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Maternal and Early Child Health

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Protocol Enhancement Project
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NHS CYMRU WALES

MATERNAL & EARLY CHILD HEALTH

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Other bulletins in the series address the following subjects:

- cancers
- cardiovascular diseases
- healthy environments
- healthy living
- injury prevention
- learning disabilities
- mental health
- oral health
- pain, discomfort and palliative care
- physical disability and discomfort
- respiratory diseases

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MATERNAL & EARLY CHILD HEALTH BULLETIN

Introduction

The original *Protocols for Investment in Health Gain* were written in the early 1990s to suggest areas where the introduction, or more widespread use, of certain practices could lead to worthwhile improvements in health for the people of Wales. The documents also highlighted current practices which were of questionable value. This revision has been prepared by reviewing the earlier *Protocol for Investment in Health Gain: Maternal and Early Child Health*[1] to provide some clear, updated statements with a precise indication of the strength of the evidence and its sources for each statement; and to introduce new statements covering subjects of important current interest.

The *Maternal and Early Child Health* Bulletin covers the health of the mother and her child from pre-conception through the perinatal period (up to one month of age). This is in contrast to the earlier Protocol which dealt with a small number of issues concerning the health of children up to the age of 5 years[2].

The statements represent a systematic summary of the evidence in this area found through a formal literature search across a wide range of sources[3]. The evidence has been critically appraised using internationally accepted methods[4] compiled into this document under the direction of a public health physician, and reviewed by a multidisciplinary team who are directly involved in patient care[5]. In addition to this document, the information will be available electronically, via the NHS Cymruweb. Information on the methodology adopted (including a copy of the documentation), the formats in which the document is issued and details of other publications in the series, is available on request[6].

The convention used in this document to indicate the **type of evidence** is[7]:

'Type I evidence' - at least one good systematic review (including at least one randomised controlled trial).
'Type II evidence' - at least one good randomised controlled trial
'Type III evidence' - well designed interventional studies without randomisation
'Type IV evidence' - well designed observational studies
'Type V evidence' - expert opinion; influential reports and studies

Many health issues do not lend themselves to investigation by randomised controlled trial. By valuing evidence from these trials more highly than observational studies there is a danger that interventions with limited effectiveness might be judged to be more worthy than those based on observation. Similarly, those observational studies which clearly prove effectiveness (and make a randomised trial unethical) might be undervalued. Randomised controlled trials are a valuable form of evidence and, when available, they are included. If not, high quality evidence has been sought within the other categories. Information assigned as type V evidence includes very important reports or recommendations which should rightly be highly regarded.

The health gain notation (used to indicate the potential **benefit** to health) is[8]:

'beneficial' - effectiveness clearly demonstrated (1)
'likely to be beneficial' - effectiveness not so firmly established (2)
'trade-off between beneficial and adverse effects' - effects weighed according to individual circumstances(3)
'unknown'- insufficient/inadequate for recommendation(4)
'unlikely to be beneficial' - ineffectiveness is not as clearly demonstrated as for 6 (5)
'likely to be ineffective or harmful' - ineffectiveness or harm clearly demonstrated (6)

It should be stressed that these gradings, while aiming to be impartial, represent only the best advice of the professionals involved in preparing the Bulletin. Although the statements are deliberately brief, statistically significant quantitative information has been provided where possible. This is usually given as Number Needed to Treat (NNT), Odds Ratio (OR) or % change, in keeping with the original source of the information[9]. Cost-benefit issues are not considered.

In keeping with the original Protocols, these revised documents are designed to assist Health Authorities in developing local strategies and in purchasing high quality health care. It is anticipated, however, that they will be of value to all health professionals in keeping abreast of the huge and increasing body of medical literature and can provide an agenda for future action in a wide variety of

settings. It should be stressed that the publications will act as a supplement to, not a substitute for, clinical skills and experience. We anticipate that some of the conclusions reached will be controversial. Every effort has been made to include the best evidence within a subject area. Readers who are aware of any important studies that have been overlooked are encouraged to contact the project team[10].

The Maternal &Early Child Health *Bulletin*

This document has drawn extensively on the pioneering and comprehensive work of Chalmers, Enkin and Keirse in *Effective Care in Pregnancy and Childbirth*[11]. References are given to this document and also to the associated handbook *A Guide to Effective Care in Pregnancy and Childbirth*[12] which, while lacking source references, is widely read and easily available. Where an updated review is available from the current edition of the *Cochrane Library*[13] this is referenced in preference to the original text

The statements within each subject area concentrate on specific interventions and the current state of knowledge. Expert recommendations for good practice which are common to all the subjects covered include:

- ongoing care and prompt diagnosis and treatment of any obstetric and neonatal problems by a suitably qualified and equipped team;
- considerate, full and informed discussion with parents which should include treatment options, aetiology and future management; Parents should participate fully in decision making.
- the incorporation of feedback from professionals and parents into the audit cycle.
- the development of evidence-based documentation for the management of serious conditions.

Support within the health service should be available to ensure that all pregnant women and their babies have access to appropriate standards of care; Intensive Care (for the mother); Special or Neonatal Intensive Care (for the baby) and transfer, when necessary, by paramedic equipped ambulance with appropriate professional help.

1 Welsh Health Planning Forum. Cardiff: Welsh Office NHS Directorate, August 1991

2 A document which discusses many of the health issues relating to the child from 1 month - 5 years of age has recently been published by the Welsh Office. Health of Children in Wales. Cardiff: Welsh Office, 1997

3 Barker J, Weightman AL and Lancaster J. Project for the Enhancement of the Welsh Protocols for Investment in Health Gain: Project Methodology2. Cardiff: Duthie Library UWCM, 1997

4 See 3.

5 See Appendix II.

6 Contact: Protocol Enhancement Project Office, Duthie Library, UWCM, Heath Park, Cardiff CF4 4XN.

7 This table is adapted from the Bandolier system (derived from the work at McMaster University, Canada) using the NHS Centre for Reviews and Dissemination criteria for a systematic review. See ref.3 or http://www.jr2.ox.ac.uk/Bandolier/band6/b6-5.html and the Database of Abstracts of Reviews of Effectiveness (DARE) in the Cochrane Library.

8 This Notation is modified from the tables used in Enkin M, Keirse MJNC, Renfrew M and Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995 pp. 389-390.

9 Number Needed to Treat (NNT) = The number of patients to be treated to be sure of gaining one positive outcome;

Odds Ratio (OR): If equal to 1, the effects of the treatment are no different from those of the control treatment. If the OR is greater (or less) than 1, then the effects of the treatment are more (or less) than those of the control treatment. Note that the effect being measured may be adverse or desirable.

10 See 6.

11 Chalmers I, Enkin M, Keirse MJNC (eds.) Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989

12 Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995.

13 Available on CD-ROM and floppy disc from Update Software, PO Box 696, Oxford OX2 7YX.
See also http://hiru.mcmaster.ca/cochrane/default/htm

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Internal Review Group, Maternal and Early Child Health Bulletin January 1998

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1 MISCARRIAGE & ECTOPIC PREGNANCY (EARLY HAEMORRHAGE)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
1a. Transvaginal ultrasound examination (of cardiac activity in embryos > 2mm) provides rapid confirmation of whether a fetus is alive or dead and if a pregnancy is likely to continue after threatened miscarriage[i]. (Health gain notation - 2 *"likely to be beneficial"*) It is essential that, in cases of doubt, the examination is repeated within 3-5 days [ii].	**i.** Jauniaux E, Gavriil P, Nicolaides KH. Ultrasonographic assessment of early pregnancy complications. Chapter 5 in Jurkovic D, Jauniaux E (eds.) Ultrasound and early pregnancy. Progress in Obstetric and Gynaecological Sonography Series. London: Parthenon, 1996. p. 58 (Type IV evidence - observational studies); **ii.** Royal College of Obstetricians & Gynaecologists. Royal College of Radiologists. Guidance on ultrasound procedures in early pregnancy, London: Royal College of Obstetricians & Gynaecologists 1995 (Type V evidence - expert opinion)
1b. The **management** of threatened miscarriage must include ultrasound confirmation of ongoing pregnancy [i]. (Health gain notation - 2 *"likely to be beneficial"*) It follows that trials involved with the management of miscarriage should include only those women where ultrasonography has confirmed that her fetus is still alive.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 620 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p.88)
1c. The diagnosis and management of miscarriage and ectopic pregnancy should be improved utilising appropriately staffed day assessment units and by recognition of early signs [i,ii,iii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Royal College of Obstetricians & Gynaecologists. Royal College of Radiologists. Guidance on ultrasound procedures in early pregnancy, London: Royal College of Obstetricians & Gynaecologists 1995 (Type V evidence - expert opinion); **ii.** Department of Health et al. Report on Confidential Enquiries into Maternal Deaths in the United Kingdom 1991-1993. London: HMSO, 1996 p.73 (Type V evidence - expert opinion); **iii.** Mascarenhas, L. Ectopic pregnancy. PACE Review 97/07. London: Royal College of Obstetricians and Gynaecologists, 1997. (Type V evidence - expert opinion)
1d There is no evidence of benefit from **bed rest** for threatened miscarriage [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 624-625 (Type II evidence - single controlled study - now out of date. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp 87-88)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
1e. Hormone administration (Progestogens or human chorionic gonadotrophin, HCG) should be used only within controlled clinical trials until the ratio of benefits to hazards has been more clearly established [i,ii] (Health gain notation - 4 *"unknown"*)	**i.** Prendiville W. Human chorionic gonadotrophin (HCG) for recurrent miscarriage. *Cochrane Database of Systematic Reviews. Cochrane Library*, 1997 Issue 4 (Type I evidence - systematic review); **i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 615-619 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp.86-87)
1f **Diethylstilboestrol** in pregnancy either for miscarriage or any other indication is both ineffective and **contraindicated** because of the risk of cancer and other side effects [i] (Health gain notation - 6 *"likely to be harmful"*)	**i** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 613-615 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995 pp. 85-86)
1g. In the **investigation** of recurrent miscarriage (defined as 3 or more miscarriages), the following should be considered [i]: (Health gain notation - 2 *"likely to be beneficial"*) ■ parental chromosome abnormality (3.5%) ■ thromophilic defect (15%) ■ polycystic ovaries	**i.** Rai R, Regan L. Recurrent miscarriage. PACE review No. 96/08. London: Royal College of Obstetricians and Gynaecologists, 1996 (Type V evidence - expert opinion)
1h **Leucocyte therapy** or **trophoblast membrane infusion** for recurrent miscarriage do not appear to be effective in the prevention of recurrent spontaneous abortion [i,ii]. Odds Ratio = 1.3 [ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Scott JR. Recurrent miscarriage: Immunotherapy. *Cochrane Database of Systematic Reviews. Cochrane Library*, 1997 Issue 4 (Type I evidence - systematic review) **ii.** Fraser EJ, Grimes DA, Schulz KF. Immunization as therapy for recurrent spontaneous abortion: a review and meta-analysis. *Obstetrics and Gynaecology* 1993;**82**:854-9 (Type I evidence - meta-analysis, 302 women in total)
1i. For the small subgroup of women with recurrent miscarriage associated with phospholipid antibodies, prophylactic aspirin and heparin rather than aspirin alone has been shown to be of value (71% vs 42% live births) [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Rai R, Cohen H, Dave M, Regan L. Randomised controlled trial of aspirin and aspirin plus heparin in pregnant women with recurrent miscarriage associated with phospholipid antibodies (or antiphospholipid antibodies). *British Medical Journal.* 1997; **314**:253-257 (Type II evidence - randomised controlled trial of 90 women)

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2 HYPERTENSIVE DISORDERS OF PREGNANCY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

A widely used classification of high blood pressure in pregnancy is that of the American College of Obstetricians and Gynaecologists (ACOG). The ACOG classification distinguishes between hypertension arising during the pregnancy (pregnancy induced hypertension, PIH) and pre-existing hypertension (chronic hypertension). The most important factor in management is the differentiation between hypertension alone and hypertension plus proteinuria[i].

i. Hypertension in pregnancy. ACOG Technical Bulletin No. 219. Washington DC: ACOG, January 1996

The *statements* | The *evidence*

2.1 MANAGEMENT OF HYPERTENSION IN PREGNANCY

2.1a **Antihypertensive medication** for moderate hypertension in pregnancy is effective in that it prevents a further increase in blood pressure but the effect on other important outcomes of pregnancy is unclear [i].
(Health gain notation - 2 *"likely to be beneficial"*)
Methyldopa and **Labetalol** are the drugs most widely used. Neither is free from side effects [ii].

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 513-514, 519-521
(Type I evidence - systematic review of limited evidence. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 93-95)

ii. Teoh TG, Redman CW. Management of pre-existing disorders in pregnancy: Hypertension. *Prescribers' Journal* 1996; **36(1)**:28-36
(Type V evidence - expert opinion)

2.1b **Diuretics** are **unlikely** to be helpful in the prevention or management of pre-eclampsia [i].
(Health gain notation - 5 *"unlikely to be beneficial"*)

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 514-516
(Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 91)

2.1c The use of **bed rest** during pregnancy should be curtailed unless randomised controlled trials suggest any benefits [i].
(Health gain notation - 5 *"unlikely to be beneficial"*)

i. Goldenberg RL, Cliver SP, Bronstein J, Cutter GR, Andrews WW, Mennemeyer ST. Bed rest in pregnancy. *Obstetrics and Gynecology.* 1994; **84**: 131-6
(Type I evidence - systematic review using MEDLINE only)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
2.1d. Hospitalisation has not been shown to be superior to day care or **home** management for **non-proteinuric hypertension** [i]. A **day-care unit** for hypertension in pregnancy significantly reduced the need for, and the length of inpatient admissions (control patients spent a mean of 4 days longer in hospital than day-care patients) and the number of medical interventions, at the cost of an increase in outpatient attendances [ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Crowther CA, Bouwmeester A, M Ashurst H.M Does admission to hospital for bed rest prevent disease progression or improve fetal outcome in pregnancy complicated by non-proteinuric hypertension. *British Journal of Obstetrics and Gynaecology.* 1992; **99(1)**:13-17 (Type II evidence - randomised controlled trial of 218 women between 28 and 38 weeks gestation); **ii.** Tuffnell DJ, Lilford RJ, Buchan PC, Prendiville VM, Tuffnell AJ et al. Randomised controlled trial of day care for hypertension in pregnancy. *Lancet.* 1992; **339:** 224-7 (Type II evidence - randomised controlled trial of 54 women)
2.1e. The measurement of **uric acid level** is likely to be useful for reflecting fetal prognosis [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 394 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 55-56)
2.1f. Although a declining **platelet count** may be an early feature of pre-eclampsia, it has a limited diagnostic value because of the large variability in normal pregnancy. It is best considered as indicative of severe end stage disease [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Hayman RG, Baker PN. The hypertensive disorders of pregnancy. Definitions, classifications and haematological investigations. PACE review 97/05. London: Royal College of Obstetricians and Gynaecologists, 1997. (Type IV evidence - observational studies)
2.2 MANAGEMENT of FULMINATING PRE-ECLAMPSIA and ECLAMPSIA *For the treatment of these conditions, drug therapy (to reduce the maternal risk of encephalopathy and cerebral haemorrhage) is coupled with early delivery. The incidence of eclampsia in the UK is nearly 1 in 2000 maternities [i].*	**i.** Douglas KA, Redman CW. Eclampsia in the United Kingdom. *British Medical Journal.* 1994; **309:**1395-1400
2.2a. The routine use of **magnesium sulphate** rather than diazepam or phenytoin is beneficial for the prevention of seizures of eclampsia [i,ii]. In one trial, women allocated magnesium sulphate had a reduced risk of recurrent convulsions compared to diazepam (52% lower) and phenytoin (67% lower) [iii] . (Health gain notation - 1 *"beneficial"*) **caveat:** The regimen recommended for intravenous administration of magnesium sulphate requires concomitant monitoring and special care, for which specific training is required.	**i.** Duley L, Henderson-Smart, D. Magnesium sulphate versus diazepam for eclampsia, Cochrane Database of Systematic Reviews *Cochrane Library*, 1997; Issue 4; (Type I evidence - systematic review); **ii.** Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists. Management of Eclampsia. RCOG Guideline No. 10, London: RCOG, November 1996 (Type II evidence - randomised controlled trial); **iii.** Eclampsia Trial Collaborative Group. Which anticonvulsant for women with eclampsia? Evidence from the collaborative eclampsia trial. *Lancet* 1995; **345:**1455-1463. (Type II evidence - randomised controlled trial)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
2.2b. The use of **magnesium sulphate** in **fulminating pre-eclampsia** in the absence of eclampsia has been reported in two small trials [i,ii]. (Health gain notation - 4 *"unknown"*) Further studies are awaited to assess the value of magnesium sulphate in prophylaxis.	**i.** Friedman SA, Kee-Hak L, Baker CA, Repke JT. Phenytoin versus magnesium sulfate in pre-eclampsia: A pilot study. *American Journal of Perinatology*. 1993; **10(3)**: 233-238. (Type II evidence - randomised controlled trial of 103 women); **ii.** Appleton MP, Kuehl TJ, Raebel MA *et al*. Magnesium sulfate versus phenytoin for seizure prophylaxis in pregnancy-induced hypertension. *American Journal of Obstetrics and Gynaecology*. 1991; **165(4)**: 907-913. (Type II evidence - randomised controlled trial of 50 women)
2.2c. The prescription of antihypertensive agents constitutes good practice for the treatment of severe pre-eclampsia [i] (Health gain notation - 2 *"likely to be beneficial"*). **caveat: Hydralazine** or **labetalol** are the most commonly used hypotensives. There is insufficient evidence to recommend one in preference to the other [ii].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 519-526 (Type I evidence - systematic review of limited evidence. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 95) **ii.** Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists. *Management of Eclampsia.* RCOG Guideline No. 10, London: RCOG November 1996 (Type V evidence - expert opinion)
2.2d. One small trial suggested that **expectant** rather than aggressive management of patients with severe pre-eclampsia at 28 to 32 weeks gestation, with close monitoring of mother and fetus at a 'perinatal centre', reduced neonatal complications and stay in the neonatal intensive care unit (From 95 eligible patients, admissions to neonatal intensive care were 76% vs 100%. Mean days stay were 20.2 vs 36.6) [i]. Timing of delivery should be judged by the health of the mother **and** the facilities available for the care of the very preterm infant [ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i** Sibai BM, Mercer BM, Eyal Schiff MD, Friedman MD. Aggressive versus expectant management of severe preeclampsia at 28 to 32 weeks' gestation: A randomized controlled trial *American Journal of Obstetrics and Gynecology* 1994; **171(3)**:818-822 (Type II evidence - randomised controlled trial of 95 women); **ii.** Internal Review Group (see inside front cover) (Type V evidence - expert opinion)
2.2e. There is insufficient evidence for the use of **plasma volume expansion** in the management of severe pre-eclampsia where the theoretical need to treat a reduced plasma volume carries a serious risk of volume overload and pulmonary and cerebral oedema in women with a low colloid osmotic pressure [i]. Further controlled trials are needed. (Health gain notation - 4 *"unknown"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. pp. 96 (Type IV evidence - uncontrolled studies.)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
2.3 SCREENING and PROPHYLAXIS against PRE-ECLAMPSIA	
2.3a. Regular monitoring of blood pressure and **testing for proteinuria** during pregnancy is accepted good practice [i] (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 383-385 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 52-54)
2.3b The prophylactic administration of **low dose aspirin** to any category of women at high risk of developing pregnancy induced hypertension (PIH) is ***unlikely*** to be effective [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** ECPPA group. ECPPA randomised trial of low-dose aspirin for the prevention of maternal and fetal complications in high-risk pregnant women. *British Journal of Obstetrics and Gynaecology* 1996; **103**:39-47 (Type II evidence - randomised controlled trial of 1009 women) **ii.** de Swiet, M. The use of low-dose aspirin in pregnancy. PACE assessment review 96/03. London: Royal College of Obstetricians and Gynaecologists, 1996. (Type I evidence - systematic review)
2.3c The screening for pre-eclampsia by **uric acid measurement, oedema, cold pressor test, roll-over test or isometric exercise test** is ***unlikely*** to be beneficial [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 385, 391-394 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 55-56)
2.3d. The effect of a **change in salt intake** in the development of pregnancy-induced hypertension is unknown [i]. (Health gain notation - 4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 294-295 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 92)
2.3e. Preliminary trials suggest that **calcium supplementation** results in a significant reduction in blood pressure in pregnant women (Odds Ratio for preeclampsia = 0.38) [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** Insufficient evidence exists of any reduction in subsequent morbidity and the results of further large trials are awaited.	**i.** Bucher, HC, Guyatt GH, Cook RJ, Cook DJ, Lang JD, Hunt D. Effect of calcium supplementation on pregnancy-induced hypertension and pre-eclampsia - *Journal of the American Medical Association* 1996; **275 (14)**: 1113-7 (Type I evidence - meta analysis of 2459 women. Further large trials are in progress)

