home environment as measured by the HOME score. Despite the limitations of their review, the authors concluded that home visiting programmes were associated with an increase in the quality of the home environment as measured using the HOME scale and in improving parenting using a range of other measures. Most of the studies reviewed used professional home visitors, most commonly nurses. Eight studies used lay workers and the results of these studies appeared similar to those using professional visitors. Only four of the studies used UK health visitors.

A Cochrane review of parenting programmes for improving psychosocial outcomes for teenage parents and their children was undertaken by Coren and Barlow (Coren & Barlow 2001). Only four randomised controlled trials were included in this analysis. The programmes reviewed were offered either antenatally or postpartum, in a variety of settings and were not combined with a home visiting programme. Despite methodological problems and the

heterogeneity of the studies the authors concluded that the results indicated that parenting programmes may be effective in improving a range of outcomes for both teenage parents and their infants including mother-infant interaction, language development, parental attitudes, parental knowledge and maternal mealtime communication.

In 2003 Coren et al published an expanded review of both individual and group based parenting programmes for teenage mothers (Coren, Barlow, & Stewart-Brown 2003). Fourteen studies which used varying study designs including RCTs, controlled studies and one-group design were reviewed. Despite considerable diversity in the parenting programmes and study designs, there was evidence to show that parenting programmes are effective in improving maternal sensitivity, identity, self-confidence and the infants' responsiveness to their parents. Only one study directly compared a group based programme with a programme delivered on a one-to-one basis. The results of this study showed that the group-based programme produced more changes than the individual programme, especially in the case of high-risk mothers.

An Australian study (Armstrong, Fraser, Dadds, & Morris 2000) aimed to assess the effectiveness of a home-based intervention for at risk families which was focused on promoting the quality of the parent-infant interaction. A total of 181 families were randomised to intervention, a series of home visits from a child health nurse, or control. At a 4 month follow up 160 families were available for assessment. A statistically significant difference was shown on all subscales as well as the total HOME score ($p<0.05$).

A Canadian systematic review (Wade et al. 1999) evaluated the evidence for the effectiveness of peer/paraprofessional one–to-one interventions in promoting positive parental and child health and developmental outcomes. Seventeen of the 21 included studies targeted high risk populations. The evidence showed that peers/paraprofessionals could have a positive impact on child development and parent child interaction whether embedded in a multifaceted programme or when intervening independently. There was also some evidence that high intensity (weekly or bi-weekly visits for at least one

year) interventions begun in infancy have both an immediate and long term positive impact on child development.

Attachment and fatherhood:

A meta synthesis of ten published articles focusing on the experiences of fathers of healthy infants was reviewed (Goodman 2005). Four themes were identified in this synthesis, one of them being 'confronting reality.' Fathers stated that their expectations for involvement in fatherhood and bonding proved unrealistic due to the immaturity and unresponsiveness of the infant and the men's lack of time to spend with the infants. Men also felt that their relationship with their infant was slower to develop than the mothers'. Many fathers, especially fathers of breastfed infants expressed a feeling of exclusion from the strong mother infant relationship. Feeling excluded from providing care to the infant was perceived as inhibiting the development of the father-infant relationship.

A further qualitative study was identified which described in depth interviews with 18 new fathers at 6-12 weeks after the birth of their child (St John, Cameron, & McVeigh 2005). Fathers found their new role to be challenging and complex. Although most fathers focused on making time to interact with their newborns, barriers such as the need to work, the wake/sleep/cry patterns of the newborn and the time spent sharing the newborn with family and friends meant that some men deferred developing their relationship with their newborn baby.

Another recent study (Bolzan, Gale, & Dudley 2004) reported the findings of 40 interviews which explored men's postnatal mental health. A very high proportion of men expressed the desire to father differently from their own fathers (72.5%). Most men in the sample (73%) were in a position of juggling both their desire to be involved fathers and the demands of full-time work and careers. They reported experiencing tension and contradictions between these competing demands on their time. The researchers conclude that increasing

workplace flexibility and provisions such as parental leave are important for men's postnatal mental health.

In 1998 the National Childbirth Trust sent questionnaires to a randomly selected sample of pregnant women throughout the United Kingdom. These women were asked to pass the questionnaire on to their partners to complete. Thirty seven percent (n=817) of the questionnaires were returned. Approximately six months later a follow up questionnaire was sent to the men who responded originally. The response rate was 57%. The sample was broadly representative of British national paternity trends.

Most men felt they had enough time together as a family immediately after the birth. However, 20% of men felt unable to be as involved as they would like because they were not welcomed to stay by the hospital or had to go home to care for other children. Half of the men said that they were 'completely involved' in caring for their child but 40% of men said that work commitments reduced their involvement in family life.

Most men whose child was breastfed thought that breastfeeding was convenient and gave the baby special comfort and security. However 20% of men said that breastfeeding made them feel left out and two fifths would have liked to be able to feed the baby.

Specific questions about fathers' emotional attachment to their babies were not asked in the questionnaires.

7.5 Physical Examinations and Screening

7.5.1 Physical Examination of the Newborn

A basic physical examination of the newborn is routinely performed immediately after birth and prior to admission to the postnatal area whether the baby is born in hospital or at home (ref intrapartum care guideline in development). A more thorough physical examination of the newborn within 72 hours after delivery is accepted as good practice and recommended by the National Screening

Committee. The dual purpose of this examination is to confirm normality, thereby reassuring parents and carers, and to identify and act upon any abnormalities. A review of the literature for the conduct of this exam was undertaken. No systematic reviews of the newborn physical exam which met NICE criteria were identified. A review of discreet components of the physical exam was not carried out for the Postpartum Care Guideline. The guidance for the newborn exam is based upon a review of expert opinion, supported by existing scientific evidence, rather than a systematic review. Three documents underpin the recommendations for this exam: The Best Practice Statement for Routine Examination of the Newborn published in April 2004 by NHS Quality Improvement Scotland (NHS Quality Improvement Scotland. 2004); Postpartum care of the mother and newborn: a practical guide published in 1998 by WHO (World Health Organization. 2005); and Textbook of Neonatology (Rennie 2005). National Screening Committee recommendations are incorporated into this examination. The Guidelines Development Group agreed that where a practice is considered valuable by experts and when such a practice is not contraindicated by the evidence and causes no harm to the infant it should be included in the exam.

Any assessment of the infant should be performed with the mother's consent and, where possible, with the mother present. The setting should ensure comfort and safety for mother and baby, with measures taken to prevent cross infection. The environment should also provide privacy during and after the examination when confidential information may be discussed. Family/maternal concerns should be ascertained and discussed, with particular reference to family history and antenatal history. All aspects of the assessment should be explained. If for any reason the mother cannot be present, other family members should be involved and the mother should be made aware of the findings as soon as possible.

The health care professional performing the exam should be appropriately trained and his/her competency assessed, possibly with the use of simulators, as conditions such as congenital hip dislocation and congenital cataracts are

rare. The health care professional should maintain competency through continued practice and review. A consistent approach between the examination and the advice offered to parents should be ensured. If any abnormalities are found on examination, this should be communicated to the parents and appropriate treatment and/or referral should be instituted. The results of the examination should be recorded in the PCHR and any other baby health record.

The initial examination is a screening procedure, which marks the commencement of ongoing child health surveillance. Continued observation of the baby during the first weeks of life by both the health care professional and the infant's carers is important. In addition, as with all other contacts with health care professionals, it is an opportunity for health promotion and education on a range of areas relevant to maintaining infant health (jaundice, vitamin K, sleeping positions, hearing screening, nutrition, hygiene, breastfeeding, cot death prevention, safe transport in cars and maternal depression). This examination also provides an opportunity to address broader psychosocial issues (mental health, substance abuse, and smoking) as well as spiritual and cultural needs.

The physical examination should include the following:

- A review of family, maternal and perinatal history
- A review of previously plotted birthweight and head circumference
- A check of whether the baby has passed meconium and urine (enquiring about urine stream in a boy) and documentation of failure to do so for follow up by midwifery staff
- Observation of the baby's general condition including colour, breathing, behaviour, activity and posture
- Ascertainment of whether parents or carers have anxieties and an opportunity to observe mother-infant interaction

- Enquiring about method of infant feeding, and if mother or staff have any concerns about feeding to date. If necessary breastfeeding should be observed, and mother assisted with this, provided the healthcare professional is competent to do so.

- Examination of the exposed parts of the baby first: scalp, head (including fontanelles), face, nose, mouth including palate, ears, neck and general symmetry of head and facial features

- Examination of the baby's eyes (size, position, absence of discharge) including with an ophthalmoscope and test for the 'red reflex'

- If exposed, examination of the baby's neck and clavicles, limbs, hands, feet and digits, assessing proportions and symmetry. Undress baby to complete the exam

- Assessment of the baby's cardiovascular system – colour, heart rate, rhythm and femoral pulse volume as well as listening to the heart for a murmur, and checking laterality disturbance of heart

- Respiratory effort and rate can be assessed simultaneously with the cardiovascular assessment and listening to air entry

- Observation of the baby's abdomen – colour, shape and palpate to identify any organomegaly, and examination of the condition of the umbilical cord

- Observation of the baby's genitalia and anus, to check completeness and patency. Check for undescended testes in male infants.

- Inspection of the bony structures and skin of the baby's spine, with the baby prone

- Noting the colour and texture of the skin as well as any birthmarks or rashes

- Observation of the tone, behaviour, movements, and posture to complete the assessment of the central nervous system (CNS)

- If concerned, undertake more detailed neurological examination e.g. eliciting newborn reflexes

- Regarding hips, check symmetry of the limbs and skin folds. Perform Barlow and Ortolani's manoeuvres on a firm flat surface. The baby should be calm when the examination is performed.

- Noting sound of baby's cry

- Consideration of any specific known risks in the baby's home, and alerting appropriate professionals to parents who may have problems in caring for their baby

- Ensuring that parents know how to assess their baby's general condition and to contact a midwife, health visitor, doctor or emergency services if required

7.5.2 National Screening Committee (NSC)

The National Screening Committee recommends that all pre-screening information for parents should be in acceptable formats and provided appropriately to support decision making.

The NSC (www.nsc.nhs.uk) recommendations are noted below:

Examination: (first 72 hours)

- Eyes – opacities, including cataracts (red reflex)

- Hips – dysplasia (Barlow & Ortolani)

- Heart – congenital disease (Cyanosis, tachypnoea, murmur, femoral pulses)

- Testes - cryptorchidism

Screening:

- A hearing screen should be completed prior to discharge or by week 4 in the hospital programme or by week 5 in the community programme..
- Newborn blood spot; 5-8 days. (Phenylketonuria [PKU], Congenital Hypothyroidism [CHT] and Sickle Cell Disease [SCD], with Cystic Fibrosis [CF] and Medium Chain Acyl CoA Dehydrogenase Deficiency [MCADD] in some areas)
- Examination: (6-8 weeks)
- Eyes – opacities, including cataracts (red reflex)
- Hips – dysplasia (Barlow & Ortolani)
- Heart – congenital disease (Cyanosis, tachypnoea, murmur, femoral pulses)
- Testes - cryptorchidism
- Immunisation, 8 weeks:
- DTaP/IPV/Hib and Men C

7.5.3 Physical Examination at 6-8 weeks

The second postpartum examination at 6-8 weeks might be performed concurrently with administration of the first set of immunisations. The Department of Health recommendations for immunisations should be followed, with parental consent. The 6-8 examination should repeat the assessments made at the physical examination of the newborn, and also include an assessment of whether the baby has a social smile and is fixing and following visually. Any parental concerns should be addressed. Documentation of the examination should be made in the PCHR and the baby's medical record.

The competencies for this examination are therefore unchanged from those of the newborn examination.

7.5.4 Growth monitoring

Routine growth monitoring, including height (length) and weight measurements are widely accepted and standard components of child health surveillance. Growth monitoring has been used as a 'screening tool' for the identification of disorders and diseases which may affect growth. As there were no nationally set norms for growth monitoring in the U.K., the Child Growth Foundation organized a meeting of paediatricians, endocrinologists, public health doctors, GPs and nurses from various disciplines in July, 1998 to consider whether growth monitoring actually fulfilled the criteria required of a screening programme (Elliman & Hall 2003). After examining the evidence regarding the potential for detection of children with growth abnormalities and looking carefully at the issues of measurement error, guidelines for clinical practice were developed. Future debate and research was also encouraged. The participants in this meeting, known as the 'Coventry Consensus,' recommended the following policies for normal newborns:

1. Birth weight, correctly taken and recorded, and related to gestational age, is an essential first step in growth monitoring

2. Measuring the length of the normal neonate is not part of a national programme of growth monitoring

3. No justification has been found for the routine monitoring of length in the first two years of life.

The group also considered further weight monitoring. They recognized that weight gain in the first few weeks of life is occasionally a cause for concern but found little evidence on optimal frequency of weighing in the neonate. During the first year of life frequent weighing was seen to be undesirable as short term fluctuations in weight may simply increase parental anxiety and stress. Routine attendance at the GP surgery at ages 2, 3, 4, 8 and 12 months (immunization

and surveillance contacts) was seen to be an opportunistic time to weigh a child if indicated. However, there was no evidence that regular weighing of a baby who is healthy and thriving is of any benefit. Weight monitoring could not be considered as a screening procedure due to variations in rate of weight gain in individual babies. The Coventry Consensus recommendations on routine weighing included the following:

1. Babies should be weighed (nude) at immunisation and surveillance contacts.

2. Normally growing babies should not be weighed more than once per fortnight under the age of six months and no more than monthly thereafter, as this may simply increase anxiety.

A Cochrane systematic review of growth monitoring in children (Panpanich & Garner 1999) found only two RCTs, both conducted in developing countries. They concluded that there was insufficient reliable information to be confident whether routine growth monitoring is of benefit to child health in any setting.

With regard to growth charts the Joint Working party on Child Health Surveillance recommended the 1990 9-centile charts. They also cautioned that:

“Growth charts show the measurements for babies and children at different ages, taken from large numbers of subjects at a range of ages. They do NOT mean that normal babies always grow along the lines shown on the chart.”

In a review of growth charts in the U.K., Sachs et al (Sachs, Dykes, & Carter 2005) described the database for the 1990 U.K. chart. Essentially this chart combines cross sectional data from the British Standards Institute for 163 children ages 0-3 months and 90 children ages 3-6 months and longitudinal data from the Cambridge Infant Growth study which included 252 children recruited between 1984 and1988. There was some selection bias of babies included. Both samples are more than 98% white and of a relatively high socioeconomic status and in the case of the Cambridge study, from the same

geographic area. One hundred and twenty of the babies in the Cambridge study population were breastfed for at least 24 weeks with solids introduced at a mean of 15 weeks.

In 2002 new U.K. growth charts based exclusively upon breastfed babies were produced (Cole, Paul &Whitehead 2002). They were developed using the data for the 120 Cambridge infants who breastfed to a minimum of 24 weeks in the Cambridge Infant Growth Study. It has been argued that these charts should be adopted as the norm for use in the U.K. for all babies. However, these charts have not been tested to see whether they improve the accuracy of referrals, affect breastfeeding duration or parental confidence and whether they are generalisable to babies outside of Cambridge. At the time of writing, new growth charts have just been launched by WHO (http://www.who.int/childgrowth/en/index.html). Evaluation of these growth charts for use in the UK has yet to be undertaken.

7.6 Physical Health and Well being

A review of eight common health problems in infancy was undertaken. Evidence in this area is not robust. When evidence was lacking, good practice recommendations were made. The Department of Health publication *Birth to Five* also addresses all of these areas in its guidance for new parents.

7.6.1 How should common health problems in the infant be identified and managed?

7.6.1.1 Jaundice

- During the first week of life approximately 50% of term infants have visible signs of jaundice (British Columbia Reproductive Care Program. 2002). In the narrative background of their guideline on jaundice in the healthy newborn, the British Columbia Reproductive Care Program identified the following potential causes of jaundice:

- Physiologic jaundice due to increased red blood cell volume and immaturity of the liver function in the newborn.
- Increased breakdown of red blood cells due to blood group and Rhesus incompatibility
- Decreased conjugation of bilirubin due to prematurity
- Increased reabsorption of bilirubin from the gastointestinal tract due to asphyxia, delayed feedings, bowel obstruction, delayed passage of meconium
- Impairment of bile excretion due to sepsis, hepatitis, biliary atresia, cholestatic syndromes
- Breast milk jaundice, cause unknown
    - Early breastfeeding jaundice develops 2-4 days after birth and may be related to infrequent feeding and/or increased reabsorption of bilirubin from the bowel
    - Late breast milk jaundice develops much less commonly, 4-7 days after birth and peaks day 7-15. Cause unknown

Most jaundice is benign, but because of the potential toxicity of bilirubin, all newborn infants must be monitored to identify those who might develop severe hyperbilirubinemia. Jaundice before 24 hours of age is always considered pathological and requires further evaluation (British Columbia Reproductive Care Program. 2002).

Jaundice is usually seen first in the face and progresses in a cephalocaudal fashion (head to toe) to the trunk and extremities. The accuracy of clinical judgment in neonatal jaundice was studied among paediatric residents (junior doctors), paediatric nurse practitioners and paediatric attending physicians (consultants) (Moyer, Ahn, & Sneed 2000). A total of 122 healthy infants underwent serum bilirubin concentration measurements and examinations by 2

observers. Infants were observed under bright indoor fluorescent lighting augmented by natural daylight from large windows in the nursery. Assessments were recorded for pre-specified parts of the body and additional specific sites that were suggested by experienced paediatric faculty such as the conjunctiva, the tip of the nose and the palate. Infant skin tone was also classified as “light” or “dark.” Finally, each observer made a prediction of the total serum bilirubin concentration based on the infant’s clinical appearance. Although agreement was good for infant skin tone, the weighted K statistic for agreement between observers for jaundice at each level was at best only marginally greater than chance alone (ranging from 2-23% greater than would have been expected by chance). A serum bilirubin value of 12 mg/dl has been used to distinguish physiological from nonphysiologic jaundice. In this study, the only consistent finding was that infants with no jaundice below the middle of the chest (nipple line) had bilirubin values less than <12 mg/dl. The researchers concluded that bilirubin testing should be based on risk factors for severe hyperbilirubinemia rather than on clinical observation alone.

No studies for risk of elevated serum bilirubin levels were identified. The British Columbia Reproductive Care Program lists risk factors in the introductory narrative review of their guideline on jaundice. These include:

- Family history of newborn jaundice (especially sibling), anaemia, liver disease, or inborn errors of metabolism
- Plethora, polycythemia, bruising, cephalhaematoma
- Poor feeding, vomiting, delayed passage of meconium
- Excessive weight loss
- Sepsis
- Asphyxia
- Relative prematurity or small for gestational age

- Hypothyroidism, hypopituitarism
- Certain ethnic groups i.e. East Asian, Native American
- Infant of a diabetic mother
- Maternal ingestion of sulfonamides or antimalarial drugs.

The effect of breast feeding frequency on serum bilirubin levels in the first 3 days after birth was studied in a randomised controlled trial of 275 full term breastfeeding mothers and infants (Maisels et al. 1994). All babies were fed within 1 hour of birth. Mothers and babies were assigned to the frequent feed group or to the demand group. Frequent feeders were asked to nurse their infants at least every 2 hours during the day and no less than every 3 hours at night. Demand feeders were asked to feed whenever the infant cried or appeared to be hungry. Records were kept of the number of feedings, time of the first stool, frequency of stools and administration of supplemental dextrose water. Serum bilirubin levels were measured in cord blood and again between 48-72 hours after birth. Infants in the frequent group nursed a median of 9 times per day and the demand group 6.5 times per day. There was no correlation between frequency of breast feeding and serum bilirubin level attained between 48 and 80 hours in either group. However, it is possible that those infants who were measured early had not yet reached maximal bilirubin levels. Measurements of all infants at 4 days would have been more clinically important because this is often when interventions for hyperbilirubinaemia are initiated.

Maisels and Gifford investigated the relationship between breastfeeding, weight loss and jaundice (1983). It has been theorized that poor intake among breastfed babies leads to excessive weight loss and subsequent jaundice. One hundred babies were grouped according to birth weight: 2500-3000 g, 3001-3500 g, 3501-4000 g, and >4000 g. There were no significant differences in the mean serum bilirubin concentrations between groups. When all serum bilirubin values were plotted against the cumulative weight loss for each infant, no relationship was found.

The treatment of jaundiced breastfeed infants was evaluated in a Swiss study (Amato 1985) which randomised 50 breast fed full terms babies with hyperbilirubinemia to receive either phototherapy or to interrupt breast feeding, substituting infant formula. There was no significant difference in the maximum bilirubin levels between the two groups ($p<0.05$). Bilirubin levels reached the maximum by a median age of 5.2 days in the first group and by 5.6 days in the second group. Ten infants had increased rebound levels after stopping phototherapy but only 3 of 25 babies treated with interruption of breast feeding had a further rise. It is noteworthy that there was no control group of babies who continued breastfeeding in this study.

A study of 27 full term formula fed infants with clinically detectable jaundice was undertaken at the University Hospital of South Manchester (Alexander & Roberts 1988) to evaluate sucking behaviours in these infants. The researchers postulated that as an infant's sucking ability gradually improves to reach optimum sucking by the fourth to seventh day of life, and as serum bilirubin values reach a peak between the third to fifth day of life then rapidly decline, that hyperbilirubinaemia would be correlated with poor feeding behaviours. A pressure transducer was attached to a measured volume of milk formula and recordings made of the length of time spent sucking, pause times, sucking rates and mean sucking pressure. Clinical observations of feeding were also recorded on four visual analogue scales. Bilirubin values from days 2-6 were measured. As expected, milk consumption, duration and pressure of sucking all showed a significant increase during the period of study. Sucking rate did not vary with age. Among infants who appeared disinterested in feeds by clinical observation, milk intake was not impaired by measurement.

The Skin Cancer Research Group at the James Cook University of North Queensland, Australia undertook an investigation of professional advice advocating therapeutic sun exposure for a number of conditions, including neonatal jaundice (Harrison, Hutton, & Nowak 2002). As the development of both melanoma and moles are related to early childhood sun exposure there is concern about early protection of infants against sunlight. This cross sectional

study of hospital based staff was designed to determine the prevalence of inappropriate and/or inexplicit advice about the therapeutic uses of sun exposure given to postpartum women. Self administered postal questionnaires were utilised. Among nurses, 42.1% said they would recommend exposing the infant to sunlight. Midwives were significantly more likely to advise exposure than other nursing professionals (45% vs. 21.4%; p=0.004). Among medics 54.2% of obstetricians, 23.8% of paediatricians advised sunlight for neonatal jaundice.

A guideline for the management of hyperbilirubinemia was published by the American Academy of Pediatrics in 2004 (Subcommittee on Hyperbilirubinemia. 2004). This is an evidence based guideline which only searched Medline and Pre-Medline. A quality assessment of the literature was conducted. Recommendations for primary prevention include:

Clinicians should advise mothers to nurse their infants at least 8-12 times per day for the first several days. (evidence quality C: benefits exceed harms).

The AAP recommends against routine supplementation of nondehydrated breastfed infants with water or dextrose water (evidence quality B and C: harms exceed benefits).

Recommendations for ongoing assessment include:

- All hospitals should provide written and verbal information for parents at the time of discharge, which should include an explanation of jaundice, the need to monitor infants for jaundice and advice on how monitoring should be done (evidence quality D: benefits versus harms exceptional).

- All infants should be examined by a qualified health care professional in the first few days after birth to assess infant well-being and the presence or absence of jaundice. The timing of this assessment may be determined by the place of birth and/or the length of stay in hospital and presence of risk factors for hyperbilirubinemia (evidence quality C: benefits exceed harms):

After birth	Should be seen by age
Before age 24 h	72 h
Between 24 and 47.9 h	96 h
Between 48 and 72 h	120 h

7.6.1.2 Skin

No research studies were identified which addressed general care of the skin of the newborn infant. Nappy rash is addressed as a distinct issue. Advice about bathing and treatment of eczema is found in *Birth to Five* (Department of Health. 2005).

Twenty one studies were evaluated in a Cochrane Review of umbilical cord care (Zupan, Garner, & Omari 2004). Most of the studies were from high income countries. No difference was demonstrated between cords treated with antiseptics compared with dry cord care that is keeping the cord clean and dry, or placebo. Antibiotics and antiseptics reduced skin bacterial colony counts but the clinical significance of this reduction is unknown. No systemic infections or deaths were observed in any of the studies reviewed. Antiseptics also appeared to prolong the time to cord separation.