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3 MEDICAL DISORDERS IN PREGNANCY

The disorders covered in this chapter reflect the coverage of the original Protocol. Other disorders, including those relating to circulatory and respiratory conditions, will be considered for inclusion in any future updates.

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

3.1 DIABETES: Pre-existing

3.1a. The following management strategies are recognised good practice for women with diabetes [i,ii].
(Health gain notation - 2 "likely to be beneficial")
Prepregnancy **counselling** by those who care for diabetic women;
Coordinated **specialist care** from **very early** pregnancy;
Home instead of hospital glucose monitoring;
Ultrasound surveillance for fetal growth, fetal abnormality and dating;
Allowing **pregnancy to continue to term** in otherwise uncomplicated diabetic pregnancies;
Careful attention to insulin requirements postpartum;
Encouraging diabetic women to **breastfeed.**

Current practice in the UK is well summarised in a report by the Pregnancy and Neonatal Care Group [ii].

i. Chalmers I, Enkin M, Keirse MJNC. Chapter 36 in Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989
(Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 126-134);

ii. Jardine Brown C, Dawson A, Dodds R, *et al*. Report of the Pregnancy and Neonatal Care Group. *Diabetic Medicine.* 1996: **13**: S43-S53
(Type V evidence - expert opinion)

3.1b. **Tight** as opposed to too tight or moderate control of blood sugar levels during pregnancy (aiming for levels between 5.6 and 6.7 mmol/litre) is *likely to be beneficial* [i]
(Health gain notation - 2 *"likely to be beneficial"*)

i. Walkinshaw SA. Very tight versus tight control of diabetes in pregnancy. Cochrane database of systematic reviews. *Cochrane Library* 1997
Issue 4.
(Type II evidence - review of two trials of 197 women in total, with slightly different methodologies [method of randomisation not stated for either trial])

3.1c. **Corticosteroids** to promote fetal maturation before preterm delivery should be used with **great** caution in diabetic women [i]
(Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 759
(Type II evidence - randomised controlled trials with 35 women only. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 177)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
3.1d. Because of the increased risk of maternal and perinatal complications, most pregnant women with diabetes are subjected to serial fetal assessment. No randomised trials have yet been carried out to identify which **regime for fetal assessment** is the most effective [i]. (Health gain notation - 4 *"unknown"*; See also Chapter 15: Suspected fetal compromise in pregnancy and labour)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p.131
3.1e Review suggests that the **following strategies** are unlikely to be beneficial for women with diabetes [i] (Health gain notation - 5 "unlikely to be beneficial"): **Elective delivery** before term in women with otherwise uncomplicated diabetes **Elective caesarean section** for pregnant women with diabetes and otherwise uncomplicated pregnancy; **Discouraging breastfeeding** in women with diabetes; **Prohibition of low dose oral contraceptives** for women with diabetes;	**i.** Chalmers I, Enkin M, Keirse MJNC. Chapter 36 in Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 126-133)
3.1f **Betamimetics** for preterm labour in women with diabetes, especially if combined with corticosteroids, carry a high risk of deregulation of diabetic control and should be avoided [i]. (Health gain notation - 6 "likely to be harmful")	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 711 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 166)

Much has been achieved in improving care for women with diabetes. There remains a need, both for well-designed trials and better survey data, to include **all** pregnant women, not just those attending specialist centres [i].

i. Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p. 133. (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

3.2 GESTATIONAL DIABETES

The term **'gestational diabetes'** previously referred to 'carbohydrate intolerance' diagnosed during pregnancy which subsequently resolved. The term has been updated to include 'disturbance of carbohydrate metabolism of variable severity with onset or first recognition in pregnancy' - thus including insulin- and non-insulin dependent diabetes diagnosed for the first time in pregnancy in addition to impaired carbohydrate tolerance. Uncertainty still surrounds this subject despite enormous scientific and clinical investigation [i,ii,iii].

i. Metzger BE and the organizing committee. Summary and recommendations of the third international workshop-conference on gestational diabetes mellitus. *Diabetes.* 1991; **40(suppl.2)**:197-201 (Type V evidence - expert opinion);
ii. Fraser R. Diabetes in pregnancy. *Archives of disease in childhood*. 1994; **71**:F224-F23 (Type V evidence - expert opinion);
iii. Jardine Brown C, Dawson A, Dodds R, *et al*. Report of the Pregnancy and Neonatal Care Group. *Diabetic Medicine*. 1996: **13**: S43-S53 (Type V evidence - expert opinion)

The *statements*	The *evidence*
3.2a **Routine population screening** for 'gestational diabetes' by: **glucose challenge test** or **measurement of blood glucose** during pregnancy is *unlikely to be beneficial* [i]: (Health gain notation - 5 *"unlikely to be beneficial"*) **caveat:** Timed random laboratory blood glucose measurements in individual cases may be beneficial [ii]. Further research is indicated to determine which women should be tested.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 403-409 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 58-59); **ii.** Jardine Brown C, Dawson A, Dodds R, et al. Report of the Pregnancy and Neonatal Care Group. *Diabetic Medicine.* 1996: **13**: S43-S53 (Type V evidence - expert opinion)
3.2b There appears to be no benefit in the use of **insulin** or **dietary regulation** for women with simple glucose intolerance and such strategies should only be advocated in the context of randomised controlled trials [i]. Treating gestational diabetes by insulin or dietary regulation to reduce blood sugar does reduce fetal weight but there is no evidence regarding the consequences of fetal macrosomia (fractures or persistent neurological damage). (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Walkinshaw SA. Dietary regulation for 'gestational diabetes'. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review)
3.2c. Where gestational diabetes is treated, the results from one trial suggest that **postprandial versus preprandial blood glucose monitoring** is beneficial in terms of glycaemic control and neonatal outcomes (Number Needed to Treat = 3, for birth size within limit for normal gestational age) [i]. (Health gain notation - 2 *"likely to be beneficial"* but see statement 3.2b).	**i.** de Veciana M, Major CA, Morgan MA et al. Postprandial versus preprandial blood glucose monitoring in women with gestational diabetes mellitus requiring insulin therapy. *New England Journal of Medicine.* 1995; **333**:1237-41 (Type II evidence - small randomised controlled trial of 66 women)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

3.3 EPILEPSY

3.3a. Expert reviews suggest the following management strategies for women with epilepsy [i,ii]:
(Health gain notation - 2 "likely to be beneficial")

- **Specialist** pre-conception **advice**;
- The pregnant woman with epilepsy should be treated with the **lowest possible dose of a single antiepileptic** and dosage should be titrated against symptoms;
- Drug **combinations** should be avoided;
- Women should be advised about the possible **teratogenicity** of antiepileptic drugs and the need to continue treatment
  [carbamazepine carries a 5-30% increased risk of facial dysmorphism and mental retardation and a 0.5-1% risk of neural tube defects];
  [sodium valproate carries a 1.5-2.0% risk of neural tube defects];
- **Screening of the fetus** should be offered for women on carbamazepine or sodium valproate because of the increased risk of **neural tube defects;**
- Information about **new anticonvulsants** [gabapentin, lamotrigine, topiramate and vigabatrin] is very limited and, while they are theoretically less teratogenic from animal experiments, the risks and benefits are yet to be established;
- **Folic acid** (5 mg daily) should be started before conception and continued for 12 weeks after.

i. Epilepsy and pregnancy. *Drug and Therapeutics Bulletin* 1994; **32(7)**:49-51
(Type V evidence - expert opinion);

ii. Cleland PG. Management of pre-existing disorders in pregnancy: epilepsy. *Prescriber's Journal*. 1996: **36(2)**: 102-109
(Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements* | The *evidence*

3.4 HAEMOGLOBINOPATHIES

3.4a. All women from populations at particular risk of haemoglobinopathy should be offered **antenatal** (or preferably **preconceptual**) **testing** followed, if positive, by appropriate referral and management [i,ii].
(Health gain notation - 2 *"likely to be beneficial"*)

i. Working Party of the Standing Medical Advisory Committee. Report on Sickle Cell, Thalassaemia and other Haemoglobinopathies. London: HMSO, 1993. p.38
(Type V evidence - expert opinion)

ii. Benbow A, Semple D, Maresh M, Royal College of Obstetricians and Gynaecologists Clinical Audit Unit. Effective procedures in maternity care suitable for audit. London: Royal College of Obstetricians and Gynaecologists, June 1997. pp. 15-16.
(Review of effective procedures, classified according to type of evidence)

3.4b. The basic requirements for women with significant haemaglobinopathies are to have:
a **designated consultant obstetrician**;
an **agreed management policy** concerning pain relief and transfusion;
regular fetal assessment; and
anaesthetic collaboration [i].
(Health gain notation - 2 *"likely to be beneficial"*)

i. Working Party of the Standing Medical Advisory Committee. Report on Sickle Cell, Thalassaemia and other Haemoglobinopathies. London: HMSO, 1993 p.38
(Type V evidence - expert opinion)

3.4c. From a small study, there is a trend for fewer sickling complications in the third trimester and puerperium if women with homozygous sickle cell disease are **exchange transfused** from 28 weeks [i]
(Health gain notation - 2 *"likely to be beneficial"*)

i. Howard RJ, Tuck SM, Pearson TC. Pregnancy in sickle cell disease in the UK: results of a multicentre survey of the effect of prophylactic blood transfusion on maternal and fetal outcome *British Journal of Obstetrics and Gynaecology* 1995; **102**:947-951
(Type IV evidence - well designed non-experimental study)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements* | The *evidence*

3.5 NAUSEA and HYPEREMESIS

3.5a. **Antihistamines** are beneficial for nausea and vomiting of pregnancy if simple measures are ineffective [i]
(Health gain notation - 1 *"beneficial"*)
caveat: These drugs have known side effects and their safety for the fetus has not been extensively studied; In addition, since the tragedy of thalidomide, many women prefer to avoid drugs during pregnancy.

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 503
(Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 75-77)

3.5b. **Acupuncture point stimulation** may be beneficial as an antiemetic and further research is recommended [i]
(Health gain notation - 2 *"likely to be beneficial"*)

i. Vickers AJ. Can acupuncture have specific effects on health?: a systematic review of acupuncture antiemesis trials. *Journal of the Royal Society of Medicine* 1996; **89**: 303-311
(Type I evidence - systematic review)

3.5c **Vitamin B6** acts as an antiemetic[i] but should be avoided since overdosage induces toxic effects [ii].
(Health gain notation - 6 *"likely to be harmful"*)

i. Jewell D, Young G. Treatments for nausea and vomiting in early pregnancy. Cochrane database of systematic reviews. *Cochrane Library* 1997, Issue 4
(Type I evidence - systematic review)

ii. *British National Formulary*, September 1996. p.399
(Type V evidence - expert opinion)

3.5d. The value of **ginger** for nausea and vomiting of pregnancy is unknown [i]
(Health gain notation - 4 *"unknown"*)

i. Jewell D, Young G. Treatments for nausea and vomiting in early pregnancy. Cochrane database of systematic reviews. *Cochrane Library* 1997, Issue 4
(Type I evidence - systematic review)

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4 INFECTIONS IN PREGNANCY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

Infection is no longer a major cause of maternal or perinatal mortality in the United Kingdom, but certain maternal infections may be transmitted to the infant. Transmission may occur in utero, at the time of delivery or, in the case of HIV, during breast feeding and may be the cause of congenital anomaly and/or fetal or perinatal infection [i].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover)

The *statements*	The *evidence*
4.1 ASYMPTOMATIC BACTERIURIA	
4.1a. 3-8% of women have asymptomatic bacteriuria in pregnancy and about one third of these will, if untreated, develop symptomatic infection. **Screening** followed by **antibiotic therapy** is *beneficial* in reducing the development of symptomatic infection and its complications [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 534-538 (Type I evidence - systematic review. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 114-116)
4.1b. There is evidence that single dose therapy may be effective in the management of asymptomatic bacteriuria [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 534-538 (Type I evidence - systematic review. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 115)
4.2. CHICKEN POX	
4.2a. Current expert advice on the management of chicken pox in pregnancy is available [i]. (Health gain notation - 2 " likely to be beneficial") The risk of congenital varicella syndrome secondary to maternal infection in pregnancy (before 20 weeks gestation) is approximately 2%.	**i.** Royal College of Obstetricians and Gynaecologists. Chicken pox in pregnancy. Guideline No. 13. London: Royal College of Obstetricians and Gynaecologists, July 1997 (Type V evidence - expert opinion)
4.3 CHLAMYDIA	
4.3a. **Screening** for, and appropriate **antibiotic treatment** of, chlamydia in pregnancy is *likely to be beneficial,* especially as newer testing methods utilizing urine make testing more acceptible to the pregnant woman [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Brocklehurst P, Rooney G. The treatment of genital chlamydia trachomatis infection in pregnancy.Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4 (Type I evidence - systematic review) **ii.** Templeton A (ed.). The prevention of pelvic infection. Recommendations arising from the 31st Royal College of Obstetricians and Gynaecologists Study Group. London: Royal College of Obstetricians and Gynaecologists, 1996. pp.4-5 (Type V evidence - expert opinion)
4.4 GROUP B STREPTOCOCCI	
4.4a. This organism is a **significant** cause of maternal and perinatal morbidity and even mortality [i].	**i.** Departments of Health. National Advisory Body. Confidential enquiry into stillbirths and deaths in infancy. Annual report for 1 January - 31 December 1993. Part II. London: Department of Health, 1996. p.38. (Type IV evidence - statistical information)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
4.4b. Intrapartum antibiotic treatment of women colonised with Group B streptococci reduced neonatal colonisation (Odds Ratio, OR = 0.10; 95% CI 0.07-0.14) and early onset neonatal infection with Group B streptococci (OR= 0.17; 95% CI 0.07-0.39) but a difference in neonatal mortality was not seen [i]. Antibiotic treatment should be allied to prompt delivery for women with signs of intrauterine infection [ii]. (Health gain notation - 1 *"beneficial"*)	**i.** Smaill F. Intrapartum antibiotics for Group B streptococcal colonisation . Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4 (Type I evidence - systematic review) **ii.** Chalmers I, Enkin M and Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989. p.689 (Type V evidence - expert opinion)
4.4c. Available data show that administration of **antibiotics** in pregnancy is only temporary in eradication of vaginal colonisation with Group B streptococci. Further trials are indicated [i]. (Health gain notation - 4 *"unknown"*)	**i.** Smaill F. Intrapartum antibiotics for Group B streptococcal colonisation . Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review)
4.4d. While there is clear evidence that treatment should be given to colonised women in labour there is insufficient evidence to recommend **population screening** for Group B streptococci in pregnancy [i]. (Health gain notation - 4 *"unknown"*) **caveat:** There is a need for rapid methods of diagnosis and a number of these are currently under development.	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 551-555 (Insufficient evidence from trials to date. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 123-124)
4.5 HEPATITIS B	
4.5a. High risk screening only is still performed in many areas but total population screening for the hepatitis B surface antigen (HBsAg) is likely to be introduced shortly [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) Where screening is carried out: Babies born to mothers who are HBeAg +ve, who are HBsAg +ve without e markers (or where e marker status has not been determined), or who have had acute hepatitis during pregnancy should receive HBIG as well as active immunisations (to prevent development of active infection and possible liver tumours). Hepatitis B vaccine, but not HBIG (Hep B immunoglobulin), is recommended for babies born to mothers who are hepatitis B surface antigen +ve but known to be anti-HBe +ve [i,ii]. (Health gain notation - 2 "likely to be beneficial")	**i.** Jenner, E. Immunisation against infectious disease. London: HMSO, 1996 pp. 95-108 (Type IV evidence - observational studies); **ii.** British Paediatric Association, Nicoll A, Rudd P (eds.). Manual on infections and immunizations in children. Oxford: Oxford University Press, 1989. pp. 194-195 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
4.6 HERPES SIMPLEX	
4.6a. There is some evidence that **Aciclovir** given to the woman with recurrent genital herpes simplex in pregnancy reduces viral shedding at delivery, symptomatic relapses and the use of Caesarean section. Controlled studies are underway[i,ii]. (Health gain notation - 4 *"unknown"*) **caveat:** Experience with the use of aciclovir in pregnancy is limited [ii]	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 549-551 (Type II evidence - one controlled trial. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 122); **ii.** *British National Formulary.* No.33 March 1997. pp. 268-269, 585 (Type V evidence - expert opinion)
4.6b. **Caesarean** section is still currently recommended where there is clinical evidence of active disease [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 549-551(Type IV evidence - observational studies. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 122-123)
4.6c **Caesarean** section ***is unlikely*** *to be beneficial* for non-active herpes simplex before or at the onset of labour [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 549-551(Type IV evidence - observational studies. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 122-123)
4.7. HIV	
4.7a. Both symptomatic and asymptomatic women may transmit HIV. Offering **counselling and screening** to women considered to be at high risk will detect only a proportion of infected women, thus limiting optimum interventions in pregnancy in terms of zidovudine treatment, delivery and infant feeding[i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) Current **recommendations** in the UK are for population screening in areas of high prevalence (e.g. in London 1:580 pregnant women are HIV positive) as compared with areas of low prevalence (1:9600 outside South East England) [ii].	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p. 124; **ii.** Newell ML, Peckham CS. HIV-1 infection in pregnancy. PACE self-assessment test. Review No. 96/05. London: Royal College of Obstetricians and Gynaecologists, 1996 (Figures relate to 1994)
4.7b. The evidence on whether elective delivery by **Caesarean** Section reduces the risk of fetal transmission is inconclusive[i] but one study suggests that this may be reduced (Number Needed to Treat = 12 Caesarean sections to prevent infection in one infant) [ii]. (Health gain notation - 4 "unknown")	**i.** Dunn DT, Newell ML, Mayaux MJ et al. Mode of delivery and vertical transmission of HIV-1 infection: a review of prospective studies. *Journal of Acquired Immune Deficiency Syndromes.* 1994; **7** :1064-1066 (Type I evidence - meta-analysis); **ii.** European Collaborative Study. Caesarean section and the risk of vertical transmission to HIV-1 infection. *Lancet.* 1994; **343**: 1464-1467. (Type IV evidence - Case study of 1253 HIV-infected mothers and their children)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
HIV Continued	
4.7c. **Zidovudine** treatment is likely to be beneficial in decreasing the risk of mother-to-child HIV infection [i] (8.3% infants infected in the zidovudine group and 25.5% infected in the control group for one trial) [ii], even at high viral loads [iii] but further trials are necessary. (Health gain notation - 2 "likely to be beneficial")	**i.** Brocklehurst, P. Zidovudine for the prevention of mother-to-child transmission of HIV infection. Cochrane database of systematic reviews. *Cochrane Library* 1997, Issue 1 (Type I evidence - systematic review); **ii.** Connor EM, Sperling RS, Gelber R, Kiselev P, Scott G et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *New England Journal of Medicine*. 1994; **331**: 1173-80 (Type II evidence - randomised controlled trial of 363 births to women known to have HIV infection); **iii.** Sperling RS, Shapiro DE, Coombs RW et al. Maternal viral load, zidovudine treatment, and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *New England Journal of Medicine.* 1996; **335**: 1621-1629 (Type II evidence - randomised controlled trial of 402 mother-infant pairs)
4.7d Transmission of HIV through **breast milk** is a substantial added risk. It is estimated that breast feeding doubles the risk of infection of the infant and should be avoided [i]. (Health gain notation - 6 "likely to be harmful")	**i.** Newell ML, Peckham CS. HIV-1 infection in pregnancy. PACE self-assessment test. Review No. 96/05. London: Royal College of Obstetricians and Gynaecologists, 1996 (Type IV evidence - observational studies)
4.7e. If the mother has received perinatal AZT treatment, **infants** should receive oral AZT for a total of 4-6 weeks, then commence co-trimoxazole as prophylaxis against pneumocystis pneumonia, until the infant's HIV status has been determined [i]. (Health gain notation - 2 "likely to be beneficial")	**i.** Sharland M, Gibb D, Tudor-Williams G, Walters S, Novelli V. Paediatric HIV infection. *Archives of Disease in Childhood.* 1997; **76(4)**: 293-296 (Type V evidence - expert opinion)
4.8 MYCOPLASMA	
4.8a There is little evidence of association of mycoplasma during pregnancy in women with previous fetal loss and **routine screening** is unlikely to be beneficial [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 546-547 (Type I evidence - systematic review. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 119)
4.9 RUBELLA	
4.9a. Screening for Rubella antibodies in pregnancy followed by **postpartum vaccination** of seronegative women is good practice in reducing congenital anomaly in subsequent pregnancy [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 541-542 (Type IV evidence - observational studies. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 117-119)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
4.10 SYPHILIS	
4.10a The introduction of routine **screening** for, and **treatment** of, syphilis in pregnancy antedated randomised controlled trials. It remains currently good practice [i]. Although the number of cases is very small in the United Kingdom (6 cases in 1996) there is evidence of an increase of syphilis among visitors to Eastern Europe [ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 538-539 (Type IV evidence - observational studies. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 116); **ii.** College of Paediatrics and Child Health. Surveillance Unit 10th Annual Report. London: CPCH, 1996. p.22 (Type IV evidence - statistical information)
4.11 THRUSH	
4.11a **Clotrimazole** is beneficial in the treatment of vaginal candida infection and associated with better compliance and this should be used in preference to nystatin [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Young GL, Jewell MD. Topical treatment for vaginal candidiasis. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 4. (Type I evidence - systematic review)
4.11b **Oral fluconazole** is effective against candida infection but has not been tested in pregnancy and should be used with caution [i]. (Health gain notation - 4 *"unknown"*)	**i.** *British National Formulary*. September 1996 (Type V evidence - expert opinion)
4.11c There is *no evidence of benefit* in screening for, and treatment of, **asymptomatic** candidiasis [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 543 (Type V evidence - expert opinion. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 79)
4.12 TOXOPLASMOSIS	
4.12a There is a relatively low incidence of toxoplasmosis in the United Kingdom (1.8 per 1000 live births) which does **not** justify **universal screening** for toxoplasmosis during pregnancy [i,ii]. (Health gain notation - 3 "trade-off between beneficial and adverse effects")	**i.** Chalmers I, Enkin M, Kierse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 547-548 (Type IV evidence - observational studies. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 119); **ii.** Palmer SR. Screening for toxoplasmosis infection in pregnancy. London: Department of Health, 1989 (Type V evidence - expert opinion)
4.13 TRICHOMONAS	
4.13a **Metronidazole** remains the **drug of choice** for symptomatic trichomonal vaginitis in pregnancy. A single oral dose of Tinidazole is effective (93% of women were free of infection after 4 weeks) but should be avoided in the first trimester [i,ii]. (Health gain notation - 1 "beneficial") **caveat:** warn patients about side effects and attempt to treat partners.	**i.** British National Formulary. September 1996 (Type V evidence - expert opinion); **ii.** Gulmezoglu AM. Trichomoniasis treatment during pregnancy. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type II evidence - single randomised controlled trial)

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5 SUPPORT IN PREGNANCY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

This chapter should be read in conjunction with **Chapter 10: "Where to be born" and Chapter 15 "Maternal support in labour"**

The *statements*	The *evidence*
5a. Continuity of care is *likely to be beneficial.* Women have repeatedly stressed the importance of receiving care from the same caregiver, or from a small group of caregivers, with whom they can become familiar [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Hodnett ED. Continuity of caregivers during pregnancy and childbirth. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 2. (Type I evidence - review of 2 randomised controlled trials)
5b. With appropriate medical back-up, **midwifery led care** for uncomplicated pregnancy is associated with a reduction in a range of adverse psychosocial outcomes in pregnancy, and interventions (regional analgesia, augmentation, operative vaginal delivery and episiotomy) in labour [i,ii]. (Health gain notation - 2 "likely to be beneficial") **caveat:** A non-significant increase in still births and neonatal deaths in 2 trials requires further evaluation. The problem, if there is one, may lie in the management of high-risk pregnancy by midwives even when good referral systems are in place[iii]. The issue of transfer of care is covered in Chapter 10 'Where to be born'.	**i.** Chalmers I, Enkin M, Keirse MJNC, Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989. pp. 169-174, 177-178 (Type I evidence - systematic review. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford:Oxford University Press, 1995. pp 15-16) **ii.** Turnbull D, Holmes A, Shields N, Cheyne H, Twaddle S *et al*. Randomised, controlled trial of efficacy of midwife-managed care. *Lancet* 1996; **348**:213-218. (Type II evidence - randomised controlled trial with 1299 women); **iii.** Hodnett ED. Continuity of caregivers during pregnancy and childbirth. Cochrane database of systematic reviews. *Cochrane Library*. 1997 Issue 2. (Type I evidence - systematic review of two randomised controlled trials)
5c. Two small trials have indicated that it is beneficial for women to **carry their case-notes during pregnancy** since they feel more in control [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p.15 (Type II evidence - Two small randomized controlled trials)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

5d. The provision of **midwife provided social support in pregnancy** (in the form of additional home visits) has been shown, in one study, to result in a 38g higher mean birth weight. The explanation for this finding was unclear - possibly through an indirect effect of other factors such as greater continuity of care or a reduction in smoking by the mothers [i].
(Health gain notation - 4 "unknown")

The *evidence*

i. Oakley A, Hickey D, Rajan L, Rigby AS. Social support in pregnancy: does it have long-term effects? *Journal of Reproductive and Infant Psychology*. 1996; **14**:7-22
(Type II evidence - randomised - non blinded - trial analysed by questionnaire of 509 women)

5e. The traditional schedule of 14 visits before term could be reduced to **six routine visits** for uncomplicated pregnancy, with possibly one to a consultant clinic [i,ii].
(Health gain notation - 2 "likely to be beneficial")
caveat: There are reservations however. In another study, the reduced schedule of antenatal visits did not reduce the clinical effectiveness of care but the women assigned to this group had more psychosocial discomfort and were less satisfied with their care. In addition, many women (26%) refused to take part because they wanted the traditional number of visits [iii].
It is very difficult to separate the effects of type of care-giver and continuity of care. Further trials are needed which do not confound the two, and which evaluate effects on all neonatal outcomes and indicators of long-term maternal well-being [iv].

i. Tucker JS, Hall MH, Howie PW, Reid ME, Barbour RS *et al.* Should obstetricians see women with normal pregnancies? A multicentre randomised controlled trial of routine antenatal care by general practitioners and midwives compared with shared care led by obstetricians. *British Medical Journal.* 1996; **312**:554-559
(Type II evidence - randomised controlled trial of 1765 women)

ii. Concensus statement on midwife led care in Wales. Cardiff: Welsh Office, 1996
(Type V evidence - expert opinion);

iii. Sikorski J, Wilson J, Clement S, Das S, Smeeton N. A randomised controlled trail comparing two schedules of antenatal visits: the antenatal care project. *British Medical Journal.* 1996; **312**:546-553
(Type II evidence - randomised controlled trial of 3252 women);

iv. Internal Review Group (See inside front cover)
(Type V evidence - expert opinion)

Date of completion of this document

23.6.97

6 MULTIPLE PREGNANCY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

With the advent of assisted conception there has been a steep increase in the incidence of multiple pregnancy from 10-15/100,000 maternities prior to 1981 to more than twice that number in 1991. Such pregnancies put added strain both on the family and on maternity and perinatal services. The increased risks associated with multiple pregnancy relate mostly to the greater chance of premature labour and to complications of the delivery [i].

i. Office of Population Censuses and Surveys, Botting B (ed.). The health of our children. Decennial supplement. London: HMSO, 1995. p.71

The *statements*	The *evidence*
6a There is **no sound evidence to support routine hospitalization** for bed rest for women with twin pregnancy [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC, Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 625-631 (Type I evidence - systematic review. Summary in Enkin M, Kierse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford:Oxford University Press, 1995. p.106)
6b. Whether a policy of **routine hospitalization** is justified for selected women such as those with triplet or higher multiple pregnancy, or for those with early cervical dilatation, has not been adequately tested. These women are often self admitted with discomfort and anxiety so controlled trials seem unlikely [i]. (Health gain notation - 4 "unknown")	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 625-631 (Type II evidence - one small trial. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 106)
6c. Neither the routine use of **cervical cerclage** or **oral betamimetics** have been shown to reduce the incidence of premature labour [i]. (Health gain notation - 4 "unknown")	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 633-646, 713-715. (To date there have been an inadequate number of controlled trials on which to base a recommendation for practice. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 107)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
6d. Home monitoring of uterine activity may reduce the incidence of babies born weighing less than1500g but the small trials available have high potential for bias and home uterine activity monitoring should only be adopted within adequately controlled trials [i]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p. 107. (Type V evidence - expert opinion)
6e. There is **little evidence regarding the best mode or type of delivery** for women with multiple pregnancy, other than general advice on optimum management of premature labour (see Chapter 13) [i]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995 p. 108
6f One limited trial found no advantage of **Caesarean Section** for a second twin presenting other than as a vertex [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Crowther CA. Effect of Caesarean delivery of the second twin. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 2. (Type II evidence - randomised controlled trial. NB In Cochrane database but poorly supported by evidence)