7.6.1.3 Thrush

Oral candidiasis (thrush) is usually caused by Candida albicans which may be transferred from mother to child at birth. Newborn babies are immunologically immature and more susceptible to infection. Treatment usually consists of oral application of nystatin. One RCT was identified which compared treatments of oral thrush in 35 newborn infants (Boon et al. 1989). In this study newborns with thrush were randomised to treatment with 1 ml (20 mg) oral ketoconazole suspension three times daily or with 1 ml nystatin topical suspension 4 times daily. Blinding and allocation concealment were not described. Two days after

clinical cure, cultures were taken from the mouth for mycological confirmation. After 1 week, symptoms in all 20 infants on ketoconazole were resolved but only 8 (53.3%) of babies on nystatin ($p<0.001$) had resolution of symptoms.

A German study compared two commercial oral gels of nystatin with miconazole oral gel (Hoppe & Hahn 1996). Ninety five infants (body weight < 10 kg) with clinical oral thrush and positive fungal cultures were randomised to one of three treatments. Blinding and allocation concealment were not described. Drugs were administered four times daily after feeding. After 14 days the clinical cure rate was significantly higher with miconazole than with either of the nystatin preparations ($p=0.0032$ and 0.00068). The duration of treatment varied according to the amount of drug contained in one tube; it was 8 days with miconazole and 10 or 14 days with the nystatin. However, even after treatment with miconazole many oral cultures were still positive. The clinical significance of this finding is unclear, therefore, the optimal duration of treatment remains to be determined.

7.6.1.4 Napkin (Nappy) rash

Napkin dermatitis is an inflammatory reaction of the skin in the area covered by a nappy and has a range of causative factors. Local irritants including urine, faeces and chemicals such as deodorants, preservatives, creams and oils have all been implicated in nappy rash. Candida albicans appears to be a causative organism in severe rash.

A U.S. based cross-sectional study (Benjamin 1987) of 1089 infants was carried out to correlate the incidence of nappy rash with possible causative factors. Infants were examined by two registered nurses trained as graders. An analysis of faeces and the presence of C. albicans was also done. Results showed a strong association between severe rash and level of Candida in the faeces. No such association was observed with mild or moderate rash. The rash incidence/severity was significantly lower when the mean number of reported changes of nappy per day was above average. ($p<0.03$). Infants wearing disposable nappies exclusively had a significantly lower mean rash

grade ($p<0.02$) and a significantly lower incidence of moderate and severe rash ($p<0.001$). The incidence of combined moderate and severe rash increased significantly with increasing number of bowel movements per day ($p=0.0004$). Breastfed infants tended to have a lower incidence of moderate and severe rash ($p=0.015$).

Different types of nappies have been studied with regard to their effect on infant skin. Four double blind clinical studies were undertaken on behalf of a commercial organisation to test conventional disposable nappies, with absorbent gelling material disposables and with home laundered cloth nappies (Campbell et al. 1987). The total test population of 1614 infants were uniformly stratified by age and diet and then randomly allocated to one of the study groups. Rash grades were assigned to all infants in each study. Skin pH measurements were made in two studies and transepidermal water loss measurements were made in a separate clinical study. Skin wetness as measured by transepidermal water loss was significantly lower in the absorbent gelling material group at all points in time ($p<0.05$). Change in skin pH inside and outside of the diapered area was significantly smaller in the nappies with absorbent gelling material. Grading of nappy rash was by the same three trained registered nurses every 2 weeks throughout the studies. The graders were blinded to the products used. Infants wearing the absorbent gelling material nappies had a significantly lower overall subjective rash grade than did infants wearing conventional disposable or home-laundered cloth diapers ($p<0.05$).

Another RCT was conducted at the University of Rochester in which 149 infants were randomised to conventional disposable nappies or to those with absorbent gelling material (Lane, Rehder, & Helm 1990). The infants were evaluated from 1 day to 14 weeks of age for nappy rash. The study was double blinded. Statistically significant differences between the infants wearing the two nappy types were identified at 14 weeks for the waistband ($p=0.03$), genitals ($p=0.05$) and leg ($p=0.02$), with the absorbent gel nappies demonstrating lower

rash scores. At no other time during the study were statistically significant differences seen.

A clinical study undertaken in Italy(Longhi et al. 1992) followed infants for up to 44 weeks. Infants aged between 3 and 24 months were examined by dermatologists at fortnightly intervals for the first 14 weeks of the study. One hundred of the infants continued in the study for a further 30 weeks during which time they were examined every 4 weeks. The report does not describe allocation concealment or blinding. A total of 2169 clinical dermatological exams were carried out. Some effort was made to standardise clinical criteria for rash but inter-rater reliability statistics were not provided. All infants used only “test nappies” both containing hydrogel superabsorbent (HS) materials but with a different distribution of the HS in the structure of the nappy. The authors found that the incidence of napkin dermatitis in this study was 15.2% and that both endogenous factors such as atopy and age and exogenous factors such as illness and treatment drugs, influenced the incidence of diaper dermatitis.

Two British studies evaluated treatment of napkin dermatitis. One double blind trial was carried out in 62 infants with moderate to severe rash to assess treatment with the antibacterial/antifungal agent miconazole(2%) and hydrocortisone (1%) with nystatin/benzalkonium chloride/dimethicone/hydrocortisone preparation which was specifically designed to treat napkin dermatitis (Bowring, Mackay, & Taylor 1984). Treatments were randomly assigned and cultures taken from each infant. The miconazole group had 80% resolution of rash in 7 days and the nystatin group 84% resolution. The nystatin combination preparation failed to cure 2 (25%) of the 8 infants with mycoses whereas all 5 infants from whom fungi were isolated in the miconazole group responded. The nystatin also caused staining of the nappy in 63% of cases.

A non-comparative multi-centre study was carried out among 112 infants with napkin dermatitis to assess the effectiveness of 1% clotrimazole plus 1% hydrocortisone cream. Symptoms were significantly improved for patients

overall ($p<0.001$) and all but a few patients became symptom free within 14 days (Jaffe & Grimshaw 1985).

A study from 1967 (Whitehouse, Bannan, & Ryan 1967) looked at the effect of bleaching on bacteria levels and rash. On a randomly selected basis, 129 mothers were given either liquid bleach or placebo bleach and new cloth nappies. The bleach products were crossed over at the end of the fourth week and new nappies supplied. Bacterial cultures were taken from the nappies at 2, 4, 6, and 8 weeks. The bleached nappies had an average of 2 organisms/sq inch, whereas the placebo-bleached nappies had an average of 277 /sq inch. Infants had less irritation while wearing the bleached nappies ($p<0.005$).

An evidence-based clinical guideline produced by the Association of Women's Health, Obstetric and Neonatal Nurses makes the following recommendations:

To maintain optimal skin environment

- Change nappies frequently (based on animal model studies which demonstrated the effect of urine and feces on skin)
- Use nappies made with absorbent gel materials

To prevent nappy rash

- Use petrolatum based lubricants or barrier creams containing zinc oxide (recommendation based on expert opinion)

To treat rash resulting from contact irritants

- Protect skin with a barrier cream containing zinc oxide (recommendation based on expert opinion)

Identify Candida albicans rash by presence of red satellite lesions.

- Treat with antifungal creams.

7.6.1.5 Constipation

No research studies were identified which addressed constipation in the newborn. One American study (Loening-Baucke 2005) reviewed records of 4,157 children <2 years of age. The prevalence rate for constipation in the first year of life was 2.9%. Advice about constipation is provided in *Birth to Five* (Department of Health. 2005).

7.6.1.6 Diarrhoea

The Paediatric Accident and Emergency Research Group based at the University of Nottingham developed an evidence based guideline for the management of children presenting to hospital with diarrhoea (Armon et al. 2002). They have defined diarrhoea as, "…a change in bowel habit for the individual child resulting in substantially more frequent and/or looser stools (Grade D, expert opinion)." Although the guideline targets hospital management, several recommendations are also relevant to the newborn in the primary care setting:

The following factors in the history of a child presenting with diarrhoea should alert the clinician to a high risk of dehydration:

- Infants < 6 months
- More than 8 significant diarrhoeal stools in the last 24 hours
- More than 4 significant vomits associated with diarrhoea in the last 24 hours (No evidence. Based on Delphi consensus).
- Signs of dehydration are unlikely when the weight loss is below 3%
- Dry mucous membranes, sunken eyes, diminished skin turgor, altered neurological status and deep breathing are present at mean weight losses of 3-8%. (Based on Level 2+ evidence).
- Oral rehydration should be the standard treatment for children with mild-moderate dehydration secondary to gastroenteritis. (Based on Level 1+ evidence).

- Breast fed infants should continue to breast feed through the rehydration and maintenance phases of their acute gastro-enteritis illness. (Based on Level 1+ evidence).

- Infants who are not weaned should recommence full strength lactose containing formula following rehydration with oral rehydration solution (ORS) . (Based on Level 1+ evidence).

The Nutrition Committee of the Canadian Paediatric Society updated their recommendations on the treatment of diarrheal disease in 2003. A quality assessment scheme was applied to the evidence, although the details of the evidence tables were not published. The Committee recommended:

- ORS should be used routinely in the treatment of watery diarrhoea and dehydration. (Based on Level I,A evidence).

- Feeding should be continued throughout rehydration to help maintain gut nutrition (Based on Level II-2, A)

- Loperamide and Lomotil antimotility drugs should not be used in children because of safety considerations (Based on Level III, E evidence).

Two American research groups performed meta analyses to determine the efficacy of probiotic treatments such as *Lactobacillus* on the duration of diarrhoea (Huang et al. 2002;Van Niel et al. 2002). Huang et al (2002) evaluated 18 studies, five of which included newborn infants. Their meta-analysis suggested that co-administration of probiotics with standard rehydration therapy reduced the duration of acute diarrhoea by 0.8 days ($p<0.001$). In the VanNiel et al (2002) analysis, five of eleven studies which met their inclusion criteria evaluated newborns. The summary point estimate from the meta analysis indicated a significant reduction in diarrhoea duration of 0.7 days (CI 0.3-1.2 days) in subjects who were given *Lactobacillus* compared with control when mean differences in days of diarrhoea.

7.6.1.7 Colic

Infantile colic is defined as excessive crying in otherwise healthy infants and is a common problem during the neonatal period. A comprehensive systematic review of the literature was conducted to evaluate the effectiveness of treatments for infantile colic including diets, drug treatment and behavioural interventions with crying or presence of colic as the primary outcome measures (Lucassen et al. 1998). Twenty seven controlled trials were included in this review. Five trials studied the effect of eliminating cows' milk on colic. Three trials used soya milk substitutes and two used a hypoallergenic formula. When data were pooled, the effect size of eliminating cows' milk was 0.22 (CI 0.10-0.34). Hypoallergenic formula had a clear effect, 0.22 (CI 0.09-0.35). However, the effect of soy was not significant. Lowering the lactose content of formula had no effect. Comparison of breast milk with standard cows' milk in infants who were weaned showed no significant difference. In one trial herbal tea containing chamomile, vervain, liquorice, fennel and balm mint seemed to be effective. Drug treatment with dicycloverine (dicyclomine) showed clear benefit, 0.46 (CI 0.33-0.60) but as 9 out of 177 (5%) of treated infants had side effects, some potentially serious such as breathing difficulties and coma use of this medication cannot be recommended. Simethicone showed no benefit. Trials of behavioural interventions had durations of 2 weeks to 3 months. Increased carrying and other specific management techniques did not reduce crying.

Another systematic review (Garrison & Christakis 2000) searched only Medline and Cochrane for clinical trials or RCTs on management of colic. Twenty two studies were identified. Quality assessment was summarized but evidence grading was not provided. Three studies of simethicone treatment were reviewed but the evidence presented did not demonstrate any conclusive benefit. In three RCTs, dicycloverine (dicyclomine) performed significantly better than placebo. However, due to potential side effects including apnoea, seizures and coma, the manufacturers contraindicated use in infants less than 6 months old. One RCT of methylscopolamine to treat infant colic found no significant impact on symptoms. Data regarding utilisation of hypoallergenic diets by breastfeeding mothers were inconclusive but suggest there may be

some therapeutic benefit. A stratified analysis of the Hill study (1995) showed that infants randomised to the hypoallergenic formula had significantly greater improvements in colic than placebo ($p<0.01$). A second study reported significant improvements in colic while infants were receiving hypoallergenic formulae but data were not presented in a manner that allowed for comparable interpretation by the reviewers. Two RCT's of soy based formulas were reviewed. One study measured the mean weekly duration of colic symptoms during treatment with soy formula as 8.7 hours compared to 18.8 hours during control periods (RR 0.33, CI .017-.65). The other study did not report the data in a way that allowed for analysis of treatment effect and therefore was not included. Neither of the 2 RCTs that studied the effects of lactase enzymes on colic found any significant difference between treatment and placebo. Behavioural studies which measured colic symptoms and carrying the infant (2) and car riding (1) showed no significant effect. Decreasing infant stimulation was studied in one trial and did appear to be significant (RR 1.87, CI 1.04-3.34). However there were methodological problems with this study as inclusion criterion were not well defined and concealment was questionable. Herbal tea containing chamomile, vervain, liquorice, fennel and balm mint was studied in one RCT. After 7 days of treatment 57% of infants no longer met the Wessel criteria for colic as opposed to 26% of infants in the placebo group. Two final randomised trials looked at sucrose as a treatment for colic. The response to sucrose in these samples appears to have lasted for <30 minutes in the first trial and only 3 minutes in the second trial. The reviewers concluded that an evidence based approach to colic might include dietary changes, particularly to hypoallergenic formula, treatment with herbal tea and reduction in environmental stimulation.

7.6.1.8 Fever

There are many variables which affect both the definition and measurement of normal and elevated body temperature. In 2004 the Brighton Collaboration *Fever* Working Group developed a case definition and guidelines for fever in an attempt to produce practical guidelines to standardise the collection, analysis

and presentation of data on temperature measurement for clinical trials of vaccine safety (Marcy et al. 2004). They defined fever as the endogenous elevation of at least one measured body temperature of $\geq 38^0$ C.

Fever in young infants under 3 months of age has generated great interest and concern in the medical community. Strategies which encouraged extensive diagnostic testing, hospitalization and antibiotic treatment of all febrile infants less than 60 days old were developed to avoid the consequences of failing to detect serious bacterial illness. A large prospective cohort study carried out in the U.S. (Pantell et al. 2004) surveyed the spectrum of disease in 3066 infants aged 3 months or younger with temperatures of at least 380 C who were seen in the outpatient office setting. The top ten primary diagnoses were:

- Upper respiratory tract infection
- Unidentified source
- Otitis media
- Bronchiolitis
- Gastroenteritis
- Urinary tract infection
- Pneumonia
- Viral syndrome, nonspecific
- Viral meningitis (nonherpes)
- Well child

The majority (64%) of these infants were treated exclusively outside of the hospital. Although this large sample allowed the researchers to assess the frequency of high risk bacteremia/bacterial meningitis in infants the sample included few African American, Hispanic or inner city infants.

A practice guideline for management of infants and children with fever of unknown origin was developed by a group of American physicians (Baraff et al. 1993). Their literature search was limited to Medline and the quality assessment measures were not described. However, meta analyses were performed where appropriate and modified Delphi techniques were employed for consensus. The definition of the lowest temperature which constitutes fever was based on expert medical opinion. A rectal temperature of 38 0 C was considered febrile. Because clinical evaluation of febrile infants is inadequate to reliably exclude serious bacterial infection, the guideline panel members recommended that all toxic appearing infants and children and all febrile infants less than 28 days of age should be hospitalised for parenteral antibiotic therapy. Febrile infants 28 to 90 days of age defined as low risk by specific clinical and laboratory criteria (previously healthy, no focal bacterial infection on physical exam and negative lab screening), may be managed as outpatients, if close follow up is assured.

There are two Cochrane systematic reviews on treatment of fever in children. Neither of these reviews includes trials with infants. The BNF recommends that paracetamol be given to children under 3 months only after consultation with a physician. Ibuprofen is only recommended for children over 7 kg.

Rectal thermometry has traditionally been considered the gold standard for temperature measurement. However in small infants axillary temperature is easy to measure and avoids the possibility of rectal perforation and contamination via stool. Recently tympanic thermometry and single use disposable thermometers have become available. The NHS no longer recommends the use of mercury thermometers due to its potential as an environmental hazard. A number of studies compare the accuracy of various temperature measurement techniques.

Two comprehensive systematic reviews were conducted at the Institute of Child Health in Liverpool (Craig, V et al. 2002;Craig et al. 2000) comparing axillary temperature measurement with the rectal route and subsequently analysing ear thermometry compared with rectal thermometry. In the first review, data on

3201 participants were included in a meta-analysis. In the studies, overall mean axillary temperature was always lower than mean rectal temperature. A sub-analysis of 652 neonates was carried out but only two studies used electronic thermometers. One study showed narrow limits of agreement. The other, with wide limits of agreement, used a pre-1980 device. In the second review, the relation between age and differences in rectal and ear temperature were investigated for 2611 children. No association was noted. Overall, there was significant heterogeneity between mean differences ($p<0.0001$) and limits of agreement ($p<0.0001$). The researchers concluded that the findings implied measurements taken with infrared ear thermometry cannot be used as an approximation of rectal temperature.

Two additional studies which evaluated methods of temperature assessment in newborns were reviewed. Sganga et al (2000) compared newborn temperatures obtained by glass, digital disposable, electronic and tympanic thermometers in 184 healthy newborns aged between 1 and 168 hours of age. Left axillary and left tympanic temperatures were measured. For each infant, glass mercury thermometers were used first, followed by the other methods in random order. The glass mercury axillary temperature measurement served as the baseline. The digital thermometer correlated most closely ($r=0.84$); the electronic thermometer correlation was $r=0.74$ and the tympanic thermometer correlation was $r=0.35$.

A study from Rochester, New York (Loveys et al. 1999) evaluated paired temperature measurements taken by digital rectal and infrared tympanic thermometers. 1175 pairs of measurements were obtained, with 200 of these >380 C. Calculating from a linear regression model, rectal and ear temperatures were identical at about 37.70 C. However, lower rectal temperatures were associated with slightly higher ear temperatures (maximum difference 0.40C) and high rectal temperatures were associated with slightly lower ear temperatures (maximum difference of 0.50C).

7.6.2 When should women be asked about health problems in their babies?

There are no studies which address the timing of health assessments in newborn infants. Recommendations have been made by the National Screening Committee (see 3.1.3.1).

7.7 Vitamin K

Narrative Summary

Available evidence indicates that Vitamin K prophylaxis is effective and prevents significant morbidity and mortality due to Vitamin K deficiency bleeding (VKDB) (Ross & Davies 2000). VKDB may present in one of three ways:

- Early onset within the first 24 hours of birth
- Classical within the first week after birth and typically presenting with oral, umbilical, rectal or circumcision bleeding.
- Late onset after the first week, almost exclusively in breast fed infants and often in those with liver disease or malabsorption. Intracranial bleeding occurs in more than 50% of babies who are diagnosed with late onset VKDB.

7.7.1.1 Is there an association between childhood cancer and IM vitamin K?

In 1992, Golding et al reported an association between childhood cancer and intramuscular (IM) administration of Vitamin K (Golding et al. 1992). This finding was based upon a case control study of 195 cases of childhood cancer and 558 controls. There was a significant association (p=0.002) with IM Vitamin K (OR 1.97, CI 1.3-3.0) when compared with oral vitamin K or no vitamin K.

Following Golding's report, additional studies were conducted by other investigators which did not support a clinical relationship between newborn parenteral administration of Vitamin K and childhood cancer. An expert group

convened in the UK in October 1997 by the Medicines Control Agency on its own behalf and for the Department of Health and Committee of Safety of Medicines reviewed the studies linking Vitamin K and childhood cancer. The Working Group considered eight case control and four ecological studies and concluded that overall, the available data did not support an increased risk of cancer, including leukaemia, caused by Vitamin K (Department of Health 1998).

A more recent UK Department of Health (Roman et al. 2002) report published in the British Journal of Cancer conducted a pooled analysis of 2431 children developing cancer before age 15 and compared them with 6338 controls matched for sex and year (but not place) of birth. The analysis confirmed that solid tumours were no commoner in children given IM vitamin K at birth. The situation with regard to childhood leukaemia was less clear and since almost every baby now gets some form of prophylaxis it is unlikely to be clarified by further data collection. The increased risk was small with an unadjusted OR of 1.25 (CI 1.06-1.46) and could be due to that fact that those selected for prophylaxis (because of prematurity, operative delivery, etc.) were already more at risk for some unknown reason.

A recently conducted large national United Kingdom Childhood Cancer Study (UKCCS) included an updated pooled analysis with data for 7017 children (1174 with leukaemia). It found no association between IM Vitamin K and any diagnostic group, with the pooled odds ratio for leukaemia diagnosed between 12 and 71 months of age of 0.98 (CI 0.79-1.22) (Fear et al. 2003). The authors concluded that in the light of all available evidence, chance was the most likely explanation for early findings regarding the link between Vitamin K and childhood cancer.

Only a controlled trial could resolve any uncertainty about the association between Vitamin K and childhood leukaemia and this would have ethical as well as methodological implications.

7.7.1.2 When and in what doses should Vitamin K be administered?

A Cochrane review (Puckett & Offringa 2000) evaluated eleven RCTs comparing biochemical indices of coagulation status between oral and IM routes of administration. A single oral compared with a single IM dose resulted in lower plasma Vitamin K levels at two weeks and one month whereas a 3 dose oral schedule resulted in higher plasma vitamin K levels at two weeks and two months than a single IM dose.

A study undertaken in the north of England, between 1993 and 1998, (Wariyar et al. 2000) treated 182,000 healthy babies with 1 mg of an oral Vitamin K preparation (Orakay) at birth. Babies judged to be at high risk, (13,472) received 0.1 mg/kg IM Vitamin K after birth. Regardless of their treatment at birth, it was further recommended that the parents of all breastfed babies should then be given three 1 mg. capsules of Orakay and told to give their baby the contents of one capsule at fortnightly intervals after discharge. None of the babies treated with Orakay developed any sign suggestive of Vitamin K deficiency bleeding in the first seven days of life. Four documented cases of late Vitamin K deficiency bleeding occurred to babies in the study. Two babies had underlying alpha-1-antitrypsin deficiency and the mothers of two others did not receive instructions or capsules for prophylaxis. A postal survey of 458 mothers (61% response rate) and interviews with 173 randomly selected mothers both indicated that 93% of the babies still being breastfed had all four doses as recommended and that 98% had had at least three doses.

7.7.1.3 What is the most clinical and cost effective route (IM or oral) of delivering Vitamin K?

Narrative Summary

The intramuscular route was the most common route of administration of Vitamin K until the Golding report. Subsequently, the British Paediatric Association (now known as the Royal College of Paediatrics and Child Health) recommended that infants should receive Vitamin K supplementation orally with several doses to be given to infants who are breast fed.

As there was uncertainty about the optimum dosage, regimens in Britain became quite varied. In addition some inherent problems with oral dosing, which potentially compromised effectiveness, were identified. These include:

Compliance: Several doses of oral Vitamin K were needed over several weeks. A hospital in London surveyed mothers in June 1993 to evaluate its new policy of prescribing three 0.5 mg doses of Vitamin K for breast fed babies. The survey (n=207) showed a compliance rate of 99% for the first dose, 88% for the second at 1 week of age and 39% for the third at 6 weeks (Croucher & Azzopardi 1994).

Absorption: There was potential unreliability of absorption of oral Vitamin K, e.g. variable absorption or regurgitation

In December 1992 the Australian College of Paediatrics and the Royal Australian College of Obstetricians and Gynaecologists recommended replacing IM Vitamin K with three oral doses of 1 mg. each. However, the decision was rescinded in 1994 due to increased incidence of VKDB, thereby emphasising the efficacy of a regimen of IM prophylaxis.

In several European countries, oral regimens of Vitamin K administration were initiated in light of the Golding report. Surveillance studies on late VKDB (days 8-84) in countries which adopted oral therapy are reported below:

1. 325,000 newborns given 1 mg Vitamin K IM at birth; 0 cases of VKDB

2. 1,200,000 newborns in Germany given 1 mg Vitamin K orally at birth and two additional 1 mg doses between days 4-10 and days 28-42; 32 cases of late VKDB (2.7 per 100,000)

3. 800,000 newborns in Germany given 2 mg Vitamin. K orally at birth and two additional 2 mg doses between days 4-10 and days 28-42; 7 cases of late VKDB (0.9 per 100,000).

3. 325,000 newborns in Australia given three doses of 1 mg oral Vitamin K at birth and again between days 3-5 and days 21-28; 8 cases of late VKDB (2.5 per 100,000)

4. 83,000 newborns in Switzerland given 2 mg of mixed micellar preparation of Vitamin K (Konakion MM- better absorbed and produces higher plasma K levels than the standard oral preparation) by mouth on days 1 and 4; four cases of late VKDB (4.8 per 100,000)

5. 439,000 newborns in the Netherlands given 1 mg oral Vitamin K at birth and 25 micrograms daily from week 1 to week 13; 5 cases of late HDN (two did not receive the prophylaxis as recommended and three had "predisposing illness" and did not receive additional Vitamin K which would have been appropriate). (1 per 100,000).