Date of completion of this document

23.6.97

7 ISOIMMUNIZATION

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
7a. There is evidence of the value of **routine assessment of Rhesus D status** and subsequent screening for antibodies [i]. (Health gain notation - 1 *"beneficial"*)	**i.** British Committee for Standards in Haematology. Guidelines for blood grouping and red cell antibody testing during pregnancy. *Transfusion medicine*. 1996; **6**: 71-74 (Type V evidence - expert opinion)
7b. Other antibodies such as **c** (incidence 1.3/1000 pregnant women) and **Kell** can on occasion cause severe haemolytic disease of the newborn (in both Rhesus D positive and negative women) and should be **screened** for in all pregnancies [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** British Committee for Standards in Haematology. Guidelines for blood grouping and red cell antibody testing during pregnancy. *Transfusion medicine*. 1996; **6**: 71-74 (Type V evidence - expert opinion)
7c. There is strong evidence of the effectiveness of anti-D immunoglobulin in the prevention of rhesus isoimmunization in Rhesus D negative women. (Health gain notation - 1 *"beneficial"*) The details of who, when and how to treat are less clear [i,ii].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 565-573 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 109); **ii.** Whittle MJ. Antenatal serology testing. PACE review No. 97/02. London: Royal College of Obstetricians and Gynaecologists, 1997 (Type IV evidence - observational studies)
7d. The most common time for fetal maternal transfusion is at delivery, following the birth of a Rhesus positive baby and routine **postpartum administration of anti-D immunoglobulin** (500 iu -100µg - given either immediately or within 72 hours) is effective in protecting against maternal sensitization in the majority of cases. Higher doses are required in women with evidence of larger fetomaternal bleeds [i,ii,iii]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 566-569 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 110-111); **ii.** *British National Formulary* March 1997. p.521 (Type V evidence - expert opinion); **iii.** Letsky EA, de Silva M. Preventing rhesus immunization, Editorial *British Medical Journal* 1994; **309**: 213-214 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
7e. Anti-D should always be given to Rhesus negative women at evacuation after miscarriage, at therapeutic abortion or if there is an ectopic pregnancy [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 569-571, 605 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 111)
7f. Placental trauma, procedures such as amniocentesis or the delivery of a pale distressed baby should alert carers to an increased risk of fetomaternal bleeding [i].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 571 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 111)
7g. If monoclonal techniques make anti-D immunoglobulin more freely available then **routine administration of anti-D immunoglobulin at 28 weeks** should prove of value. However it has been suggested that more careful application of current recommendations should be evaluated before considering routine antenatal prophylaxis or the European recommendation of a larger dose [i,ii,iii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Crowther CA, Keirse MJNC. Anti-D administration in pregnancy. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 2 (Type I evidence - systematic review with one randomised controlled trial only); **ii.** Letsky EA, de Silva M. Preventing rhesus immunization, Editorial *British Medical Journal* 1994; **309**: 213-214 (Type V evidence - expert opinion); **iii.** Howard HL, Martlew VJ, McFadyen IR, Clarke CA. Preventing Rhesus D haemolytic disease of the newborn by giving anti-D immunoglobulin - are the guidelines being adequately followed? *British Journal of Obstetrics and Gynaecology*. 1997; **104**: 37-41 (Type IV evidence - case note study of 922 women)
7h. The **management** of women who are shown to be sensitized with Rhesus or other antibodies known to cause haemolytic disease of the newborn requires expert care in terms of assessing severity, optimum timing of delivery and/or antenatal transfusion and postnatal transfusion, possibly best coordinated in regional centres [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Whittle MJ. Antenatal serology testing. PACE review No. 97/02. London: Royal College of Obstetricians and Gynaecologists, 1997 (Type IV evidence - observational studies)
7i. Other treatments such as **plasmapheresis** and attempts at **desensitization** have not been evaluated by controlled trials [i]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p. 112

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23.6.97

8 THROMBOEMBOLISM IN PREGNANCY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
8a. Pregnant women and, in particular, those with a history of thromboembolic disease are at **appreciable risk** during pregnancy. The reported incidence of deep vein thrombosis (DVT) and non-fatal pulmonary embolism varies considerably because of the peculiar diagnostic difficulties in pregnancy. Real time ultrasound scanning combined with Doppler studies, being noninvasive, are the first line diagnostic techniques for DVT in pregnancy [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Report of the RCOG Working Party. Prophylaxis and management against thromboembolism in gynaecology and obstetrics. London: Royal College of Obstetricians and Gynaecologists, 1995. p.15 (Type V evidence - expert opinion)
8b. In the absence of randomised controlled trials of sufficient size in the obstetric literature, current **recommendations** for management are derived from nonpregnant population trials and observational studies in pregnancy [i,ii]. Well designed trials are needed in this area.	**i.** Barbour LA, Pickard J. Controversies in thromboembolic disease during pregnancy: a critical review *Obstetrics and Gynecology* 1995; **86**:621-33 (Type V evidence - expert opinion); **ii.** Report of the RCOG Working Party. Prophylaxis and management against thromboembolism in gynaecology and obstetrics. London: Royal College of Obstetricians and Gynaecologists, 1995 (Type V evidence - expert opinion)
8c. The **majority of deaths** from pulmonary embolism following Caesarean Section occur after the **first week** of the puerperium, after discharge from hospital. **All** those involved with the care of women in the puerperium must be alert to this possibility [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Department of Health and Others. Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. 1991-1993. London: HMSO, 1996. p.52 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
8d. In the UK, **Heparin** and **Warfarin** are the two anticoagulants relevant to clinical practice in pregnancy. They each require special consideration regarding safety in pregnancy [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Clagett CJ, Reisch CJ. Prevention of venous thromboembolism in general surgical patients. Results of a metanalysis. *Annals of Surgery*. 1988; **208(2)**: 227-40 (Type I evidence - meta analysis)
8e. Detailed **recommendations** for prophylaxis and management have been published by the Royal College of Obstetricians and Gynaecologists, based on best available evidence and assessment of risk factors including evidence from general surgery. These are summarised below [i]. (Health gain notation - 1 *"beneficial"*) **Prophylaxis against thromboembolic disease following Caesarean section:** ■ a risk assessment should be performed ■ in uncomplicated pregnancy only early mobilisation and attention to hydration are required. ■ patients at moderate risk should receive subcutaneous heparin or mechanical methods. ■ patients at high risk should receive heparin prophylaxis and, in addition, leg stockings would be beneficial. ■ prophylaxis should be continued for 5 days. ■ the use of subcutaneous heparin in patients with an epidural or spinal block remains contentious. Current evidence from general surgery does not point to an increased risk of spinal haematoma. **Prophylaxis against thromboembolism in pregnancy:** ■ patients with a past history of thromboembolism in pregnancy/puerperium (and no other risk factor) should receive thromboprophylaxis for 6 weeks postpartum. ■ patients at high risk (multiple previous thromboembolism) may require anticoagulation in pregnancy. **Diagnosis and management:** ■ the importance of accurate diagnosis is stressed. Inappropriate full anticoagulation carries risk to mother and fetus and has long term implications for contraceptive methods and management of subsequent pregnancy. ■ the duration of anticoagulation in patients with proven deep vein thrombosis should be for local policy agreements but is likely to be for a minimum of three months.	**i.** Report of the RCOG Working Party on prophylaxis (and management) against Thromboembolism in Gynaecology and Obstetrics. London: Royal College of Obstetricians and Gynaecologists, 1995 (Type V evidence - expert opinion)

Date of completion of this document

23.6.97

9 HAEMORRHAGE IN LATE PREGNANCY (AND LABOUR)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
9a. Placental abruption and placenta praevia are important causes of maternal and perinatal mortality and morbidity and must be managed by **experienced staff in well equipped obstetric units** [i,ii]. (Health gain notation - 1 *"beneficial"*)	**i.** Department of Health and Others. Report on Confidential Enquiries into Maternal Deaths in the United Kingdom 1991-1993. London: HMSO,1996. pp.42-43 (Type V evidence - expert opinion); **ii.** Department of Health. Confidential Enquiry into Stillbirths and Deaths in Infancy. Annual Report for 1 January - 31 December 1993. Part 1. London: HMSO,1996 p.36 (Type V evidence - expert opinion)
9b. Early ultrasound scan showing a low lying placenta (placenta praevia) **should be repeated** at 32 weeks when 90% will be found to be normally situated [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 603 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 137)
9c. When placenta praevia is suspected on clinical grounds, **diagnosis should be confirmed** by **ultrasound** and **elective Caesarean section** planned. Expectant management to 37 weeks is generally accepted but has not been subjected to controlled trial [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 605-607 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 138-139)
9d **Pelvic examination** should be **avoided** other than in an operating theatre [i] (Health gain notation - 6 *"likely to be harmful"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 604 (Type IV evidence - observational studies Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 138-139)
9e. A **high index of suspicion** should exist in regard to placental abruption allowing early diagnosis and optimum management [i]. (Health gain notation - 1*"beneficial"*)	**i.** Department of Health. Confidential Enquiry into Stillbirths and Deaths in Infancy. Annual Report for 1 January - 31 December 1993. Part 1. London: HMSO,1996 p.39 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
9f. When placental abruption is diagnosed, **meticulous blood accountancy and replacement,** with early tests for **blood clotting** are essential [i,ii]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 598-599 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 136); **ii.** Department of Health and Others. Confidential Enquiries into Maternal Deaths 1988-1990. London: HMSO, 1994. pp. 43-44 (Type V evidence - expert opinion)
9g. In a case of placental abruption with a **live fetus** and no evidence of fetal distress, **vaginal delivery** may be the management of choice providing facilities exist for efficient monitoring and immediate Caesarean section, if required [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 599-600 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 136)
9h. Vaginal delivery is the treatment of choice in the presence of a **dead fetus** [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 600 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 136)
9i. With every episode of bleeding , a Rhesus negative woman should have a **Kleihauer test** and be given prophylactic anti-D immunoglobulin [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 605 (Type II evidence - one small trial. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 138); **ii.** Whittle MJ Antenatal serology testing. PACE review No. 97/02. London: Royal College of Obstetricians and Gynaecologists, 1997 (Type IV evidence - observational studies)
9j. In the management of massive haemorrhage in **women who do not wish to receive a blood transfusion** expert advice is available [i].	**i.** Department of Health and Others. Confidential Enquiries into Maternal Deaths 1988-1990. London: HMSO, 1994. p. 44 (Type V evidence - expert opinion)

Date of completion of this document

9.1.98

10 WHERE TO BE BORN

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

This chapter should be read in conjunction with **Chapter 15 *"Maternal support in labour"***

The continuing debate on 'Where to be born', is reviewed by Campbell and Macfarlane [i]. Reports prior to the 1920s are limited but the change to almost universal institutional delivery was based on a concept of greater safety of hospital confinement. Recent reports on the benefit/risk of different settings share the common problem of choosing outcomes to measure. Mortality is now fortunately small while morbidity and maternal satisfaction are more difficult to define and measure [i]. As far back as 1986, Eva Alberman concluded that *'all available evidence suggests that in **carefully selected and well-supervised** low-risk deliveries the extra risk to the mother and baby attributable only to the absence of hospital facilities must be low, and the **satisfaction** of a successful delivery high. Against this must be set the chance of needing an **emergency transfer"*** [ii]. Any bias in analysis of outcome by place of birth can be avoided in selection, by place of booking not place of delivery, and by inclusion of all women, both high and low risk. Rates of transfer are important and the poorer outcomes noted among women transferred from home or general practitioner units compared with women not transferred may result from selective transfer of women with problems [i,ii].

i. Campbell R, Macfarlane A,. 'Where to be born? The debate and the evidence.' 2nd ed. Oxford: National Perinatal Epidemiology Unit, 1994.

ii. Alberman E., (Epidemiological advisor to the House of Commons Select Committee) in 'Place of Birth', *British Journal of Obstetrics and Gynaecology* 1986; **93**: 657-658.

The *statements*	The *evidence*
10a. The Scottish study on perinatal **mortality** shows the strength of **using population based data** and birthweights and cause of death [i].	**i.** Cole S Macfarlane A. Safety and place of birth in Scotland. Journal of Public Health Medicine 1995; **17**:17-24.
10b. Confidential enquiry reports and additional analyses reported by Settatree show that, for 1993, births which were planned to take place at home and actually did so experienced a higher rate of intrapartum mortality (9 deaths and 7826 survivors) than all other births (379 deaths and 668578 survivors). This is equivalent to about one extra death per thousand births [i,ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Confidential Enquiry into Stillbirths and Deaths in Infancy 1993 Part II.London: Department of Health, 1995 (Type IV evidence - well designed non-experimental studies); **ii.** Settatree, RJ. Mortality is still important, and hospital is safer. *British Medical Journal* 1996; **312**:756-7 (Type IV evidence - observational studies)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
10c. Campbell and Macfarlane conclude that, since women prefer to have a choice, it is probably **too late to utilise randomised controlled trials** in areas such as home confinement and that while descriptive research, case-control or non-randomised cohort studies are possible there is inherent difficulty in avoiding bias [i,ii,iii]. Recommendations from the National Birthday Trust regarding home confinement may be of value to purchasers [iii]. A further study is currently underway [iv]. (Health gain notation - 4 *"unknown"*)	**i.** Campbell R, Macfarlane A. Where to be born? The debate and the evidence. 2nd ed. Oxford: National Perinatal Epidemiology Unit, 1994. (Type I evidence - systematic review, mostly observational studies); **ii.** MacVicar J, Dobbie G, Owen-Johnstone L, Jagger C, Hopkins M, Kennedy J. Simulated home delivery in hospital: a randomised controlled trial. *British Journal of Obstetrics and Gynaecology* 1993; **100**: 316-323 (Type II evidence - randomised controlled trial); **iii.** Chamberlain G, Wraight A, Crowley P (eds.) Home Births. The report of the 1994 confidential enquiry by the National Birthday Trust Fund. New York: Parthenon, 1997. (Type IV evidence - case matched study of midwife-led care); **iv.** Davies J, Hey E, Reid W, Young G. Home Birth Study Steering Group. Prospective regional study of planned home births. *British Medical Journal*. 1996; **313**: 1302-1306. (Type IV evidence - prospective study)
10d. Trials of the efficacy of midwife led care report **transfer rates** of between 32% and 54%. There is **no dispute** on the importance of agreed standards for selection and transfer whether from home, community hospital or midwife led care [i].	**i.** Consensus statement on midwife-led care in Wales. Cardiff: Welsh Medical and Nursing Committees. Welsh Office, 1996 (Type V evidence - expert opinion)
10e. Choice for a woman regarding place of birth is inevitably **interrelated with choice of carer and continuity of care** [i].	**i.** See Chapter 15 'Maternal support in labour';
10f. Continuity of caregivers has been shown to result in fewer antenatal admissions. Women receiving continuity of care are more likely to be satisfied with that care. It is unclear whether these benefits are due to greater continuity or more midwifery involvement [i,ii,iii]. (Health gain notation - 2 *"likely to be beneficial"*) The effects of continuity of care in labour are covered in Chapter 15.	**i.** Hodnett ED. Continuity of caregivers during pregnancy and childbirth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review of two trials); **ii.** Hundley V A, Cruickshank FM, Lang GD *et al*. Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *British Medical Journal.* 1994; 309: 1400-1404 (Type II evidence - randomised controlled trial of 2844 women); **iii.** Rowley M, Hensley MJ et al. Continuity of care by midwife team versus routine care during pregnancy and birth: a randomised trial. *Medical Journal of Australia.* 1995; 163: 289-293 (Type II evidence - randomised controlled trial)

Date of completion of this document

3.10.97

11 CONTROL OF PAIN IN LABOUR

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

There is evidence that support from caregivers reduces the need for analgesia in labouring women but does not reduce the importance of informed choice and availability [i].

i. Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995 p.247 (Type I evidence - systematic review. See pp. 806-807 in Chalmers *et al*. Effective care in pregnancy and childbirth. Oxford:Oxford University Press, 1989)