6. 396,000 newborns in Denmark given 1 mg oral Vitamin K at birth and 1 mg weekly; 0 cases of VKDB (Hansen, Minousis, & Ebbesen 2003)

7. The efficacy of 3 oral 2 mg doses with Konakion MM remains to be established (von Kries 1999)

Cost Effectiveness

Current Advice from the DH

The DH continues to advise that all new born babies receive an appropriate Vitamin K regimen to prevent the rare, but serious and sometimes fatal, disorder of VKDB.

The recommendations state that Vitamin K can be given in a single dose of 1 mg IM. Oral regimens for vitamin K, on the other hand, must be repeated. Arrangements must be in place to ensure that all recommended oral doses are given at the appropriate ages. Doses of Vitamin K given at or shortly after birth should suffice for formula fed babies. Breastfed babies need additional Vitamin K. Konakion MM is licensed for oral use in 2 doses of 2 mg to be given in the first week for all babies and, for exclusively breastfed babies, a third dose of 2

mg is to be given at one month of age. Konakion MM is formulated in glass ampoules and currently it is necessary for a health care professional to administer the doses (Department of Health 1998). Orakay is not yet licensed in the UK.

Cost Perspective

There are two major costs associated with the administration of Vitamin K in neonates. The first is the cost of the drug and the second is the cost of the HCP required (for certain situations) to administer it.

In this case, issues surrounding effectiveness are of less importance than those of cost. The first reason is that Vitamin K Deficiency Bleeding (VKDB) is highly unusual among babies who had successful administration of a Vitamin K regimen (so either regime will have a similar outcome). The second is that intramuscular treatments are generally considered more likely to eliminate the threat of VKDB than an oral approach. Since this costing summary will show a lower cost level for the IM approach, the inclusion of effectiveness will only accentuate the advantages of the IM strategy.

The comparison undertaken here is the cost of an oral region of Konakion MM against an intra-muscular (IM) regimen of the same drug. Orakay is a possible future alternative but is, as yet, unlicensed. General guidance on the effect of introducing Orakay on cost effectiveness issues are outlined later for information.

Another major issue is the suggested link between IM Vitamin K prophylaxis and childhood leukaemia. Other than the Bristol study (Golding, Birmingham, Greenwood, & Mott 1992), there is a wide consensus that no solid link has been established. Therefore, this view was followed.

The oral regimen that seems to be prevalent is a series of three doses of 2mg, one at birth, one within the first week and one after around one month for breastfed babies (since breastfed infants do not receive the Vitamin K supplementation found in formula). This contrasts with the IM route which

requires one dose of 1mg soon after birth. The cost of a dose of oral Konakion MM Paediatric is £1.00 (as of April 2006) while the intramuscular option (Konakion Neonatal) costs 21p. On the 31st of March 2006, Konakion Neonatal was discontinued. Thus, the results of the analysis for the alternative intramuscular option, namely Konakion MM Paediatric, are reported.

The drug cost of the oral approach is therefore £2.00 or £3.00 depending on whether the baby is breastfed. Thus, the total drug cost is (£2.00 x (1 - breastfeeding rate) x 640 000) + (£3.00 x breastfeeding rate x 640 000). Assuming a breastfeeding rate of 50%2, this gives a total drug cost of £1.6 million.

As of March 2006, the IM route costs £1.00 per baby. This is based on the assumption that the second half of each 2 mg vial is wasted. Thus, the total implementation of this strategy would cost £640 000 (the drug cost is the total cost). It was felt that the non-usage of the second half of the vial was best representative of current practice.

The assumption made on the cost side was that the administering of the IM injection and the first and second oral was effectively costless as it can be tied-in with other routine visits (in hospital or otherwise) from the HCP.

For breastfed babies, this assumption of costlessness of provision was much less certain as the third dose is at a later stage. It seems that the strategy across England and Wales for administering this third dose is rather mixed. It is sometimes the case that a HCP would go to the baby to administer it (a health visitor in this case). Cost figures for this were taken from Curtis and Netten, Unit Costs of Health and Social Care 2004 (Curtis & Netten 2004).

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[2] (UNICEF. 2005)gives a breastfeeding rate of 71% at birth for England and Wales (2000) falling to 43% at 6 weeks and 14% at 9 months.

The total annual cost of a health visitor (wages plus NI contributions and overheads) was calculated and divided by the suggested workload (37.5 hours multiplied by 42 weeks) to provide an hourly cost. Assuming the trip takes half an hour and adding the cost of travelling (taken from the same source), this gives a total of £11.86 per visit. The non-drug costs of the oral Konakion MM regime were calculated thus,

£11.86 x breastfeeding rate x 640 000

If we use the previous assumption of a 50% breastfeeding rate, this means a non-drug cost of £3.795 million. If the guardian administers the third dose, this cost would be eliminated but further costs would be incurred through dealing with VKDB cases due to uneven compliance.

The summing of these produces a cost of an oral Konakion MM regimen of £1.6 million (£5.395 million if the third dose is HCP administered) and an IM regimen cost of £640 000.

The option most commonly cited as an alternative to these two approaches is Orakay. At present, this is unlicensed. Therefore, it can be recommended only if the clinical and cost-effectiveness evidence is compelling in favour. If, and when, Orakay is licensed, the effect of this would be to lower the cost of the oral approach (since the cost is around 31.7p per dose)

If Orakay was to be recommended and administered by parents, it would be necessary to repeat the analysis allowing for a non-compliance rate. It is important to note that, a recommendation for Orakay based on cost-effectiveness criteria would necessarily require either significantly better clinical outcomes than the intramuscular approach or lower costs. At present, the evidence suggests neither is proven.

Economic Summary

From a costing side, an IM regimen of Vitamin K prophylaxis is less expensive than a licensed oral regimen. The respective annual costs are £640 000 and £1.6 Million. If we follow the view on the lack of a link between IM prophylaxis

and childhood leukaemia, adding a measure of effect to this analysis will make IM prophylaxis relatively more cost-effective compared to its oral alternative.

If Orakay is to be included in the calculation, the evidence on cost-effectiveness relative to the IM route is uncertain but it is likely to be preferred to an oral Konakion MM system due to a lower level of costs.

7.8 Safety

7.8.1 Accident prevention

Narrative Summary

7.8.1.1 Incidence:

Accidental injuries are a major cause of childhood morbidity and mortality throughout the United Kingdom. Three children die as the result of a home accident every week (Royal Society for the Prevention of Accidents 2004). Those most at risk from a home accident are in the 0-4 year old group. The figures in Table 7-1 were provided by the Royal Society for the Prevention of Accidents, and identify the most common fatal and non fatal accidents incurred by children from 0-1 year of age.

Table 7-1 Common fatal and non fatal accidents incurred by children from 0-1 years

Fatal Accidents in the Home, 2002, UK	0-1 years of age	Non-fatal Accidents in the Home, 2002, UK (estimates)	0-1 years of age
Choking/suffocation	14	Falls	229
Drowning	5	Cuts	11
Fires	7	Struck	84
Falls	5	Foreign body	34
Poisoning	0	Burns/scalds	26
Other	1	Poison	25
		Pinch/crush	22
		Other	46
Total	**32**	**Total**	**477**

Source: Office of National Statistics, Registrar's General Scotland and Northern Ireland 2002		**NB: Figures are quoted in 000s**	**Source: Home Accident Surveillance System, DTI, 2002**

ALSPAC (Avon Longitudinal Study of Parents and Children, formerly the Avon Longitudinal Study of Pregnancy and Childhood) collected data on injuries resulting from accidents in pre-mobile infants (Warrington, Wright, & Team 2001). A total of 11466 responses were collected by postal questionnaire. When their infants reached the age of 6 months, mothers were asked to describe any accident that had occurred to their babies since birth. Falls and burns were the two events reported by the ALSPAC study group. A total of 3357 falls were reported for 2554 children (22% of the total). The most common types of falls were from beds or settees. Only 166 infants sustained a burn or scald (1.5% of the total).

A Canadian epidemiological analysis of injuries experienced by infant children less than 12 months old presented data by circumstances and age (Pickett et al. 2003). In babies 0-2 months, falls accounted for 52% of injuries. Sixteen percent of injuries were unspecified. Falling objects (7.4%) and motor vehicle accidents (7.4%) were the next most common causes of accidental injury to infants.

7.8.1.2 Risk

According to the Child Accident Prevention Trust the number of children's accidents has been declining steadily, however, children of all ages from the poorest families are still at much greater risk than those from the most affluent households.

Reading et al (Reading et al. 1999) investigated the relationship between social disadvantage and accidental injury in preschool children, attempting to separate the risks associated with individual family circumstance from those associated with wider environmental and area characteristics. The research group identified 21 large socially homogeneous areas in Norwich and collected

accident records for 3580 accident attendances of which 1134 were for moderate or severe injuries. The researchers used a multilevel modelling technique particular to geographic epidemiology where information is available on individuals nested within a hierarchical structure of areas, or units such as hospitals and clinics, all of which may independently influence the outcome of interest. In this study, factors which explained the variation in accident rates at the level of individuals included child's sex, the number of siblings, the age of the mother and whether the mother was a lone parent. For all accidents and for moderate and severe accidents, the proportion of variance explained in the model by individual characteristics was about 90%, the remaining 10% being explained by the social area. The significance of the effect of living in a deprived neighbourhood was greater in the model for more severe accidents with an odds ratio for risk of an accident which was equivalent to 1.49 times greater (CI 1.01-1.08) in the most deprived social area compared to the least deprived. The authors suggest that these finding may have implications for preventative measures which might include social policy changes to improve child care among unsupported families and targeting accident prevention measures at a local level towards deprived neighbourhoods. Several studies have assessed risk factors for injury in young children. Ramsay et al (Ramsay et al. 2003) used a health visitor questionnaire to investigate the physical, social and psychological environment of 79 families with preschool children under 5 years of age presenting to an A & E department with an injury sustained in the home. These families were matched with 128 control families by postcode, age and sex of children. Matching on postcode effectively matched for deprivation and therefore this factor could not be analysed. The main carers of cases had a lower level of educational attainment than controls ($p<0.01$). Socket cover utilization was also lower in case families.

A prospective American study (Harris & Kotch 1994) interviewed 367 mothers six to eight weeks after delivery and again one year later, when 132 infants (36%) were reported as injured. The infants were recruited through a high priority infant tracking program (HPIP). One low risk infant was recruited for every four "HPIP" infants. In the crude analysis maternal unemployment,

number of siblings living in the home, families receiving welfare, maternal stress, maternal depression, family conflict and seeking spiritual support were associated with unintentional injury. After adjusting for potential confounding only three variables remained as significant risk factors for injured infants: family conflict, maternal unemployment and families that had fewer than two other children, OR 1.3 (CI 1.1-1.4). Among mothers with high levels of social support the odds of injury were 0.38 (0.04-3.44) in contrast to those with low levels of social support, where the odds of injury were significantly increased, 2.41 (1.37-4.24).

In another American study (Gielen et al. 1995)150 mothers of babies aged 6 and 36 months were interviewed about injury prevention practices and personal beliefs about safety. The interviewees were residents of a disadvantaged inner city community. In this population factors significantly associated with the number of injury prevention practices implemented were family income, housing quality and environmental factors such as moving house frequently or living alone.

7.8.1.3 Prevention:

In 2001 the Health Development Agency published an updated systematic review of health promotion intervention to prevent unintentional injuries in childhood and young adolescence (Towner et al. 2001). The review included studies published between1975-2000. One hundred and fifty five studies were evaluated. A range of interventions shown to reduce injury or to change behaviour were identified. Those which might apply to young infants have been extracted and are presented in Table 7-2:

Table 7-3 Interventions to Reduce Injury

Good Evidence*	Reasonable Evidence*	Some Evidence*
20 mph zones , leading to injury reduction and behaviour change	Area wide urban safety measures, leading to injury reduction	Interventions targeted at specific injuries, such as cot suffocation, may lead to injury

		reduction.
Child restraint loan schemes, leading to behaviour change	Child restraint education campaigns, leading to behaviour change	Tap water temperature reduction, leading to behaviour change
Child restraint legislation, leading to behaviour change	Child restraint legislation, leading to injury reduction	Parent education regarding burns and scalds, leading to behaviour change
Smoke detector programmes, leading to injury reduction and behaviour change	Parent education on hazard reduction, leading to behaviour change	Parent education regarding falls, leading to injury reduction
	Some general community prevention initiatives targeting a range of injury types may lead to both injury reduction and behaviour change.	
	General mass media campaigns and training events have been shown to increase safety knowledge but have not been shown to reduce injuries.	

*The terms 'good,' 'reasonable' and 'some' refer to judgements made by Towner and colleagues (Towner, Dowswell, Mackereth, & Jarvis 2001) about the quality of research evidence they examined.

The HDA report also reviewed ten studies which evaluated the effectiveness of community based childhood injury prevention programmes. Six of these were based on the WHO Safe Communities model which combines local surveillance systems and a reference group to coordinate activities. Eight of the programmes were at least partially effective in either reducing injury or increasing knowledge about safety. A meta-analysis was not performed.

The U.S.-based Institute for Clinical Systems Improvement (2004) developed a guideline for childhood preventive services. A systematic review of the literature was not done. The evidence which was reviewed was graded as 'good,' ' fair' or 'insufficient.' They concluded that there is fair evidence to support counselling on several safety topics which relate to young infants including child

safety seats, flame resistant sleepwear, protection from UV light and infant sleep position and SIDS.

An RCT was conducted in a large urban teaching hospital in the US to develop and evaluate an injury prevention anticipatory guidance training programme for paediatric residents (Gielen et al. 2001). The goal was to improve parents' safety practices for the prevention of burns, falls and poisoning in young children aged 0-2 years old living in low-income inner-city neighbourhoods. Thirty one paediatric residents were randomised either to standard safety training plus a 5 hour experiential instruction programme on injury prevention and counselling skills or to the standard one hour seminar about injury prevention alone. Parents seen by physicians in the intervention group (n=117) received significantly more injury prevention counselling and were significantly more satisfied but their knowledge, beliefs and home safety behaviours did not differ significantly from parents seen by the control group of doctors (n=73). The researchers concluded that because low-income families face many barriers to carrying out recommended safety practices, supplemental strategies are needed to ensure safer homes.

A study was conducted in the UK at a GP practice in Nottingham (Clamp & Kendrick 1998) to assess the effectiveness of counselling on injury prevention by a general practitioner in conjunction with access to low cost safety equipment for families on a low income. One hundred and sixty five families responded to a questionnaire on child safety practices. They were then randomly assigned to an intervention or a control group. The intervention consisted of standardised advice and safety leaflets. Families receiving means tested benefits were offered a smoke alarm for 50p and two window locks, three cupboard locks, six socket covers, or a door slam device for 20p, all available at the surgery at the time of the consultation. Stair gates and fireguards were offered at £5 per item. After the intervention, significantly more families in the intervention group used fireguards (RR 1.89, CI 1.18-2.94), smoke alarms (RR 1.14, 1.04-1.25), socket covers (RR 1.27, 1.10-1.48), locks on cupboards for storing cleaning materials (RR 1.38, 1.02-1.88) and door slam

devices (RR 3.60, 2.17-5.97). Also significantly more families in the intervention group showed very safe practice in storage of sharp objects (RR1.98, 1.38-2.83), storage of medicines (RR 1.15, 1.03-1.28), window safety (RR 1.30, 1.06-1.58), fireplace safety (RR 1.84, 1.34-2.54),socket safety (RR 1.77, 1.37-2.28),smoke alarm safety (RR 1.11, 1.01-1.22), and door slam safety (RR 7.00, 3.15-15.6). Stratifying results by receipt of state benefits showed that the intervention was at least as effective in families receiving benefits as others.

Kendrick et al (Kendrick 1999) evaluated a package of safety advice provided at child health surveillance consultations; provision of low cost safety equipment including stair gates and fireguards, cupboard locks and smoke alarms; and home safety check and first aid training by health visitors. Overall 44 health visitors from 36 practices in Nottingham took part. Eighteen practices were randomly allocated to the intervention group (n=823) and 18 practices comprised the controls (n=771). No significant difference in injuries was demonstrated. However, as severe injury is a rare event, a larger study may be required to assess the effect of the intervention in these cases.

7.8.1.4 Role of Home Visiting in Prevention of Childhood Injury:

In 1983 a study was published in the Lancet which evaluated the first seven years of the Sheffield Intervention Programme, from 1973-1979 (Carpenter et al. 1983). In this study 39,452 infants born to parents resident in Sheffield were scored at birth for risk of unexplained infant death. Infants in Sheffield were normally seen by their health visitor at 10 days, 4 weeks and 3 months. High risk infants were seen every 2 weeks up to 3 months and every month up to 6 months. Thus high risk infants received at least five extra home visits in the first 6 months. A campaign to promote breast feeding and to ensure that bottle feeds were made up correctly decreased the risk of hypernatraemia. Before 1973 post-perinatal mortality in Sheffield was, on average, 11.5% above the rate for England and Wales. Since 1973 it has only once exceeded the rate for England and Wales. “Possibly preventable” deaths have fallen from 5.2 to 1.9 per 1000. Twelve percent of this decline is associated with a rise in the average age of the mother and a fall in the number of pregnancies, 9% with a

reduction in precipitate deliveries, 24% with an increase in breastfeeding, 18% with extra care given by health visitors to high-risk infants, and 36% with other factors.

A systematic review of home visiting and the prevention of childhood injury was conducted by Ian Roberts of the Institute of Child Health and published in 1996 (Roberts, Kramer, & Suissa 1996). Eleven RCTs were reviewed. Eight of these examined the effectiveness of home visiting in the prevention of childhood injury. The pooled OR for the eight trials was 0.74 (CI 0.60-0.92). Four studies examined the effect of home visiting on injury occurrence in the first year of life only. The pooled OR was 0.98 (0.62-1.53). Most of the trials in this review used non-professional home visitors. In all but one of the trials the intervention was targeted at groups considered to be at increased risk for adverse child health outcomes.

A Canadian multicentre randomised controlled trial was conducted to evaluate the effect of a single home visit by a research assistant which included the provision of an information package, discount coupons, and specific instruction regarding home safety measures (King et al. 2001). Initially, 1172 homes were inspected for safety. They were then randomised to intervention or control. The median age of children in the homes was 2 years. Outcomes included (1) parental injury awareness and knowledge; (2) the extent that families used home safety measures (3) the rate of injury and (4) the cost effectiveness of the intervention. There were no significant differences in prenatal injury awareness and knowledge from baseline between the intervention and control groups. Significant changes were observed in the number of intervention homes who had hot water not exceeding 54 degrees centigrade (OR 1.31, CI 1.14-1.50) and who had smoke detectors on some or all levels (OR 1.45, CI 0.94-2.22). There was a significant difference, favouring the control group, in the number of homes with a fire extinguisher (OR 0.81, CI 0.67-0.97). The intervention group reported significantly less injury visits to the doctor compared with the non-intervention group (rate ratio: 0.75, CI 0.58-0.96). The total costs of care for

injuries were significantly lower in the intervention group compared with the controls with a cost of $372 per injury prevented.

7.8.2 Reducing the risk of SIDS

7.8.2.1 SIDS Risk (a review of modifiable risk for SIDS after initiation of the "Back to Sleep" campaign)

The study of risk of Sudden Infant Death Syndrome has resulted in the identification of a number of modifiable risk factors which have subsequently been targeted in public health campaigns. Advice from Chief Medical Officer in England formed the basis of a national intervention campaign in November 1991 called "Back to Sleep" to reduce the prevalence of modifiable risk factors for SIDS. In 1992 the U.K. Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) was established to 'improve understanding of ways in which the risks of death might be diminished with particular regard to avoidable factors' (Saunders 1997). Early studies identified sleeping position, maternal smoking and bedding as factors affecting the risk of SIDS (Beal & Finch 1991;Dwyer et al. 1991;Fleming et al. 1990;Mitchell et al. 1992). Other factors such as breast feeding, use of dummies and bed sharing were not consistently found to be associated with risk of death (Ford et al. 1993). In 1993 the Department of Health funded a large scale detailed case control study of sudden unexpected deaths in infancy (SUDI study) in three NHS regions in the United Kingdom (Southwest , Yorkshire and Trent, population 17.7 million) combined with a confidential inquiry into such deaths over a two year period starting one year after the national risk reduction campaign (Blair et al. 1999;Blair et al. 2000;Blair et al. 1996;Fleming et al. 1999;Fleming et al. 1996). Cases (n=195) were reported within 24 hours and data were collected on a standard questionnaire by research interviewers. Each bereaved family was visited twice within two weeks of the death. Four controls were selected for each case (n=780), with babies matched on age and geographical location. Controls were visited within a week of the case baby's death. In the multivariable analysis the following environmental risk factors were significant:

	OR	95% CI
• Prone sleeping	9	(2.84-28.47)
• Side sleeping	1.84	(1.02-3.31)
• Head covered by bedding	21.58	(6.21-74.99)
• Bed sharing with parents all night	4.36	(1.59-11.95)
• Using dummy	0.38	(0.21-0.70)

An important new observation in this data was that the side sleeping position carried significantly increased risk when compared with supine. Total head covering emerged as the most potent of all risk factors (21.58; 6.21-74.99).

Subgroup analysis of bed sharing showed that the associated risk was significant only among smokers, OR 9.25 (2.51-34.02). There is no suggestion that taking the baby into bed for a short time for feeding or for comfort poses any risk except that the mother may then fall asleep and keep the baby in her bed all night long. There were no differences in the proportions of babies sharing a room with an adult or another child. There were factors related to bed sharing among young babies that seem to be associated with increased risk. These included maternal alcohol consumption (OR 3.40; 1.88-6.16), parental fatigue (OR 1.61-3.63), overcrowded housing conditions (OR 18.49; 3.62-94.48) and infant being under a duvet (OR 3.97; 2.43-6.46).

The risk associated with smoking during pregnancy was significant (1.78; 1.04 - 3.05). Paternal smoking had an additional independent effect (2.50; 1.48 - 4.22). If one or both parents smoked the OR for SIDS was 3.79 (2.09 - 6.88) in

a multivariable analysis. The additive effect of smoking in pregnancy and postnatal exposure was also significant (2.93; 1.56 - 5.48).

No protective effect of breastfeeding was identifiable in the multivariable analysis.

The SUDI study was carried on for a third year in which pacifier use was recorded. The proportion of infants who had ever used a pacifier for day or night sleeps was exactly the same (66%) but significantly fewer SIDS infants used a pacifier for the last/reference sleep, OR 0.41 (0.22-0.77), giving an apparent protective effect against SIDS.

Prospectively recorded weight observations for cases (n=325) and controls (n=1300) were collected in the SUDI study as well. Poor weight gain in the first six weeks emerged strongly as a risk factor only for those babies with birth weights above the 16th centile (OR 1.97, 1.49-2.61, p<0.0001).

An American study published in 2005 (Alexander & Radisch 2005) presented the results of a retrospective review of 102 SIDS deaths. The researchers aimed to evaluate the overlap of known risk factors such as sleep position, sleep surface and co-sleeping. Of particular interest was the frequency of infants who died with no risk factors. Of the 102 deaths, 67(65.7%) were not in a crib, 63 (61.8%) were prone and 48 (47.1%) were co-sleeping. Overall, 94 (92.2%) of these deaths had at least one risk factor present. Only 8 (7.8%) of infants had none of these risk factors, leading to the conclusion that for infants in this study a SIDS death was rare if the baby was sleeping alone, in a crib, on its side or back.

The relationship between routine infant care practices and Sudden Infant Death Syndrome was investigated in a four year case control study by the Scottish Cot Death Trust (Brooke et al. 1997). Questionnaires were completed by parents recruited for this study, with the assistance of a fieldworker at a home visit. Forms were completed for 147 cases out of a total of 201 reported SIDS deaths and on 276 controls. Sleeping prone (OR 6.96; 1.51 to 31.97) and drug treatment the previous week (OR 2.33; 1.10-4.94) were more common in cases

than controls in the multivariable analysis. Smoking was a significant risk factor if the mother smoked (OR 5.05; 1.85 to 13.77), the risk increasing if both the mother and father smoked (OR 5.19; 2.26 to 11.91). However paternal smoking on its own was not significant. The risk of SIDS increased with the number of cigarettes smoked by the mother or the father (p=0.0001) and also with bed sharing (P<0.005). Sleeping on a previously used mattress was also significant (OR 2.51; 1.39 to 4.52), although the risk was not established for mattresses completely covered by polyvinyl chloride.