The *statements*	The *evidence*
11a. Maternal movement and **choice of position** may be beneficial in reducing pain in labour [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 896 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 248-249); **ii.** MIDIRS and the NHS Centre for Reviews and Dissemination. Positions in labour and delivery. Informed Choice for Professionals Leaflet No.5. MIDIRS, 2nd ed. July 1996 (Type I evidence - systematic review)
11b. Epidural analgesia is the most effective pain relief in labour. Some studies have described an associated increase in assisted delivery, both forceps and Caesarean section [i,ii,iii,iv]. An association between epidural anaesthesia and long term backache has not been substantiated [v,vi]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects*)	**i.** Thorp JA, Hu DH, Albin RM et al. The effect of intrapartum epidural analgesia on nulliparous labor: A randomized, controlled, prospective trial. *American Journal of Obstetrics and Gynaecology.* 1993; **169(4)**: 851-858 (Type II evidence - randomised controlled trial); **ii.** Dewan DM, Cohen SE. Epidural analgesia and the incidence of Caesarean section. Time for a closer look. *Anesthesiology.* 1994; **80(6)**: 1189-1192 (Type V evidence - expert opinion); **iii.** Morton SC, Williams MS, Keeler EB, Gambone JC, Kahn KL. Effect of epidural analgesia for labour on the Caesarean delivery rate. *Obstetrics and Gynecology.* 1994; **83(6)**: 1045-1052 (Type I evidence - meta analysis); **iv.** Miller AC. The effects of epidural analgesia on uterine activity and labor. *International Journal of Obstetric Anaesthesia.* 1997; **6**: 2-18 (Type V evidence - expert opinion); **v.** MacArthur A, Macarthur C, Weeks S. Epidural anaesthesia and low back pain after delivery: a prospective cohort study. *British Medical Journal*. 1995: **311**: 1336-1339 (Type IV evidence - prospective cohort study); **vi.** Russell R, Dundas R, Reynolds F. Long term backache after childbirth: prospective search for causative factors. *British Medical Journal.* 1996; **312**: 1384-1388 (Type IV evidence - prospective cohort study)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
11c. There is no firm evidence yet to guide the choice of method of epidural analgesia by **continuous infusion** or **intermittent top-ups** on maternal request [i]. (Health gain notation -4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 929-930 (Type II evidence - single randomised controlled trial. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 258)
11d. Combined spinal epidural analgesia has the advantage over standard epidural analgesia of faster onset and less motor block, with retention of the ability to walk [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Collis RE, Davies DWL, Aveling W. Randomised comparison of combined spinal-epidural and standard epidural analgesia in labour. *The Lancet*. 1995: **345**; 1413-1416 (Type II evidence - randomised controlled trial of 197 women; outcomes assessed by questionnaire)
11e. Epidural/spinal opiates have the advantage over conventional epidural techniques of reducing motor block, prolonging analgesia and reducing shivering but with the problems of respiratory depression and pruritis in the mother [i]. (Cochrame health gain notation - 2 *"likely to be beneficial"*)	**i.** Expert Anaesthetic Advice to the Internal Review Group (see inside front cover) (Type V evidence - expert opinion)
11f. Epidural instead of **narcotic** analgesia is *likely to be beneficial* for **preterm** labour and birth although there have been no controlled studies to substantiate this view [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1283 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 281)
11g. There is a *trade-off between beneficial and adverse effects* in the use of **inhalation analgesia** to relieve pain in labour [i]. (Health gain notation -3 *"trade-off between beneficial and adverse effects"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 920-923, 944-945 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 257)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
11h. **Intramuscular pethidine** (and, to a lesser extent, morphine) is widely used for the relief of pain in labour. Use is associated with an increased risk of respiratory depression in the infant (reversible by the antidote Naloxone) [i,ii]. One very small trial has suggested that labour pain is not significantly reduced by intravenously administered morphine or pethidine but that these cause decreased anxiety and increased exhilaration [iii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Chalmers I, Enkin M, Keirse MJN (eds.) Effective care in pregnancy and childbirth. Oxford:Oxford University Press, 1989. pp. 917-919. (Type I evidence - systematic review); **ii.** *British National Formulary* March 1997 p.200. (Type V evidence - expert opinion); **iii.** Olofsson Ch, Ekblom A, Ekman-Ordeberg G, Hjelm A, Irestedt L. Lack of analgesic effect of systemically administered morphine or pethidine on labour pain. *British Journal of Obstetrics and Gynaecology* 1996; **103**: 968-972. (Type IV evidence - observational study)
11i. The value of the following treatments to relieve pain in labour are, as yet, *unknown* [i]. (Health gain notation -4): **Abdominal decompression;** **Immersion** in water; (Further studies in relation to the use of water baths are in progress) **Acupuncture; Hypnosis;** **Music** and **audioanalgesia;** **Intradermal injection of sterile water;** **Aromatherapy; Acupressure;** **Counterpressure;** **Superficial heat or cold;** **Touch** and **massage;** **Attention focusing** and **distraction;**	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 Chapters 56/57. (Not enough evidence on which to base a clinical judgement. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 247-255)
11j. **Paracervical block** provides adequate analgesia but is little used because of reports of fetal brachycardia [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 939-944 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 259)
11k **Sedatives** and **tranquillizers** are ***unlikely*** to be beneficial for pain relief in labour [i]. (Health gain notation -5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 923-924 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 256)
11l. **Transcutaneous electrical nerve stimulation (TENS)**, while possibly ineffective in providing pain relief during labour (Number Needed toTreat = 14) [i], has no known complications. (Health gain notation - 4 *"unknown"*)	**i.** Carroll D, Tramer M, McQuay H, Nye B, Moore A. Transcutaneous electrical nerve stimulation in labour pain: a systematic review. *British Journal of Obstetrics and Gynaecology*. 1997; **104**: 169-175 (Type I evidence - systematic review)

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9.1.98

12 INTERVENTIONS

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents. Both discussion and procedure should be carried out by staff with appropriate expertise [i].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover)

The *statements*

The *evidence*

12.1 INDUCTION of LABOUR

12.1a. There is **little controlled research on the indications** for elective delivery (by induction or Caesarean Section) which range from the lifesaving to the trivial. The most important decision is whether induction is justified rather than how it may be achieved. The place of elective delivery in association with severe haemorrhage, severe pre-eclampsia, diabetes or preterm prelabour rupture of membranes are discussed in the appropriate section [i].

(Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)

i. Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. pp 297

(Type V evidence - expert opinion)

12.1b. Following **intrauterine fetal death** many women prefer induction and early delivery. Others may prefer to wait for the spontaneous onset of labour and there is little disadvantage other than a small risk of disturbance of blood coagulation (if labour is delayed for 4 weeks or more) and the risk of fetal maceration affecting postmortem findings [i].

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1119-1120

(Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 184-187)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
12.1c. Perinatal mortality is increased in **post-term pregnancy** and reduced by induction at or after 41 weeks (at 42 weeks: Number Needed to Treat = 500 inductions to prevent one death). There is, however, no clear evidence on optimum management. There is a need for a well planned randomised controlled trial dealing with management at either 41 or 42 weeks (following accurate ultrasonic dating of pregnancy, which reduces the chance of unnecessary intervention) [i,ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Managing post-term pregnancy. *Drug and Therapeutics Bulletin* 1997; **35(3)**: 17-18 (Type I evidence - systematic review); **ii.** Grant JM. Induction of labour confers benefit in prolonged pregnancy *British Journal of Obstetrics and Gynaecology*. 1994; **101**: 99-102 (Type I evidence - systematic review)
12.1d. There is no increase of either **epidural usage** or **Caesarean section** following induction for postmaturity [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 781-790 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 180-181)
12.1e. The principle determinant of the progress of labour following induction is the **state of the cervix** at the time that induction is attempted [i]. (Health gain notation - 1*"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 988-1056 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 297-298)
12.1f. **Preliminary ripening** of an unfavourable cervix with **prostaglandin** (Dinoprostone) is effective with vaginal PGE2 gel being the method of choice [i,ii]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1043-1053 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 298-302); **ii.** *British National Formulary* March 1997. p.333 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
12.1g. **Oxytocin combined with amniotomy** remains widely used for induction but is associated with more painful contractions, a risk of intrauterine infection and fetal heart irregularities, although severe complications are rare [i,ii]. (Health gain notation - 4 *"unknown"*) **caveat:** If oxytocin is used (having excluded other causes for delay in labour) the dose should be the smallest possible, controlled in the most effective manner.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1058-1063 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 305-306); **ii.** Reichler A, Romem Y, Divon MY. Induction of labour. *Current Opinion in Obstetrics and Gynecology.* 1995; **7**:432-436 (Type I evidence - review of the literature including a meta-analysis)
12.1h. **Prostaglandin** has been shown to be more effective than oxytocin in the induction of labour with the option of retaining intact membranes [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** Side effects include gastrointestinal problems and pyrexia.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1080-1111 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 308-312)
12.1i. Where oxytocin is used, **automated versus standard** methods have been subjected to only limited review [i]. (Health gain notation - 4 *"unknown"*) Methods and risks of automated systems should be more thoroughly evaluated	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1063-1066 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 307)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.2 AUGMENTATION of LABOUR

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents. Both discussion and procedure should be carried out by staff with appropriate expertise [i]. The precise time of the onset of labour (defined as the start of the latent phase) is often difficult to determine as is the differentiation between a prolonged latent phase and a 'false labour' These problems make any decision to augment labour more difficult [ii].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);
ii. Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. pp. 262-263 (Type V evidence - expert opinion)

The *statements*	The *evidence*
12.2a. Augmentation of the first stage of labour, including amniotomy, is likely to be required less often if women are allowed to move about as they please, have continuity of care and friendly support [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 952 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 262)
12.2b. A policy of **early amniotomy** in normal spontaneous labour reduces the length of labour (by an average of 1-2 hours) and is associated with less use of oxytocin but has no effect on the use of analgesia, forceps or Caesarean section [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** One more recent trial has suggested a minimal increase in the Caesarean section rate [iii].	**i.** Brisson-Carroll G, Fraser W, Breart G, Krauss I, Thornton J. The effect of routine early amniotomy on spontaneous labour: a meta-analysis. *Obstetrics and Gynecology.* 1996; **87**:891-896 (Type I evidence - meta-analysis); **ii.** Fraser WD, Krauss I, Brisson-Carrol G, Thornton J, Breart G. Amniotomy to shorten spontaneous labour. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review); **iii.** Johnson N, Lilford R, Guthrie K et al. Randomised trial comparing a policy of early with selective amniotomy in uncomplicated labour at term. *British Journal of Obstetrics and Gynaecology.* 1997; **104**: 340-346 (Type II evidence - randomised controlled trial with some flaws of 1132 women)
12.2c. There is no direct evidence that **amniotomy to augment slow or prolonged labour** is beneficial although given the evidence from controlled trials in normal labour, and from data on induction, it is highly likely that amniotomy would enhance the progress of prolonged labour [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 955-956 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 265)
12.2d. While there is no evidence that early amniotomy affects the **mothers' view of management** a review showed a reduction in the percentage of women reporting severe pain in labour [i]. (Health gain notation - 2 "likely to be beneficial")	**i.** Fraser WD, Krauss I, Brisson-Carrol G, Thornton J, Breart G. Amniotomy to shorten spontaneous labour. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
12.2e. **Active management of labour** by the liberal use of both amniotomy and oxytocin may be instrumental in reducing Caesarean section rates [i,ii]. (Health gain notation - 4 *"unknown"*) **caveat:** The management was based on largely uncontrolled studies and the intervention in otherwise normal labours is unacceptable to many professionals and pregnant women	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 958 (Type I evidence - systematic review of 4 small trials. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 266-267); **ii.** O'Driscoll K, Strong J, Minogue M. Active management of labour. *British Medical Journal* 1973; **3**: 135-137 (Type IV evidence - prospective study of 1000 consecutive primigravidae)
12.2f. Despite little evidence of benefit **intravenous oxytocin** is widely used to expedite labour. Expert opinion would recommend its use in selected cases of inadequate uterine action [i]. (Health gain notation - 4 *"unknown"*) **caveat:** If oxytocin is used (having excluded other causes for delay in labour) the dose should be the smallest possible, controlled in the most effective manner	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 956-960 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 265-266)
12.2g. Management following spontaneous rupture of membranes is discussed in Chapter 13: 'Premature labour'.	

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.3 FORCEPS/VENTOUSE DELIVERY

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents. Both discussion and procedure should be carried out by staff with appropriate expertise.

Curtailing the length of the 2nd stage of labour should be based on evidence of fetal or maternal distress or lack of progress of labour. With epidural analgesia, where a prolonged 2nd stage is a recognised association, there is a dearth of trials of expectant as against assisted vaginal delivery [i].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover)

The *statements*	The *evidence*
12.3a. In most circumstances when operative vaginal delivery is required it is preferable to use **vacuum extraction** rather than forceps [i]. (Health gain notation - 1 *"beneficial"*) While the two procedures are largely interchangeable and both have known complications [ii], the use of forceps is associated with more maternal injury and requires more extensive analgesia.	**i.** Johanson RB, Menon VJ. Vacuum extraction vs forceps delivery. Cochrane Database of Systematic Reviews. *Cochrane Library.* 1997 Issue 4. (Type I evidence - systematic review) **ii.** Drife JO. Choice and instrumental delivery. *British Journal of Obstetrics and Gynaecology*. 1996; **103**: 608-611 (Type V evidence - expert commentary)
12.3b. There is no convincing evidence that **elective forceps** for preterm delivery confers any benefit [i]. (Health gain notation - 4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1283-1284 (Type III-IV evidence - non-randomised trials and observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 281)
12.3c. Direct comparison suggests that soft (Silastic) cups compared with traditional metal cups are less likely to achieve vaginal delivery although with less neonatal trauma [i,ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1221-1226 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 316); **ii.** Kuit JA, Eppinga HG, Wallenburg HCS, Huikeshoven JM. A randomized comparison of vacuum extraction delivery with a rigid and a pliable cup. *Obstetrics and Gynecology*. 1993; **82(2)**: 280-284 (Type II evidence - randomised controlled trial of 100 women)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.4 MANAGEMENT of BREECH PRESENTATION

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents [i]. The prevalence of breech presentation decreases as pregnancy progresses from about 15% at 29 weeks to 3-4% at term. The risk associated with breech presentation are primarily those of the hazards of the breech delivery (if congenital anomaly and postural deformities are excluded) [ii]. i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);
ii. MIDIRS. Breech presentation - options for care. Informed choice for professionals. Leaflet No.9. MIDIRS, January 1997 (Type I evidence - systematic review)

The *statements*	The *evidence*
12.4a. The value of **Caesarean section for breech delivery** depends primarily on gestation. The place of elective Caesarean section for breech presentation at term is unclear although 85% or more of breech presentations are now delivered by Caesarean section. Key factors are the experience of the attendant, absence of disproportion and maternal choice [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) Expert recommendation is for Caesarean section where there is any risk of disproportion. The place of x-ray pelvimetry is not established [ii].	**i.** Hofmeyr GJ. Planned elective Caesarean section for term breech. Cochrane database of systematic reviews. *Cochrane Library* 1997, Issue 4. (Type I evidence - systematic review); **ii.** Internal Review Group (see inside front cover) (Type V evidence - expert opinion)
12.4b. The value of routine elective Caesarean section for **preterm breech delivery** is unknown [i,ii]. While observational studies have usually found higher survival after Caesarean section, all studies are affected by confusing variables. A trial designed to overcome these biases was discontinued because of difficulties in recruitment [ii]. (Health gain notation - 4 *"unknown"*)	**i.** Penn ZJ, Steer PJ, Grant A. A multicentre randomised controlled trial comparing elective and selective caesarean section for the delivery of the preterm breech infant. *British Journal of Obstetrics and Gynaecology*. 1996; **103(7)**: 684-689 (Type II evidence - randomised controlled trial, discontinued) **ii.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1280-1282 (Type III evidence - Non-randomised studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 278-280);
12.4c. **External cephalic version at term** (after 36 weeks gestation), by a practitioner experienced in the technique, is good practice since it reduces the incidence of breech delivery and of Caesarean section, provided fetal wellbeing is first confirmed and monitored (and anti-D given if appropriate) [i,ii]. (Health gain notation - 1 *"beneficial"*) Following version, 67% of babies will proceed to a cephalic birth compared to 22% who turn spontaneously before delivery [ii].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 655-658 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 145); **ii.** Zhang J, Bowes WA, Fortney JA. Efficacy of external cephalic version: a review. *Obstetrics and Gynaecology*. 1993; **82(2)**: 306-312. (Type II evidence - review of clinical trials included in the Medline database)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.5 CAESAREAN SECTION

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents [i].

There is considerable debate about the optimum rate for Caesarean Section. Inevitably unit rates will vary according to referral patterns and there is a need for population based denominator data. The four commonest indications for performing a Caesarean section are: breech presentation (see 'management of breech presentation' in this Chapter); failure to progress in labour (see 'augmentation' in this chapter); suspected fetal compromise(see Chapter 14); and a previous Caesarean section (see below) [ii,iii].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);
ii. National Childbirth Trust, Savage W, Churchill H, Francome C. Caesarean birth in Britain. London, Middlesex University Press, 1993 and 1994 supplement (Type V evidence - expert opinion);
iii. Patel N, Chamberlain G (eds.) The future of the maternity services. London: Royal College of Obstetricians and Gynaecologists Press, 1994 (Type V evidence - expert opinion)

The *statements*	The *evidence*
12.5a. The use of Caesarean section for **potential 'fetal compromise'** is dependent on accurate diagnosis of that condition. There is no strong evidence of improvement in outcome with extensive use of electronic fetal monitoring. Whether this is due to wrong hypothesis or currently less than optimum monitoring methods is unclear. There is a need for controlled trials to determine both indications for and extent to which labour should be monitored [i]. (Health gain notation - 4 *"unknown"* - see also Chapter 14 'Suspected fetal compromise in pregnancy and labour)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1186-1189 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 214)
12.5b. The use of Caesarean Section following a **previous Caesarean section** has been subject to much review but little controlled trial. Most expert opinion would support a woman's wish for a trial of vaginal delivery provided the first Caesarean section had not been for gross disproportion. There are also some women who choose delivery by Caesarean section if previous experience has been of a difficult labour or delivery [i,ii]. (Health gain notation - 4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1189, 1204-1215 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 284-293); **ii.** Roberts LJ, Beardsworth SA, Trew G. Labour following Caesarean section: current practice in the United Kingdom. *British Journal of Obstetrics and Gynaecology*. 1994; **101**: 153-155 (Type IV evidence - study by questionnaire of 741 Consultants: 71.7% response rate)
12.5c. The following are *good practice* when carrying out Caesarean section : ■ the use of **low dose heparin** to prevent thromboembolism in moderate or high risk patients [i]. ■ **antibiotic prophylaxis** [ii]. ■ a **transverse lower segment uterine incision** [iii]. (Health gain notation - 1 *"beneficial"*)	**i.** Report of the RCOG Working Party on prophylaxis (and management) against Thromboembolism in Gynaecology and Obstetrics. London: Royal College of Obstetricians and Gynaecologists, 1995 (Type V evidence - expert opinion); **ii.** Department of Health and Others. Report on Confidential Enquiries into Maternal Deaths in the United Kingdom 1991-1993. London: HMSO,1996. p.83 **iii.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1239-1241 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
12.5d The small amount of information available suggests that routine **manual removal of the placenta** at Caesarean section does more harm than good [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Enkin MW, Wilkinson C. Manual removal of placenta at Caesarean section. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997, Issue 4 (Type I evidence - systematic review)
12.5e. The **type of anaesthesia** for Caesarean section is dictated mainly by availability and maternal choice, rarely for reasons of extreme haste or coagulation disorder. Regional anaesthesia has the advantage over general anaesthesia of avoiding aspiration of stomach contents and allowing earlier contact between mother and child [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1235-1239 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 319)
12.5f. When **general anaesthesia** is used for Caesarean section, cricoid pressure, restriction of food and drink and the use of antacids or H2-receptor antagonists (eg Ranitidine) are only partially effective in prevention of gastric aspiration [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1237-1238 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 320)
12.5g. On limited data, there are only minor differences between **spinal** and **epidural block** [i]. The technique of combined spinal epidural offers the advantages of both methods. (Health gain notation - 4 *"unknown"*)	**i.** Expert anaesthetic opinion to the Internal Review Group (see inside front cover) (Type V evidence - expert opinion)
12.5h. On the basis of good observational evidence, **lateral tilt** should always be used in Caesarean section to prevent vena caval compression [i] and intravenous pre-loading should also be carried out for the prevention of hypotension [ii]. (Health gain notation - 1 *"beneficial"*)	**i.** Enkin MW, Wilkinson C. Effect of lateral tilt during Caesarean section. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997, Issue 4. (Type I evidence - systematic review) **ii.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p. 258 (Type V evidence - expert opinion)
12.5i. The value of routine **exteriorization of the uterus** versus **intraperitoneal repair** at Caesarean section is *unknown* [i]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin MW, Wilkinson C. Uterine exteriorization vs intraperitoneal repair at Caesarean section. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997, Issue 4 (Type I evidence - systematic review)
12.5j. Preliminary evidence suggests that **non-closure of the parietal peritoneum** at Caesarean section should be considered, in that it saves 5-8 minutes of operating time with no significant difference in post operative morbidity and length of hospital stay [i,ii]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin MW, Wilkinson C. Peritoneal non-closure at Caesarean section. Cochrane Database of Systematic Reviews. *Cochrane Library* 1997, Issue 4. (Type I evidence - systematic review); **ii.** deZerega GS, Duffy DM. Is peritoneal closure necessary? PACE review No. 96/02. London: Royal College of Obstetricians and Gynaecologists, 1996. (Type II evidence - review of randomised controlled trials)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.6 EPISIOTOMY/PERINEAL TRAUMA

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents [i].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);

The *statements*	The *evidence*
12.6a. There is a *trade-off* between the beneficial and adverse effects of **episiotomy** (Health gain notation - 3) and its **routine use in spontaneous delivery** should be strongly discouraged [i,ii,iii]. (Health gain notation - 6 *"likely to be ineffective or harmful")*	**i.** Carroli G, Belizan J, Stamp G. Episiotomy policies in vaginal births. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review); **ii.** Thompson DJ. No episiotomy?! *Australian and New Zealand Journal of Obstetrics and Gynaecology* 1987; **27**: 18-20 (Type V evidence - expert opinion); **iii.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1136-1141 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 232-233)
12.6b In assisted delivery by **ventouse,** and in the delivery of the **premature infant** there is no evidence of the benefit of routine episiotomy [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial")*	**i.** The T G. Is routine episiotomy beneficial in the low birth weight delivery? *International Journal of Gynecology and Obstetrics* 1990; **31**:135-40 (Type IV evidence - case note study of 439 singleton deliveries of babies of <2500g) **ii.** Lobb MO, Duthie SJ, Cooke RWI. The influence of episiotomy on the neonatal survival and incidence of periventricular haemorrhage in very low birth weight infants. *European Journal of Obstetrics and Gynecology. Reproductive Biology*. 1986; **22**:17-21 (Type IV evidence - retrospective study of 94 babies of <1500g);
12.6c. In the delivery of mature breech babies, or in the use of Kielland's or other rotational forceps, the use of episiotomy is recommended [i,ii]. (Health gain notation -2 *"likely to be beneficial"*)	**i.** Internal Review Group (See inside front cover) (Type V evidence - expert opinion)
12.6d. There have been numerous trials regarding **optimum technique for repair** of either episiotomy or a perineal tear but there is still the need for trials where operator skill, type of skin suture and degree of tightness of repair are controlled [i].	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995 pp. 269-273

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
12.6e. **Absorbable** instead of non-absorbable **sutures** are *beneficial* for skin repair. They are associated with less short term pain but more irritation sufficient to lead to removal in an important minority. The findings in favour of absorbable sutures may only reflect differences in tightness of suture rather than suture material [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1173-1181 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 270-271)
12.6f. Where absorbable skin sutures are used the following are likely to be beneficial [i]: (Health gain notation - 2 *"likely to be beneficial"*) ■ **polyglycolic acid sutures** instead of chromic catgut. ■ **continuous subcuticular suture**	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1171-1181 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 270-271)
12.6g **Glycerol impregnated catgut** for repair of perineal trauma is likely to be harmful [i]. (Health gain notation - 6 *"likely to be harmful"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1173-1181 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 270-271)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

12.7 ANALGESIA FOR PERINEAL PAIN

Avoiding unnecessary interventions should result in a reduction in complications of the intervention and less use of resources. The problem comes in deciding at which point the desires of the mother conflict with any risk to mother and child. Where an intervention may be indicated, the options must be fully discussed with the parents. Much of the discomfort from perineal pain can be relieved by the use of sympathy and mild analgesia while avoiding constipation [i]. i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);

The *statements*	The *evidence*
12.7a. The use of **crushed ice** or **warm water** gives short-term symptomatic relief from perineal pain and discomfort [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1347-1349 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 364)
12.7b. The choice of **oral analgesia** is a balance between effectiveness and unwanted side effects. Paracetamol is probably the drug of choice for mild perineal pain with ibuprofen among the non-steroidal anti-inflammatories having few side-effects, with little excreted in breast milk [i,ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1355-1356 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 369); **ii.** *British National Formulary* March 1997 p.414 (Type V evidence - expert opinion)
12.7c. There is a *trade-off between beneficial and adverse effects* for locally applied anaesthetics such as **aqueous 5% lignocaine spray** or **lignocaine gel** but their effect may last longer than ice or tap water [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** Potential allergic reactions.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1351 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 366)
12.7d. The value of the following treatments for reducing perineal pain is unknown [i]. (Health gain notation - 4 *"unknown"*): ■ **Oral proteolytic enzymes;** ■ **Ultrasound** and **pulsed electromagnetic energy**	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1351-1354 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 364-371)
12.7e The following are *unlikely* to be beneficial for the treatment of perineal pain [i]. (Health gain notation - 5 *"unlikely to be beneficial"*) ■ **Witchhazel;** ■ **Adding salt to bathwater;** ■ **Antiseptic solutions added to bathwater**	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1347-1350 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 364-371)
12.7f. Combinations of **local anaesthetics** and **topical steroids** for the relief of perineal pain are unlikely to be beneficial and may be harmful [i,ii]. (Health gain notation - 6 *"likely to be ineffective or harmful"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1351 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 364-371); **ii.** *British National Formulary* March 1997 p.539 (Type V evidence - expert opinion)

13 PREMATURE LABOUR

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

13.1 PRETERM LABOUR

Preterm labour may follow preterm rupture of membranes, or become established with intact membranes.

The *statements*	The *evidence*
13.1a. It is of proven value to administer **corticosteroids** to women in premature labour with intact membranes between 24 and 36 weeks (2 doses of betamethasone [12 mg im] 24 hours apart, or 4 doses of dexamethasone [6 mg im] 12 hours apart) to promote fetal lung maturation before preterm delivery (Number Needed to Treat = 5 to prevent one case of respiratory distress in babies of less than 31 weeks gestation) [i]. (Health gain notation - 1 *"beneficial"*)	**i.** RCOG guideline No.7. Antenatal corticosteroids to prevent respiratory distress syndrome. London: Royal College of Obstetricians and Gynaecologists, April 1996 (Type I evidence - review including one large meta-analysis)
13.1b. No evidence is yet available to support or condemn the **repeated use of corticosteroids** (one week after the initial course) in those women who remain undelivered and at continued risk of preterm birth. Controlled trials are needed [i]. (Health gain notation - 4 *"unknown"*)	**i.** Crowley, P. Corticosteroids prior to preterm delivery. Cochrane Database of systematic Reviews; *Cochrane Library* 1997 Issue 4 (Type I evidence - systematic review)
13.1c. The indications for the use of **ritodrine** (or other betamimetics) are restricted to the management of uncomplicated preterm labour between 24 and 33 weeks' gestation [i]. (Health gain notation - 2 - *"likely to be beneficial"*) **caveat:** Trials suggest that the number of women delivering within 48 hours of commencement of treatment is significantly reduced but no reduction in perinatal mortality or serious morbidity was detected through use. However, short term use enables the time gained before delivery to be used to administer corticosteroids and arrange for transfer to a centre with intensive care facilities. Strict adherence to recommended dosage is required to avoid side effects, including pulmonary oedema and myocardial ischaemia.	**i.** RCOG guideline No.1A. Beta-agonists for the care of women in preterm labour. London: Royal College of Obstetricians and Gynaecologists, January 1997 (Type I evidence - review including a meta-analysis)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
13.1d. **Short term indomethacin** to stop preterm labour may be beneficial but, because of the known and unknown side-effects (such as bronchopulmonary dysplasia), more and better controlled data are needed to assess its value in preterm labour [i]. (Health gain notation - 4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 716-721 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 166-168)
13.1e After the successful treatment of acute preterm labour, **maintenance therapy** with **oral β-agonists** (ritodrine or tertutaline) does not decrease the risk for preterm delivery (Odds Ratio, OR 1.09), recurrent labour (OR 1.05) or respiratory distress syndrome (OR 0.91). They also do not increase the time to delivery or birth weight [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Macones GA, Berlin M, Berlin JA. Efficacy of oral beta-agonist maintenance therapy in preterm labour: a meta-analysis. *Obstetrics and Gynaecology.* 1995; **85(2)**:313-7. (Type I evidence - meta-analysis)
13.1f. There is a *trade-off between beneficial and adverse effects* in the use of **cervical cerclage** for women at risk of preterm birth because of cervical incompetence [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** A small proportion of women will benefit (especially those who have had two or more past pregnancies which have ended too early) but there are hazards associated with the surgery and the risk of stimulating uterine contractions.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 633-645 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 162)
13.1g. There is some evidence that **infection** is a **causal agent** in a proportion of cases of premature labour. An ongoing trial should resolve whether antibiotics are effective in the prevention of preterm birth [i]. (Health gain notation - 4 *"unknown"*)	**i.** Oracle Trial: Contact the Medical Research Council, London.
13.1h. The following strategies are of unknown benefit [i]: ■ **Routine cervical assessment** for identification of women at risk of preterm birth; ■ The use of **magnesium sulphate, calcium antagonists** or **oxytocin antagonists** in suppression of preterm labour. (Health gain notation - 4 *"unknown"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 Chapter 44, particularly pp. 694-695, 730-745 (Type I evidence - systematic review for MgSO4; Types II-V evidence for other interventions. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 163, 168-170)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
13.1i Two randomised controlled trials of adding **thyroid trophic releasing hormone (TRH) to corticosteroids** to promote fetal lung maturation have shown no benefits [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** National Institute of Health study (USA) submitted to the *New England Journal of Medicine* (Ballard et al). **ii.** Chilean trial: *American Journal of Obstetricians and Gynaecologists* (in press)
13.1j The following strategies are unlikely to be beneficial in the management of preterm delivery [i]: **Routine elective forceps;** **Routine use of episiotomy.** (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1283-1284 (Type I evidence - systematic review of limited trials. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 281)
13.1k The use of **ethanol** to stop preterm labour is *likely to be ineffective or harmful* [i]. (Health gain notation - 6 *"likely to be ineffective or harmful"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 721-727 (Type I evidence - systematic review of limited trials. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 168)
13.1l Two strategies have been suggested to promote early recognition of preterm labour: **Educational programs** and **home uterine activity monitoring.** Neither have an effect on neonatal survival, low birthweight rates or preterm delivery rates while, in the case of educational programmes, there is a doubling of the risk of being diagnosed as having preterm labour during pregnancy [i,ii]. (Health gain notation - 6 *"likely to be ineffective or harmful"*)	**i.** Hueston WJ, Knox MA, Eilers G, Pauwels J, Lonsdorf D. The effectiveness of preterm-birth prevention educational programs for high-risk women: a meta-analysis. *Obstetrics and Gynaecology*. 1995; **86(2)**: 705-712 (Type I evidence - meta-analysis of randomised controlled trials in Medline); **ii.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 695 (Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 162)

13.2 PRETERM PRE-LABOUR RUPTURE OF MEMBRANES

13.2a. **Corticosteroid administration** (see statement 13.1a.) **after prelabour rupture of membranes preterm** is *likely to be beneficial* with advantages greater than the added risk of infection [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Crowley, P. Corticosteroids prior to preterm delivery. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review); **ii.** Guideline No.7. Antenatal corticosteroids to prevent respiratory distress syndrome. London: Royal College of Obstetricians and Gynaecologists, April 1996 (Type I evidence - review including one large meta-analysis)
13.2b. An **initial vaginal culture** should be taken after prelabour rupture of membranes [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 689 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 150)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
13.2c. **Antibiotics** given routinely subsequent to preterm (27-33 weeks) rupture of membranes reduce the odds of early delivery and infection although they have not been proven to affect the incidence of respiratory distress or mortality in the neonate [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Divers M. Infection and preterm labour. PACE review No. 95/12. London: Royal College of Obstetricians and Gynaecologists, 1995. (Type I evidence - systematic review)
13.2d. In populations with a high prevalence of **Group B streptococci carriers**, either screening for the organism or routine antibiotic treatment should be adopted as standard care following pre-labour rupture of membranes [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 689 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 150)
13.2e. It is likely to be beneficial to allow **labour to progress** after prelabour rupture of membranes preterm depending on the stage of pregnancy [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 680-682 (Type II evidence - Two trials. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 153-154)
13.2f. If there are signs of **intrauterine infection** following prelabour rupture of membranes, antibiotic treatment should be started and delivery effected. A skilled neonatologist should be present at the birth [i]. (Health gain notation - 2 "likely to be beneficial")	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 689 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 159)
13.2g. The delivery of a **very preterm baby** (32 weeks or less) should be in a centre with neonatal intensive care facilities and in the presence of an appropriately experienced paediatrician. In utero transfer is preferable [i]. At 33 weeks the need for transfer should be weighed against facilities and staff available [ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1286 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 277, 283); **ii.** Internal Review Group (See inside front cover) (Type V evidence - expert opinion)
13.2h Trials of **antenatal administration of phenobarbital** to women at risk of very preterm birth have shown a minimal reduction in the incidence of intraventricular haemorrhage with an increase in the incidence of respiratory distress and a requirement for ventilation [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Horbar JD. Prevention of periventricular-intraventricular hemorrhage. In: Effective care of the newborn infant. Editors. J Sinclair and MB Bracken. Oxford: Oxford University Press, 1992 pp.565-566 (Type I evidence - systematic review); **ii.** Doyle L. Antenatal phenobarbitone and neonatal outcome. *Lancet* 1996; **348:** 975-6 (Type I evidence - review including a meta-analysis and several trials)

Date of completion of this document

23.6.97

14 SUSPECTED FETAL COMPROMISE IN PREGNANCY AND LABOUR

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

Fetal compromise in pregnancy is difficult to assess, not least because the ability to predict fetal growth retardation is not the same as the ability to predict low birth weight. Many cases have no obvious cause and management has to be aimed at determining the optimum time of delivery.

In the prevention of poor fetal growth, maternal smoking, alcohol and drug addiction are potentially avoidable factors.