A study conducted in southeast Norway and published in 2001 compared changes in risk factors for SIDS during the time of increasing SIDS rate (1984-1989), the period of rapid decline (1990-1992) and the time of stable low rates (1993-1998) (Arnestad et al. 2001). A questionnaire was distributed by mail to 266 parents who had lost a child to SIDS during the period 1984-98 and to 698 control parents. The controls were chosen at random from the national population register, and matched on sex, date of birth and place of birth. The questionnaires were distributed in 1993 and 1998. The response rate was 69% in the SIDS parents group and 75% in the control parents group. The mean time between death and completion of the questionnaire was three years. The SIDS rate in southeast Norway decreased from 1.8/1000 in 1989 to 0.6/1000 in 1993 at which point it stabilised. During this time, the proportion of infants found dead in the prone sleeping position decreased from 93% to 63%, however, over half of the SIDS victims were found in the prone position. No increased risk of side sleeping was demonstrated by this study. Although co-sleeping as a usual mode of sleep increased over the time period studied, it could not be related to changes in the SIDS rate for the region.

There was a positive interaction between co-sleeping and maternal smoking during pregnancy (OR 8.63, 1.87-39.85, p<0.01). Maternal smoking before, during and after pregnancy was significantly associated with SIDS in this study in both the crude and multivariable analysis. The OR postnatally was 3.7 (2.5 to 5.5). When paternal smoking was adjusted for maternal smoking in pregnancy there was no effect shown. A clear dose response relationship was

demonstrated for maternal smoking with the highest rates of SIDS occurring in the children of the heaviest smokers.

Caffeine during or after pregnancy was not found to be an independent risk factor for SIDS after adjusting for maternal age, education, parity and smoking during pregnancy.

Heavy postnatal alcohol intake was significantly associated with SIDS (OR 5.9; 1.0 to 33.9) but was based on a very small sample of 7 cases and 2 controls.

Both the usual age peak for SIDS deaths between 2 and 4 months and the seasonal peak during autumn/winter became less pronounced during the time period of this study.

The European Union Concerted Action of SIDS (ECAS) was founded in January, 1994 to combine data from across Europe with the aim of re-examining the epidemiology of SIDS (Carpenter et al. 2004). Data were derived from 20 centres between September, 1992 and April, 1996. The Nordic study and three regions in England which made up the first 2 years of the SUDI study were included. New studies following the same ECAS protocol were also set up in 12 centres, six of which were in Eastern Europe. Interview data were collected for 745 cases and 2411 controls. Highly significant risks were associated with prone sleeping (OR 13.1; 8.51 to 20.2); head covered (OR 12.5; 6.47 to 24.1); maternal alcohol consumption in last 24 hours of 3 drinks or more (OR 2.33; 1.28 to 4.21); illegal drug use by the mother (OR 1.92; 1.00-3.70). Maternal smoking was significant and there was a dose response (< 10 cigarettes per day OR 1.52; 1.10 to 2.09; >10 cigarettes per day OR 2.43; 1.76 to 3.36).

In this study the OR associated with bed sharing all night with an adult was progressively greater for younger infants whether or not the mother smoked, the increase being 5.2% per week in both groups (p=0.002). Adjusted OR's for smokers who bed shared was 11.3 times greater than for non smokers and ranged from OR 27 (13.3-54.9) at 2 weeks to 7.5 (4.3-13.2) at 26 weeks. For

non smokers, the risk of bed sharing was significant only at less than 8 weeks (OR 2.4; 1.2-4.6).

Regular dummy use and use in the last sleep was significantly less than one in this data analysis (OR 0.74; 0.58-0.95 and OR 0.44; 0.29-0.68, respectively). Similarly infants who regularly shared a room with their parents and did so on the last occasion were at significantly less risk (OR 0.48; 0.34-0.69 and OR 0.32; 0.19-0.55, respectively). Duvet use on the last occasion was significant with an adjusted OR 1.82; 1.30-2.58).

Overall, sleeping position, type of bedding used, and sleeping arrangements were the modifiable factors identified in this study for future SIDS reduction campaigns.

A five year case control study was conducted using data on SIDS victims in the Republic of Ireland between January 1994 and December 1998 (McGarvey et al. 2003). Despite dramatic reductions in SIDS deaths after the “Back to Sleep” campaign, SIDS remained the leading cause of infant death in Ireland. The purpose was to examine the role of factors relating to the infant’s sleeping environment which might constitute modifiable risk factors for SIDS. A total of 203 SIDS cases and 622 control infants were included in this study. Parents were interviewed in their homes within 6 weeks of the case infant’s death. Only the use of the prone sleeping position (OR 11.47; 1.24-106.06), co-sleeping (OR 16.47; 3.73-72.75) and absence of routine soother (dummy/pacifier) use (OR 5.86; 2.37-14.36) were statistically significant in the multivariable analysis.

The risk of co-sleeping for infants whose mothers did not smoke was significant with a CI ranging between 1.42 and 13.91. However in cases where the mothers smoked, the OR varied between 13.21 and 711.69. In fact, 90% of all SIDS cases who were co-sleeping during the last sleep period had mothers who smoked during pregnancy. The mechanism by which maternal smoking exerts a fetal biological effect is generally thought to be by impaired fetal growth, chronic hypoxia and impaired brain stem function with subsequent

poorer cardio-respiratory control postnatally. Thermal stress of the co-sleeping may combine with physiological vulnerability to prove a lethal combination.

In this study more cases than controls habitually used a soother. However, 47% of these babies did not have their soother on the night they died. Infants who usually used a soother and did not have it during the last sleep were almost six times more at risk than regular users who did have it. It appears that the absence of habitual soother may present a risk.

Secondary analyses of the New Zealand Cot Death Study (Mitchell et al. 1992) were conducted by Ford et al (1993, 1996, 1997). These researchers looked at lack of social support and the experience of stressful life events as well as breastfeeding and illness/acute medical care as risk factors for SIDS (Ford et al. 1996). The original data for the New Zealand Cot Death Study was collected by a comprehensive parental questionnaire answered one month after the death of the case infant. The study ran from 1 November 1987 to 31 October 1990. Subject ascertainment was 81% (n=393) for case families and 88.4% (n=1259) for controls families interviewed. A full set of data for the analysis of social support and life events was available for 390 cases and 1592 controls. Mother's social support index (MSSI) was used and questions relating to family stress were derived from previous studies. In this study there were only minor differences between SIDS families and control families for social support. Families who had experienced more than six stressful life events in the preceding year had three times the risk for a SIDS event. This result was nonsignificant when socio economic and demographic confounders were included in the model. The researchers concluded however that it was possible that sociodemographic influences on SIDS may work through additional life event stresses. These two factors are difficult to disentangle.

The analysis of duration of breastfeeding and the risk of SIDS (Ford et al. 1993) utilised data from 356 cases and 1529 controls. In a multivariate analysis, exclusive breastfeeding at discharge from the hospital appeared to be protective (OR 0.52, 0.35-0.77) and the protective effect was also present for infants exclusively breastfed in the 'last two days' (OR 0.65, 0.46-0.91).

Finally, the analysis of illness and acute medical care (Ford et al. 1997) was evaluated using data from 390 cases and 1592 controls. Severe illness (based on BabyCheck) was associated with an increased risk of SIDS (OR 2.36, 1.14-4.90). SIDS infants were taken to the GP more often than control infants for the same severity of illness but the difference was not significant on multivariate analysis. Only 1.3% of all SIDS cases had symptoms suggestive of severe illness and had not seen a GP. The researchers concluded that lack of appropriate medical contact for illness could not be implicated as a risk factor for SIDS.

A before and after cohort study conducted in Tasmania assessed the effect of supine positioning on SIDS rates in the state (Dwyer et al. 1995). Infants were assessed for risk of SIDS using a locally constructed predictive model. Of 5534 high risk infants included in the study, 39 died of SIDS. The cohort was divided into pre-intervention (May 1, 1988 through April 30, 1991) and post-intervention (May 1, 1991 through October 31, 1992) cohorts. Three interviews were conducted, at 4 days of age, at home during the fifth postnatal week and by telephone during the 10th postnatal week. The SIDS rate in Tasmania from 1975 through 1990 was 3.8/1000. In 1992 the rate of 1.4/1000 was significantly lower ($p<.01$). During the pre-intervention period the SIDS rate in the high risk cohort study was 7.6/1000. The rate decreased to 4.1/1000 and when adjusted for season of birth the decline was significant ($p=.04$). Multiple logistic regression analysis was used to estimate the individual contribution of the various risk factors. The largest individual contribution to the decline in SIDS was made by the change in usual prone position, accounting for 70% of the decline in the cohort. All other factors accounted for less than 10% of the reduction in SIDS rate. The decrease in SIDS rate after the intervention, adjusted for season of birth and usual prone position, was not materially altered by further adjustment for any of the individual factors.

Two additional studies were reviewed which assessed the role of other potential risk factors for SIDS. The role of breastfeeding (McVea, Turner, & Peppler 2000) was the subject of a meta analysis performed at the University of

Nebraska. This analysis included 23 studies. Medline and dissertation abstracts were searched. Cohort and case control studies were included. The studies were heterogeneous and the majority were of fair or poor quality. The result of the meta-analysis suggested that breastfeed is associated with a 50% reduction in SIDS risk but this result is highly suspicious due to severely flawed methodology.

The seasonality of SIDS has been noted since the 19th century. A Scottish study evaluated this factor in the light of the fall in the incidence of SIDS after advice on infant sleeping position was issued (Douglas et al. 1996). An analysis was carried out looking at the role of seasonality for the years 1988-1990 and for 1992-1994. Seasonality persisted as a risk factor. There is a lowering of risk, by one third, amongst babies born in February-May compared to those born in August-November. Once a mother has had an infant with SIDS there is an estimated risk of recurrence, possibly three to 10 times greater than in the rest of the population. The authors suggest that advice on subsequent pregnancy delivery date should be given to families who have already experienced SIDS.

7.8.2.2 What reduces/eliminates the risk of death among infants in the first 6-8 weeks?

Six key health messages came out of the SUDI studies. These include the following:

- Back to sleep: Babies should be put down to sleep lying on their backs. Sleeping on the back is preferable to sleeping on the side and sleeping prone should be avoided

- Feet to foot: Babies should sleep in such a way that their head does not become covered during sleep. This is most easily achieved by putting a baby to sleep with his or her feet close to or touching the foot of the cot. Blankets are preferred to duvets and should be tucked in so that the baby's head is exposed and uncovered without a hat.

- Not too hot: Although it is important to prevent a baby becoming cold, becoming too hot is also a danger. Room heating is not required at night except when the weather is very cold. Babies' bedrooms should be kept at approximately 16-200 C.

- Smoke free zone: Cigarette smoking in pregnancy and around babies increases the risk of cot death. There should be no smoking around the baby's sleeping place.

- Prompt medical advice: The risk of cot death may be reduced by seeking prompt medical advice for babies who become unwell, particularly those with a raised temperature, breathing difficulties and who are less responsive than usual.

- Bed sharing for comfort, not sleep: While it is likely to be beneficial for parents to take their baby into bed with them to feed or comfort, it is preferable to place the baby back into a cot to sleep. This is especially important if the parents smoke or have consumed alcohol.

The National SIDS Council of Australia reviewed the evidence concerning risk factors of SIDS and developed recommendations based on this review (Henderson-Smart, Ponsonby, & Murphy 1998). The National Health and Medical Research Council of Australia provides a methodology for guideline development which includes a systematic identification and synthesis of the evidence including quality assessment. However, the evidence tables and grading were not provided in the review article on SIDS. Thus the recommendations are categorized as 'expert opinion.' The forum developed three recommendations for which there was strong evidence:

- Put your baby on the back to sleep, based on at least 19 retrospective case control studies with OR's ranging from 1.2 to 14.1.

- Make sure your baby's head remains uncovered during sleep

- Keep your baby smoke free before and after birth

This group also found that most studies suggest that there is no significantly increased risk of SIDS for babies of non smoking parents who bed share. They found that if infants become either too hot or too cold the risk of SIDS is increased, although this appeared to be related to sleeping position as well. The review group did suggest that it was important to try to maintain infants in a comfortable temperature zone. They found no consistent evidence that breastfeeding decreases the risk of SIDS.

Clinical Evidence published by the BMJ reviewed the effects of interventions to reduce the risk of sudden infant death (Creery & Mikrogianakis 2002). A broad based literature search was performed. Studies were chosen based on critical appraisal of abstracts and then summarised. Each topic was subsequently peer reviewed. A formal quality assessment of chosen studies was not undertaken. Based on this review, advice to avoid prone sleeping was supported. This was based on one non- systematic review and 12 observational studies which found that eight campaigns encouraging non-prone positioning and seven campaigns involving, among other recommendations, advice to encourage non-prone sleeping positions, were followed by a reduced incidence of SIDS.