In labour, electronic fetal monitoring has been widely adopted in an attempt to identify the fetus at risk of hypoxia, and associated morbidity and long term damage, but this may conflict with maternal wishes [i]. A full multidisciplinary review of intrapartum fetal surveillance is available which covers etiology and technique and makes recommendations for practice [ii].

i. Internal Review Group (Type V evidence - expert opinion. See inside front cover);
ii. Spencer JAD, Ward RHT (eds.). Intrapartum fetal surveillance. Recommendations arising from the 26th RCOG Study Group. London: Royal College of Obstetricians and Gynaecologists, 1993

The *statements*

The *evidence*

14.1 In PREGNANCY

14.1a. **Smoking cessation programmes,** in particular behavioural strategies, can be effective for a small minority of smokers in increasing mean birthweight. Poorly structured advice may lead to some smokers spending their pregnancy in a state of guilt and inadequacy. There are no trials of pre-pregnancy intervention to determine if such advice reduces the prevalence of smoking or, more importantly, improves outcomes [i,ii].
(Health gain notation - 4 *"unknown"*. The efficacy of smoking prevention programmes in general will be covered in the *Healthy Living Bulletin* - due for publication in 1998)

i. Dolan-Mullen P, Ramirez G, Groff JY. A meta-analysis of randomized trials of prenatal smoking cessation interventions. *American Journal of Obstetrics and Gynecology*. 1994; **171(5)**: 1328-1334.
(Type I evidence - meta-analysis);

ii. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 244-247, 251
(Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 22-23)

14.1b **Excessive alcohol consumption** in pregnancy is associated with increased morbidity and mortality in the fetus. While no trials of cessation programmes exist, guidelines on management are available [i].
(Health gain notation - 5 *"potential for harm"*)

i. Royal College of Obstetricians and Gynaecologists. Alcohol consumption in pregnancy RCOG Guidelines No. 9. London: RCOG, 1996
(Type V evidence - expert opinion)

14.1c There is **no** evidence to recommend **nutrient therapy** by dietary interventions and supplementation in suspected fetal growth impairment [i].
(Health gain notation - 5 *"unlikely to be beneficial"*)

i. Gulmezoglu AM, Hofmeyr GJ. Nutrient treatment for suspected impaired fetal growth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 1.
(Type I evidence - systematic review of small trials with methodological limitations)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
14.1d. There is evidence of the value of an **accurate early ultrasonic dating** of all pregnancies in avoiding unnecessary induction for suspected poor growth [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 424-426 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 41); **ii.** Managing post-term pregnancy. *Drug and Therapeutics Bulletin* 1997; **35(3)**: 17-18 (Type V evidence - expert opinion)
14.1e. In prediction of poor growth, **measurement of fundal height** has shown quite good specificity and sensitivity [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 415 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 62)
14.1f. **Fetal movement counting** has been widely used as a test of fetal compromise. The two randomised controlled trials available provided no evidence of reduction in intrauterine death [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** Its widespread use does result in more hospital attendances, induction and elective deliveries. Limiting to selected at risk cases may be better practice.	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 440-452 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 62)
14.1g There is no evidence that **routine** screening by **repeat biophysical profiles** or **Doppler** studies identifies affected pregnancies [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Neilson JP, Alfirevic Z. Doppler ultrasound in high risk pregnancies. Cochrane database of systematic reviews. *Cochrane Library*. 1997 Issue 4. (Type I evidence - systematic review); **ii.** Neilson JP, Alfirevic Z. Biophysical profiles for fetal assessment in high risk pregnancies. Cochrane database of systematic reviews. *Cochrane Library*. 1997 Issue 1. (Type I evidence - systematic review)
14.1h. There is evidence that **selective ultrasound** is effective in identifying at-risk pregnancies but there is a need for prospective studies to identify optimum techniques [i]. (Health gain notation -1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 420-436 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 63-70)
14.1i. There is evidence that **Doppler studies**, to monitor the high risk infant, are effective to determine the optimum timing of delivery [i]. (Health gain notation -1 *"beneficial"*)	**i.** Neilson JP, Alfirevic Z. Doppler ultrasound in high risk pregnancies. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 4. (Type I evidence - systematic review)
14.1j There is no evidence that **biophysical profiles** to monitor the high risk infant are effective in improving outcome [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Alfirevic Z, Neilson JP. Biophysical profile for fetal assessment in high risk pregnancies. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 4. (Type I evidence - systematic review)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
14.1k The value of **hospitalization and bed rest** for suspected fetal compromise have not been substantiated [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Gulmezoglu AM, Hofmeyr GJ. Hospitalisation for bedrest for suspected impaired fetal growth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type II evidence - randomised controlled trial)
14.1l. **External cardiotocography** may be effective in identifying deteriorating fetal condition (in at-risk pregnancies) following suddent reduction of fetal movement or ante-partum haemorrhage [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** Because of the difficulties in interpretation, its widespread use is not recommended	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 479-492 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 66-67)
14.1m Preliminary and limited trial evidence gives initial support to the value of **maternal oxygen therapy** but this should only be used in the context of well-designed trials [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Gulmezoglu AM, Hofmeyr GJ. Maternal oxygen therapy in suspected impaired fetal growth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type I evidence - systematic review of two trials)
14.1n. There is inadequate evidence at present to support the routine use of **calcium channel blockers** in pregnancy where the risk of impaired fetal growth is increased, but further trials are indicated [i]. (Health gain notation - 4 *"unknown"*)	**i.** Gulmezoglu AM, Hofmeyr GJ. Calcium channel blockers in suspected impaired fetal growth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type II evidence - randomised controlled trial)
14.1o. **Plasma volume expansion** for impaired fetal growth is theoretically promising but further research is needed [i]. (Health gain notation - 4 *"unknown"*)	**i.** Gulmezoglu AM, Hofmeyr GJ. Plasma volume expansion for suspected impaired fetal growth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4. (Type V evidence - expert opinion; The two randomised controlled trials reviewed were both excluded because of methodological shortcomings)
14.2 IN LABOUR	
14.2a. There is no dispute regarding the value of **fetal surveillance** to identify distress in labour. Auscultation of the fetal heart during, and immediately following, contractions has been conventionally used to identify changes indicative of imminent hypoxia [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 846-882 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 208-209);

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
14.2b. The passage of **thick meconium** is associated with an increased risk of fetal and neonatal mortality (thick meconium at onset of labour carries a 5-7 times increased risk of perinatal death) [i].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 847-848 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 208)
14.2c. **Electronic fetal heart monitoring** by electocardiography provides the most reliable method of monitoring the fetal heart in labour by identification of changes in base rate, decelerations and loss of baseline variability [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** Continuous electronic monitoring, while reassuring for many women creates anxiety for others, and limits activity in labour (see statement 14.2e).	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 846-878 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 210-214)
14.2d. The use of **continuous electronic monitoring** versus **auscultation,** especially without the capacity to measure fetal pH increases the use of Caesarean section (relative risk = 1.33) and operative vaginal deliveries (relative risk = 1.23) [i]. (Health gain notation - 3 "trade-off between beneficial and adverse effects") **caveat:** The increase in Caesarean section is not associated with a reduction in mortality (provided there is equal emphasis on recognition and action in the presence of fetal heart abnormality) although a decrease in Apgar scores of <4 at 1 minute and neonatal seizures has been demonstrated [ii].	**i.** McDonald D, Grant A, Sheridan-Pereira M, Boylan P, Chalmers I. The Dublin randomised controlled trial of intrapartum fetal heart rate monitoring. *American Journal of Obstetrics and Gynecology.* 1985; **152(5)**: 524-539 (Type II evidence - randomised controlled trial of 12,964 women); **ii.** Thacker SB, Stroup DF, Peterson HB. Continuous electronic fetal heart monitoring during labour. Cochrane Database of Systematic Reviews. *Cochrane Library*. 1997 Issue 4. (Type I evidence - systematic review)
14.2e. **Current consensus** is to limit continuous electronic fetal heart monitoring to high risk cases, including those with interventions (induction, agumentation or epidural analgesia), and use either intermittent auscultation or electronic monitoring for those with neither signs nor risk of compromise. Further trials are needed for both low and high risk groups [i,ii,iii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Thacker SB, Stroup DF, Peterson HB. Continuous electronic fetal heart monitoring during labour. Cochrane Database of Systematic Reviews. *Cochrane Library.* 1997 Issue 4. (Type I evidence - systematic review); **ii.** Spencer JAD, Ward RHT (eds.). Intrapartum fetal surveillance. Recommendations arising from the 26th RCOG Study Group. London: Royal College of Obstetricians and Gynaecologists, 1993 (Type V evidence - expert opinion); **iii.** MIDIRS. Fetal heart rate monitoring. Leaflet No. 2 MIDIRS, January 1996 (Type V evidence - expert opinion)

Date of completion of this document

27.10.97

15 MATERNAL SUPPORT IN LABOUR

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

This chapter should be read in conjunction with **Chapter 10 "Where to be born"**

The *statements*

15a. There is no doubt that **continuity of care** from pregnancy to labour should be provided whenever possible [i] and that all labouring women should receive **emotional and psychological support** from those close to them and from carefully trained caregivers [ii,iii].
Continuity of caregivers may result in less need for induction, pharmacologic pain relief, neonatal resuscitation and fewer episiotomies, with an increased risk of perineal tear. Women receiving continuity of care are more likely to be satisfied with that care. It is unclear whether these benefits are due to greater continuity or more midwifery involvement [iv,v,vi,vii].
(Health gain notation - 2 *"likely to be beneficial"*)

The *evidence*

i. see Statement 5a. in Chapter 5. 'Support in Pregnancy'

ii Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 810-813
(Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 196);

iii. MIDIRS and the NHS Centre for Reviews and Dissemination. Support in labour. Informed choice for professionals Leaflet No. 1. MIDIRS, January 1996
(Type I evidence - systematic review);

iv. Hodnett ED. Continuity of caregivers during pregnancy and childbirth. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4.
(Type I evidence - systematic review);

v. Hundley VA, Cruickshank FM, Lang GD, Glazener CMA, Milne JM *et al*. Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *British Medical Journal*. 1994; **309**:1400-1404
(Type II evidence - randomised controlled trial of 2844 women);

vi. Rowley MJ, Hensley MJ, Brinsmead MW, Wlodarczyk JH. Continuity of care by midwife team versus routine care during pregnancy and birth: a randomised trial. *Medical Journal of Australia.* 1995; **163**: 289-293
(Type II evidence - randomised controlled trial of 405 women);

vii. McCourt C, Page L (eds.). Report on the evaluation of one-to-one midwifery. London: Centre for Midwifery Practice, 1996. pp.70-73
(Type IV evidence - prospective cohort study)

15b. Women should be permitted **free mobility** and **choice of position** during the **first stage of labour.** There is no evidence from controlled studies to suggest that the supine position should be encouraged [i].
(Health gain notation - 1 *"beneficial"*)

i. MIDIRS and the NHS Centre for Reviews and Dissemination. Positions in labour and delivery. Informed Choice for Professionals Leaflet No.5. MIDIRS, 2nd ed. July 1996
(Type I evidence - systematic review)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
15c. There is a continued debate between the advantage of complete restriction of food and drink, with the aim of avoiding gastric aspiration at general anaesthetic, against the advantages of allowing a low-residue low-fat diet for women in normal early labour [i]. (Health gain notation - 4 *"unknown"*)	**i.** Expert anaesthetic opinion to the Internal Review Group (see inside front cover)
15d. Women in labour should be given **as much information as they desire** [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 825 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 206)
15e. It is *likely to be beneficial* to allow the woman her **own choice of position** for the **second stage** of labour and for giving birth, whenever possible [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1129-1144 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 228-229)
15f. Early mother-child contact should be encouraged. The inflexible use of central nurseries has jeopardized breastfeeding and may have increased the risk of infection [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1323-1336, 1339-1340 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 340-343)

Date of completion of this document

23.6.97

16 POSTPARTUM HAEMORRHAGE (PREVENTION AND MANAGEMENT)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
16a. In comparing active and passive management of the third stage of labour, routine administration of oxytocics results in an **important reduction** in blood loss and the risk of postpartum haemorrhage (by 60%) [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** Routine administration of oxytocics increases the risk of rare but serious morbidity and of retained placenta. This latter finding might reflect selective presentation of outcome data or be an effect of chance	**i.** Prendiville WJ, Elbourne D, McDonald S. Active versus expectant management of the third stage of labour. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 2. (Type I evidence - systematic review)
16b. **Syntometrine (Ergot + oxytocin)** remains the most effective oxytocic in active management of the third stage [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1151-1157 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 238)
16c. Optimum management of postpartum haemorrhage depends on **rapid assessment** and **prompt arrest** of the bleeding. **Oxytocic** drugs remain the traditional first line approach [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1146 (Type III evidence - non-randomised studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 241); **ii.** Department of Health and Others. Guidelines for the Management of massive obstetric haemorrhage in Confidential Enquiries into Maternal Deaths 1988-1990 London: HMSO, 1994 (Type V evidence - expert opinion)
16d. **Prostaglandins** (Carboprost) are effective in severe postpartum haemorrhage due to uterine atony, which is unresponsive to ergometrine and oxytocin [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** This should be used with caution in women with a history of asthma, epilepsy, glaucoma and hypertension.	**i.** *British National Formulary.* March 1997, p.328 (Type V evidence - expert opinion)
16e. In the management of retained placenta in the absence of haemorrhage **expectant care should be considered** as an alternative to anaesthesia and manual removal, with appropriate consideration to alternative strategies after 60 minutes [i].	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1146 (Type II evidence - single trial. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 241)

17 INFANT FEEDING

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements* | The *evidence*

17.1 BREAST FEEDING

17.1a. IBreast feeding, compared with artificial feeding, has been clearly shown to protect against

- gastrointestinal infection in the infant [i] and
- necrotising enterocolitis among babies born at more than 30 weeks gestation [ii].

Breast feeding may also

- enhance neurological development in the child [iii]
- protect against allergy in neonates (of <1850g) with a family history of atopy (Odds Ratio, OR=3.6) [iv]
- protect against breast cancer in premenopausal women (OR= 0.78) but not postmenopausal women [v], and
- protect against ovarian cancer [vi]

(Cohrane health gain notation - 2 *"likely to be beneficial"*)

i. PW, Forsyth JS, Ogston SA, Clark A, duV Florey C. Protective effect of breast feeding against infection. *British Medical Journal.* 1990; **300**: 11-16
(Type IV evidence - prospective observational study over 2 years of 618 pairs of mothers and infants);

ii. Lucas A, Cole TJ. Breast milk and neonatal necrotising enterocolitis. *Lancet.* 1990; **336**: 1519-1523.
(Type IV evidence - prospective multicentre study of 926 preterm infants);

iii. Statement of the Standing committee on Nutrition of the British Paediatric Association. Is breast feeding beneficial in the UK? *Archives of disease in childhood.* 1994; **71**: 376-380 (Type IV evidence - observational studies);

iv. Lucas A, Brooke OG, Morley R, Cole TJ, Bamford MF. Early diet of preterm infants and development of allergic or atopic disease: randomised prospective study *British Medical Journal* 1990; **300**: 837 - 840
(Type II evidence - randomised prospective study of 777 infants - 75 with a family history of atopy);

v. Newcomb PA, Storer BE, Longnecker MP et al. Lactation and a reduced risk of premenopausal breast cancer. *New England Journal of Medicine.* 1994; **330(2)**: 81-87 (Type IV evidence - case study of 5878 women with breast cancer and 8216 controls);

vi. Rosenblatt KA, Thomas DB. WHO collaborative study of neoplasia and steroid contraceptives. Lactation and the risk of epithelial ovarian cancer. *International Journal of Epidemiology*. 1993; **22(2)**: 192-197
(Type III evidence - case control study of 393 cases of ovarian cancer compared with 2565 age matched controls)

17.1b. The following are recommended in promoting successful breast feeding [i]:
(Health gain notation - 2 *"likely to be beneficial"*)

- **Consistency** in advice and support;
- **Personal support** from a knowledgable individual;
- **Unrestricted breastfeeding.**
- **Encouragement of early feeding** although there is no evidence of advantage of any particular time;
- **Skilled help with the first feed**
- **Correct positioning** of the baby;
- **Flexibility** in feeding practices in both duration and frequency;
- **Well designed information** about breast feeding.

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 Chapters 21, 80, 81, 82.
(Review of types I-V evidence. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. Chapters 46 & 48. See also pp. 73-75 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

17.1d. **Oxytocin** nasal spray to improve milk supply is of unknown benefit
(Health gain notation - 4 *"unknown"*)

17.1e The following practices are unlikely to be beneficial:
(Health gain notation - 5 *"unlikely to be beneficial"*)
- **Antenatal breast or nipple care;**
- The use of **nipple shields**;
- **Switching breasts before baby spontaneously finishes feeding**

17.1f The following practices have been shown to be ineffective or harmful:
(Health gain notation - 6 *"ineffective or harmful"*)
- **Antenatal breast shells** for inverted nipples;
- **Routine supplementation** of either water or formula milk for breast fed babies;
- **Pressing excess fluid intake** (beyond the demands of thirst) to breast feeding mothers;
- **Test weighing** of breast fed infants - both inaccurate and a major cause of maternal anxiety;
- **Free offers of formula feeds;**
- **Nipple creams**

17.2 BREAST ENGORGEMENT

17.2a. Unrestricted access for the baby to the breast still appears to be the most effective way to prevent and treat breast engorgment
(Health gain notation - 2 *"likely to be beneficial"*)

17.2b. The effect of **oral proteolytic enzymes** or **cabbage leaves** for breast engorgement is unknown (Health gain notation - 4 *"unknown"*)

17.2c In simple **breast engorgement, antibiotics and oxytocin** are unlikely to be beneficial
(Health gain notation - 5 *"unlikely to be beneficial"*)

17.2d. If **mastitis** does not rapidly resolve with **good feeding practice** and **expression,** then **antibiotics** (and bacterial culture of milk) should be instituted.
(Health gain notation - 2 *"likely to be beneficial"*)

The *evidence*

Evidence for the statements on this page is derived from:

Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 Chapters 21, 80, 81, 82.
(Review of types I-V evidence. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. Chapters 46 & 48. See also pp. 73-75 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements* | The *evidence*

17.3 CONTRACEPTION AND BREAST FEEDING

17.3a Combined oestrogen-progestogen oral contraceptives should be avoided - as use increases the incidence of breast feeding failure
(Health gain notation - 6 *"ineffective or harmful"*)

17.4 LACTATION SUPPRESSION

17.4a. Women may not breast feed for a variety of reasons, ranging from personal choice to stillbirth or neonatal death. For the majority of women who decide not to breast feed **simple supportive methods** (binding and fluid restriction) are effective in suppression of lactation and in reducing breast pain and engorgement. While associated with more discomfort than drug suppression in the short term, they appear to be at least as effective in the long term.
(Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)

17.4b. For those who have lost a baby or where simple supportive methods are unsuccessful then **pharmacological suppression of lactation** may be considered: **Bromocryptine** is effective in lactation suppression but rebound lactation is common.
(Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)

Carbergoline, compared with bromocryptine, is more effective and may be used as a single dose.
(Health gain notation - 2 *"likely to be beneficial"*)

Further comparative trials including women's views in any evaluation are needed.