Interventions including avoidance of tobacco smoke exposure, bed sharing and over heating were all based on studies which evaluated campaigns to reduce several risk factors and therefore it was not clear whether the effects were specifically due to any particular intervention.

7.8.2.3 What are the risks and benefits of co-sleeping?

An investigation of the characteristics of parent-infant bed-sharing prevalence in England was published in 2004 (Blair & Ball 2004). Using sleep logs and interviews information on night time care giving was obtained for a broadly representative sample of 261 families in Stockton-on-Tees. Data on 1095 infants from the CESDI study of five English health regions were also used. Data from both studies found that almost half of all infants bed-shared, that is, slept with an adult for at least part of their night sleep, at some time with their

parents (46% locally; 47% nationally). On any one night in the first month over a quarter of parents slept with their baby (27% locally; 30% nationally). Statistical analysis showed that bed sharing was not significantly related to younger mothers, single mothers or larger families and was not more common in the colder months, at weekends or among the more socially deprived families. Breastfeeding among young infants was strongly associated with bed sharing ($p<0.0001$).

The evidence about co-sleeping reviewed thus far indicates that:

- Risk was significant only among smokers in the SUDI study, but not in the ECAS study.
- Risk is increased if smoking and bed sharing are combined (Scottish Cot Death Trust).

Although co-sleeping as a usual mode of sleep increased over the time period studied, it could not be related to changes in the SIDS rate for the region. There was a positive interaction between co-sleeping and maternal smoking during pregnancy (Nordic study and European Union study).

In the European Union study the OR associated with bed sharing all night with an adult was progressively greater for younger infants whether or not the mother smoked.

A paper published in 1999 reported the results of the SUDI study specifically on the risk of babies sleeping with parents (Blair et al. 1999). In a three year period 325 cases and 1300 controls were identified. There was no increased risk of death for infants who shared the bed but were put back in their own cot. There were significant associations with infants who were found in the parent's bed (9.78; 4.02-23.83), who shared a sofa (48.99; 5.04-475.60) and who slept alone (10.49; 4.26-25.81). Removal of three variables including death in the prone sleeping position, placed on a pillow or head covered halved the strength of the association of bed sharing and SIDS (4.62; 2.34-9.09). As previously noted there was no increased risk if parents were non smokers. If at least one

parent smoked and the bed was shared, the OR was 12.35 (7.41-20.59) for SIDS. There was also no risk for infants older than 14 weeks. Among younger infants risk appears to be associated with recent parental consumption of alcohol (3.40; 1.88-6.16), overcrowded housing conditions(18.49; 3.62-94.48), extreme parental tiredness (2.42; 1.61-3.6) and the infant being under a duvet (3.97; 2.43-6.46).

Bed sharing and SIDS was assessed in a case control study reported in the BMJ in 1995 (Klonoff-Cohen & Edelstein 1995). Two hundred cases and two hundred matched controls were identified. The parents were interviewed by telephone. Routine bed sharing was assessed independently for day and night. The adjusted OR's for both daytime and night routine bed sharing were not significant (OR 1.38; 0.58-3.22 and 1.21; 0.59-2.48 respectively). Bed sharing was adjusted for routine sleep position, birth weight, medical conditions at birth, passive smoking, exclusive breast feeding, intercom use and maternal age and education. Prenatal smoking was not included in the analysis. The study was underpowered for OR's less than 2.9.

A study by Sheers et al (2003) compared the sleep location of 348 cases younger than 8 months at death with the sleep location of 4220 living infants younger than 8 months. The risk of suffocation was approximately 40 times higher for infants in an adult bed than those in cribs. The increase in risk remained high even when overlying deaths were discounted (32 times higher) or the estimate of rates of bed sharing among living infants doubled (20 times higher). The risk to younger infants also appeared to be greater when they slept in adult beds (87 deaths in adult beds at one month of age compared to 56 deaths at 5 months). This study did not control for potential confounders in the analysis.

The Chicago Infant Mortality Study (Hauck et al. 2003) was designed to examine risk factors for SIDS using a population based case control study. All 260 Chicago infant SIDS cases between November 1993 and April 1996 were evaluated. The adjusted OR for shared bed with mother alone or with mother and father was not significant but maternal smoking was not included as a

potential confounder. Shared bed with others, meaning other children or children and parents had an OR of 2.0 (1.2-3.3).

A study of the role of parental bed sharing with consideration to parental weight was undertaken in Cleveland, Ohio (Carroll-Pankhurst & Mortimer 2001). An analysis of 84 SIDS deaths was carried out, 30 of which were bed sharing and 54 of which were non-bed sharing infants. Large maternal size was not associated with increased risk of earlier SIDS death in the absence of bed sharing but there was a significantly younger age of SIDS among infants of large mothers who shared a bed than among those who did not share a bed (p=.01). This study is limited by lack of a control group and by the fact that the population studied was urban and disproportionately minority and low income.

Bed sharing and the infant's thermal environment was studied by Baddock et al (Baddock et al. 2004). Forty routinely bed sharing infants and 40 routinely cot sleeping infants aged 5-27 weeks were evaluated. Overnight video and physiological data were recorded including rectal, shin and ambient temperature as well as frequency of face covering events. The mean rectal temperature two hours after sleep was higher for bed share infants but not statistically significant (0.05, -0.03-0.14). However the rate of increase in rectal temperature in bed sharing infants was significant (0.01, 0.00-0.02) as was the frequency of face covering events ($p<0.001$) and the amount of bedding ($p<0.001$). The researchers conclude that bed share infants experience warmer thermal conditions than cot sleeping infants but appear to be able to maintain adequate thermoregulation to maintain a normal core temperature.

A study published in 2005 by Tappin et al (Tappin, Ecob, & Brooke 2005) described a 1:2 case control study conducted in Scotland which included 123 infants who died of SIDS between January 1996 and May 2000 and 263 controls. Sharing a sleep surface during the last sleep was associated with an OR 2.89 (CI 1.40-5.97) for SIDS. The largest risk was associated with couch sharing (OR 66.9, CI 2.8, 1597). Sharing a bed when <11 weeks (OR 10.20, CI 2.99, 34.8) was associated with a greater risk, p=0.01, compared with sharing when older (OR 1.07, CI 0.32-3.56). The association remained for young

infants if mother did not smoke (OR 8.01, CI 1.20, 53.3) or the infant was breastfed (OR13.10, CI 1.29, 133). Previous studies failed to show an associated risk for bedsharing if the mother was a non-smoker.

However age groups were not stratified. Despite small numbers and wide confidence intervals, these researchers support the revised UK Department of Health advice that the safest place for your baby to sleep is in a cot in your room for the first six months.

The benefits and risks of bed sharing and co-sleeping are presented in a guidance paper published by the Royal College of Midwives (RCM) (Royal College of Midwives 2004). This guidance is based on good practice recommendations. The RCM advises:

- Parents should be informed of the benefits of bed sharing and co-sleeping including successful breastfeeding and better sleep;
- Parents should be discouraged from:
    - co-sleeping on sofas and armchairs;
    - bed sharing and co-sleeping at home if either parent is a smoker, has recently had alcohol, is on sleep inducing medication or illicit drugs, is unwell, excessively tired or unaware of body periphery;
    - co-sleeping if the baby is bottle feeding, is bed sharing or co-sleeping with father only or if the father comes to bed later;
    - allowing the baby to bed share or co-sleep with children or bed share with unwell or restless children
    - using heavy quilts duvets, electric blankets or pillows;
    - sleeping on waterbeds, feather, soft or sagging mattresses, beanbags and V shaped pillows;

- permitting gaps between the mattress, furniture and wall.

A qualitative study was conducted in North Tees, UK to examine parents motives for sleeping with their infants (Ball 2002). Sleep logs were recorded and then mothers (n=253) were interviewed at the end of the first and third months postpartum using a semi structured interview format. Forty seven percent of the babies in the sample bed shared with their parents at least once during the first month. The most common reason given by mothers for sleeping with their infants was the ease and convenience of night-time breastfeeding. Among mothers who ever breastfed, 65% of infants had co-slept. Among those who breastfed for a month or more, 72.3% of infants were bed sharers. For the 19% of families where bed sharing was unrelated to breastfeeding, settling the baby who was either irritable or ill, was the reason for bed sharing. Eleven families described having their baby sleep in their bed during periods of overt illness. Other bed sharing motives included:

- Fear of baby dying
- For enjoyment to increase time spent with baby
- To ease maternal discomfort following birth
- Nowhere else for the baby to sleep
- Parenting ideology: family bed

7.8.3 Child Abuse

7.8.3.1 What tools exist to identify the child at risk of abuse?

The prevention of child abuse depends upon correctly targeting families who are at increased risk of maltreatment. The use of screening tools to identify such families presents a number of ethical and practical concerns. These include the stigmatisation of parents identified as being at risk and the application of accurate screening measures. The causes of child abuse are multifactorial and developing tools with adequate sensitivity (e.g. percentage of

maltreated children correctly identified as being at risk), specificity (e.g. percentage of non-maltreated correctly identified as not being at risk) and positive predictive value (e.g. percentage of the high-risk group who go on to maltreat) is fraught with difficulties. Peters and Barlow (Peters & Barlow 2003) assessed the accuracy of instruments specifically designed for use in the antenatal and postnatal periods. A systematic review resulted in 8 studies which had prospectively evaluated a standardized instrument. One study was exclusively an antenatal intervention and one tool was implemented when a child was admitted to intensive care. Most of the more methodologically rigorous studies yielded sensitivity greater than 50%. However a majority of these studies had a positive predictive value less than 50%, which means that the majority of children categorized as high risk were not actually maltreated. It has been suggested that acceptable criteria for instruments that predict maltreatment are a sensitivity of 40-60%, a specificity of 90% and a positive predictive value of 25%. Only one instrument reached these levels for all three operator characteristics. Despite this level of accuracy 75% of families who have been predicted to be at increased risk will not go on to abuse.

In U.S. law, child abuse and neglect is defined as, "…any recent act or failure to act on the part of a parent or caretaker which results in death, serious physical or emotional harm, sexual abuse or exploitation, or an act or failure to act which presents an imminent risk of serious harm. " A recent systematic review for the US Preventive Services Task Force (Nygren, Nelson, & Klein 2004) evaluated the benefits and harms of screening children in primary health care settings for abuse and neglect. Evidence on screening instruments and the effectiveness of interventions was examined. Six studies on screening methods met the eligibility criteria but none of them addressed the effectiveness of screening in reducing harm and premature death and disability. A meta analysis was not done. Four of the studies were rated as poor, one fair and one good-fair. Three screening instruments had a fairly high sensitivity but low specificity, that is, they did not correctly identify the non-abusers. Screening instruments require high sensitivity and specificity because falsely implicating a parent as a potential abuser may have serious consequences. A Canadian systematic

review update (Macmillan 2000) found that the primary difficulty with approaches to screening for risk of child maltreatment was the unacceptably high false positive rates. They reviewed three studies published between 1993 and 1999. The predictive validity was either not measured or was very poor. They concluded that the harms outweighed the benefits of screening for risk of child maltreatment.

One study (Browne 1989) assessed the predictive value of a checklist of risk factors utilised by home visitors in Surrey. An initial screening checklist of thirteen factors was collected on 62 abuse cases and 124 matched non-abusing families. Risk factors were weighted using discriminant function analysis and it was found that the sensitivity of the checklist was 82% and specificity was 88%. This means that 18% of abusers were missed and 12% of non abusers were falsely identified as high risk. When the checklist was applied prospectively to a sample of over 14,000 births it was found that 6.7% of Surrey families with a newborn were assessed to be high risk. On follow up, only one out of 17 of these 'high risk' families went on to abuse a child within two years of birth. The researchers hypothesized that risk factors may be buffered by secure relationships within a family.

A follow up study on maternal attitudes and mother infant interaction comparing high and low risk families was also conducted by the Surrey group. During home visits the mothers and children were observed and a questionnaire was completed. It was found that abusing parents had more negative conceptions of their children's behaviour than non abusing parents as they perceived their children to be more irritable and demanding.

The Brigid Collins Risk Screener was assessed in a small sample of 49 expectant mothers who were screened on risk factors covering six areas (Weberling et al. 2003). A trained interviewer blind to family risk status completed a three month postpartum measure of parenting stress and the family environment during a one hour home interview and observation. Parental stress scores were not related to the total risk score. The only environmental factor which was significant between high and low risk groups

was the availability of learning materials in the home ($p<.05$). Abuse outcomes were not measured.

NICE guidance entitled 'Identification of children with suspected abuse' has recently been commissioned. Publication date is to be announced.

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