17.4c **Oestrogen** should not be used in lactation suppression - as it increases the risk of vaginal bleeding and of thromboembolism
(Health gain notation - 6 *"ineffective or harmful"*)

Evidence for the statements on this page is derived from

Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 Chapters 21, 80, 81, 82.
(Review of types I-V evidence. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. Chapters 46 & 48. See also pp. 73-75 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

17.5 FORMULA FEEDING

17.5a. Where formula feeds are used, **standard formulae** based on modified cow's milk with a protein concentration of 13-15 gl^{-1} provide the best nutritional source.
(Health gain notation - 2 *"likely to be beneficial"*)
caveat: Additions to feeds of small molecular weight compounds which are known to be present in breast milk may be important for growth and development.

17.5b. **Soy based formulas** (lactulose free) may be useful in the short term for **milk intolerance** but long term effects on nutrition have not been established.
(Health gain notation - 4 *"unknown"*)

17.5c. **Whey** or **casein hydrolysate** formulae may be appropriate for infants presenting with allergy to cow's milk protein but their use in prophylaxis has not been established.
(Health gain notation - 4 *"unknown"*)

17.5d. Current recommendations for **supplemental iron** are to supplement formula fed infants from birth and breast fed infants from 6 months of age.
(Health gain notation - 2 *"likely to be beneficial"*)

Statements on this page are derived from:

Atkinson, SA. Feeding the normal term infant: human milk and formula. Chapter 6, pp. 73-93 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992
(Type V evidence - expert opinion based on some descriptive studies and statistical information)

Date of completion of this document

10.1.98

18 MATERNAL SUPPORT DURING THE PUERPERIUM AND BEREAVEMENT

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

18.1 POSTNATAL SUPPORT

18.1a. Mothers should be given **consistent advice** after birth and **continuity of care** is advantageous [i,ii,iii].
(Health gain notation - 2 *"likely to be beneficial"*)

i. Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 1341
(Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 344-345);

ii. Joint working group of the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives. Communication standards - Obstetrics. London: Royal College of Obstetricians and Gynaecologists, June 1995
(Type V evidence - expert opinion);

iii. National Audit Commission. First class delivery. Improving maternity services in London: Audit Commission, 1997.
(Type IV evidence - observational studies)

18.1b. **Postnatal support programs** have no known risks and may have important benefits for socially disadvantaged mothers and their children. Further research is recommended [i].
(Health gain notation - 2 *"likely to be beneficial"*)

i. Hodnett ED. Home based social support for socially disadvantaged mothers. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 4.
(Type I evidence - systematic review)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
18.1c. It is *likely to be beneficial* to allow women **choice of length of postpartum stay** in hospital. Both randomised trials and observational studies have shown that few women or babies are readmitted to hospital after early discharge. Midwifery care continues in the home and this policy does not represent a saving in cost; Thus the woman should be allowed to choose [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1341-1344 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 345-346)
18.1d. Women who are **depressed** after childbirth should be provided with appropriate psychological support by professionals involved in their care, who have the time to listen and to talk [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 pp. 1433-1443 (Type V evidence - expert opinion. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 345-347)
18.2 BEREAVEMENT 18.2a. All those suffering **bereavement** subsequent to perinatal loss, miscarriage or termination of a pregnancy (for example after identification of a major fetal anomaly) require particular care and support from their caregivers. Guidelines for all staff and training should be an important aspect of local agreed policy and include the many aspects of grieving, burial or cremation arrangements, postmortem, good communication and appropriate referral for advice in future pregnancies, or with contraception [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Internal Review Group (See inside front cover) (Type V evidence - expert opinion)

Date of completion of this document

23.6.97

19 CARE OF THE LOW BIRTH WEIGHT BABY

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

An infant may be born small for gestational age, be born early or a combination of the two. The evidence regarding management of both suspected fetal growth impairment and of premature labour are considered in Chapters 13 and 14. Respiratory support is considered in Chapter 20.

The *statements*	The *evidence*
19a. Both premature labour and labour associated with an infant suspected to be small for gestational age should be **managed** in a unit with appropriate facilities and experienced staff [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Department of Health. Confidential Enquiry into Stillbirths and Deaths in Infancy 1993. London: HMSO,1996 (Type IV evidence - well designed non-experimental studies)
19b. Current data are not sufficient to justify a policy of **elective Caesarean Section** of all small babies [i]. (Health gain notation - 4 *"unknown"*)	**i.** Grant A. Elective versus selective Caesarean delivery of the small baby. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 2 (Type I evidence - systematic review)
19c. **Standards** for resuscitation of the newborn are available from expert groups and include [i,ii]: (Health gain notation - 1 *"beneficial"*) ■ the presence of someone skilled in neonatal resuscitation at the birth of all infants likely to be at risk; ■ oxygen for resuscitation of distressed newborn infants; ■ Naloxone for infants with respiratory depression due to narcotic administration before birth.	**i.** British Paediatric Society The Report of a BPA Working Party 'Neonatal Resuscitation'. London: BPA, 1993 (Type V evidence - expert opinion); **ii.** Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health and others. Joint advice for the resusitation of the newborn, 1997. London: RCOG, in press
19d. **Care** should be provided after birth in units staffed and equipped to the appropriate level for the needs of the child [i]. (Health gain notation - 1 *"beneficial"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. pp. 282, 335-345) (Type V evidence - expert opinion)
19e. Administration of **Vitamin K** to the infant (1 mg intramuscular) is currently an effective way of reducing the incidence of late haemorrhagic disease [i]. An association with childhood cancer has been reported but not substantiated. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** See statements 21.1a. and 21.1b. in Chapter 21: 'Prevention of neurological handicap'.

Date of completion of this document

23.6.97

20 NEONATAL RESPIRATORY SUPPORT

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

Neonatal respiratory support may be required for immature infants, for mature babies following asphyxia and/or infection and for those with a variety of congenital anomalies.

The *statements*	The *evidence*
20.1 RESPIRATORY SUPPORT	
20.1a. **Prophylactic post-extubation continuous positive airways pressure (CPAP)** for pre-term babies is effective in preventing failure of extubation and in reducing oxygen use. Further definition is needed of the gestational age and weight groups to whom these results apply [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Davis PG, Henderson-Smart DJ. Prophylactic post-extubation CPAP in preterm infants. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 2. (Type I evidence - systematic review)
20.1b. There is no evidence of the effectiveness of **elective endotracheal intubation** for very low birth weight infants (1500g) showing no signs of respiratory distress or depression, because of the associated risks [i]. (Health gain notation - 4 *"unknown"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. p.335 (Type II evidence - single, flawed, trial. See p.27 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992)
20.1c. The use of **exogenous surfactant therapy** in the newborn has proved the greatest advance in the care of preterm babies in the last decade. A 40% reduction in mortality and 50% reduction in pneumothorax has been reported in babies of less than 30 weeks [i]. (Health gain notation - 1 *"beneficial"*) Most studies suggest that prophylactic early treatment (as early as possible, and preferably within 2 hours) has a greater beneficial effect than later administration [i,ii,iii] although optimum regimes have been subjected to limited trial [i,ii].	**i.** Hennes HM, Lee MB, Rimm AA, Shapiro DL. Surfactant replacement therapy in respiratory distress syndrome: Meta-analysis of clinical trials of single-dose surfactant extracts. *American Journal of Diseases of Children* 1991;**145:**102-4 (Type I evidence - meta-analysis); **ii.** The OSIRIS Collaborative Group. Early versus delayed neonatal administration of a synthetic surfactant - the judgement of OSIRIS. *Lancet* 1992; **340:**1363-1369 (Type II evidence - randomised controlled trial of 6757 infants); **iii.** British Association of Perinatal Medicine Working Party. The use of exogenous surfactants in newborn infants. London:British Association of Perinatal Medicine, 1994 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
20.1d. **Natural surfactant extract** and synthetic surfactant in the treatment of established respiratory distress are both effective. Natural surfactant has a more rapid onset [i,ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Soll RF. Natural surfactant extract vs synthetic surfactant in the treatment of established respiratory distress syndrome. Cochrane database of systematic reviews. *Cochrane Library* 1997 Issue 1 (Type I evidence - systematic review); **ii.** Halliday HL. Overview of clinical trials comparing natural and synthetic surfactants. *Biology of the Neonate*. 1995; **67(suppl.1)**: 32-47 (Type I evidence - systematic review)
20.1e. **Expert guidance** is that two doses of **surfactant** should be given, 12 hours apart via the endotracheal tube. There is no additional benefit observed with the **routine** use of 3 or more doses [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** British Association of Perinatal Medicine Working Party. The use of exogenous surfactants in newborn infants. London: British Association of Perinatal Medicine. 1994 (Type V evidence - expert opinion)
20.1f. **Neonatal extracorporeal membrane oxygenation (ECMO)** is a complex and expensive technique. However, preliminary results demonstrate the clinical effectiveness of a **well staffed and organised neonatal ECMO service** when compared to conventional management in a similar tertiary centre for mature newborn infants (≥35 weeks gestation and ≥2 kg) with severe respiratory failure [i]. (Health gain notation - 2 *"likely to be beneficial"*) **caveat:** Infants who develop signs of intractable respiratory failure outside a tertiary unit (ie outside a unit suitably equipped and staffed for the intensive care of neonates) should be moved to such a unit at the earliest opportunity. Access to specialist care (with or without ECMO - which is currently only available in a few centres) is **the** most important consideration for these babies [ii]. (Health gain notation - 1 *"beneficial"*)	**i.** UK Collaborative ECMO Trial Group. UK collaborative randomised trial of neonatal extracorporeal membrane oxygenation. *Lancet.* 1996; **348**: 75-82 (Type II evidence - randomised controlled trial of 185 neonates); **ii.** Internal Review Group (See inside front cover) (Type V evidence - expert opinion and current good practice)
20.1g. **Nitric oxide** (NO) inhalation improves oxygenation in some infants with **persistent pulmonary hypertension** (PPHN) [i,ii]. In one trial, systemic oxygenation was doubled in 53% of the NO group but only 7% of the control group although the number of deaths was similar in both groups [ii]. Research is currently underway to determine which infants are most likely to benefit from NO and whether it is appropriate in pre-term, as well as term, infants [iii]. **caveat:** NO exposure may be significant in terms of toxicity, including human cancer risk [ii].	**i.** Mariani G, Barefield ES, Carlo WA. The role of nitric oxide in the treatment of neonatal pulmonary hypertension. *Current Opinion in Pediatrics.* 1996; **8(2):** 118-125 (Type I evidence - systematic review); **ii.** Roberts JD, Fineman JR, Morin FC et al. Inhaled nitric oxide and persistent pulmonary hypertension of the newborn. *New England Journal of Medicine.* 1997; **336(9)**: 605-610 (Type II evidence - randomised controlled trial of 58 full-term infants); **iii.** The INNOVO Trial. A multicentre randomized controlled trial currently in progress. Funded by the Medical Research Council. (Trial in progress)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

20.1h. **Nitric oxide** inhalation during conventional mechanical ventilation for **respiratory failure** reduced the use of extracorporeal membrane oxygenation (46% versus 64% dying or needing ECMO in the control group) [i] but had no apparent effect on mortality in full or nearly full term infants [i,ii] and the effect may be slightly worsened for infants with diaphragmatic hernia[ii]. A full evaluation, with longer term follow-up, is underway [iii].
(Health gain notation - 4 *"unknown"*)

i. The Inhaled Nitric Oxide Study Group. Ehrenkranz RA, Stork E, Gorjanc E, Verter J, Younes N *et al*. Inhaled nitric oxide in full-term and nearly full-term infants with hypoxic respiratory failure. *New England Journal of Medicine.* 1997; **336(9)**: 597-604
(Type II evidence - randomised controlled trial of 135 infants of (34 weeks);

ii. Finer NN, Barrington KJ. Nitric oxide in respiratory failure in the newborn infant. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 2.
(Type I evidence - systematic review. NB Incomplete review. A complete review will be available in a later edition of the *Cochrane Library*);

iii. The INNOVO Trial. A multicentre randomized controlled trial currently in progress. Funded by the Medical Research Council
(Trial in progress)

20.2 PREVENTION OF CHRONIC LUNG DISEASE

20.2a. A meta-analysis of randomised controlled trials of early (< 72 hours), moderately early (7-14 days) and late (>3 weeks) **corticosteroid** treatment showed that early or moderately early steroids facilitate weaning from the ventilator and increase survival without chronic lung disease (CLD), without affecting neonatal mortality. Risks of pulmonary air leak and patent ductus arteriosus were reduced although hypertension, hyperglycaemia and gastrointestinal bleeding were increased. Late steroids also facilitated weaning from the ventilator but did not reduce neonatal mortality[i].
(Health gain notation - 3 *"trade off between beneficial and adverse effects"*)

i. Halliday HL. A review of postnatal corticosteroids for treatment and prevention of chronic lung disease in the preterm infant. *Prenatal and Neonatal Medicine.* 1997; **2**: 1-12.
(Type I evidence - systematic review);

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

The *evidence*

20.2b. Meta-analysis of four studies suggests that there is no difference in mortality and **chronic lung disease (CLD)** between the routine use of **High Frequency Oscillatory Ventilation (HFOV)** and conventional ventilation in preterm infants with acute pulmonary dysfunction but there were trends towards an increase in intraventricular haemorrhage (IVH) or periventricular leucomalacia (PVL). In the subgroup of trials where a high volume strategy was used there was a significant reduction in CLD (Odds Ratio, OR = 0.39) and a similar effect was noted when surfactant was used (OR=0.43). For these subgroups, there were no differences in the odds of having IVH or PVL [i]. Further study is clearly indicated.
(Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)

caveat: The value of HFOV for 'rescue' therapy has not been subjected to trial.

i. Bhuta T, Henderson-Smart DJ. Elective high frequency oscillatory ventilation vs conventional ventilation in preterm infants with acute pulmonary dysfunction. Cochrane database of systematic reviews. *Cochrane Library.* 1997 Issue 2.
(Type I evidence - systematic review)

20.3 BRONCHOPULMONARY DYSPLASIA

20.3a. The value of **steroids** in producing short-term improvement in lung function during the treatment of **bronchopulmonary dysplasia** is established (pulmonary compliance improved in 64% of the treated group and 5% of the control group)[i] although long term efficacy and safety has yet to be demonstrated [i,ii].
(Health gain notation -1 *"beneficial"*)

i. Avery GB, Fletcher AB, Kaplan M, Brudno DS. Controlled trial of dexamethasone in respirator-dependent infants with bronchopulmonary dysplasia. *Paediatrics.* 1985; **75(1)**: 106-111
(Type II evidence - randomised controlled trial of 16 infants weighing (1500g);

ii. Ehrenkranz RA, Mercurio MR. Bronchopulmonary dysplasia. Chapter 18, pp. 399-424 in Sinclair JC, Bracken MB (eds.) Effective care of the newborn infant. Oxford: Oxford University Press, 1992
(Type I evidence - systematic review)

Date of completion of this document

9.1.98

21 PREVENTION OF NEUROLOGICAL HANDICAP

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

21.1 ALL INFANTS

Factors predicting a high risk of subsequent neurological handicap include: prematurity, perinatal asphyxia, haemorrhagic disease of the newborn, congenital anomalies and infections. The major determinants of neurological handicap in preterm survivors are intraventricular haemorrhage (IVH) (the incidence may be as high as 40% in very low birth-weight infants[i]) and cerebral ischaemia/atrophy. The aetiology is multifactorial but is associated with fetal distress and labour problems, and postnatal factors such as seizures, hypothermia and respiratory distress syndrome and its complications (see Chapter 20 'neonatal respiratory support').

Efforts to prevent preterm labour, the importance of transfer to an appropriate unit for specialized neonatal care, antenatal steroids and optimum resuscitation are discussed in Chapter 13 'premature labour' and Chapter 19 'care of the low birth weight baby'. Management must include sustained neurodevelopment follow up of all at risk infants. Much of the evidence relating to the reduction of neurological handicap in the pre-term infant is related to short term outcome measures such as improved appearance on cerebral ultrasound. Data on long-term clinical benefit are relatively scanty[i,ii].

i. Wells JT, Ment LR. Prevention of intraventricular hemorrhage in preterm infants. Early Human Development. 1995; **42**: 209-223. (Type I evidence - systematic review);

ii. Internal Review Group. (Type V evidence - expert opinion See inside front cover)

The *statements*

21.1a. Administration of **Vitamin K** (1mg intramuscular) to the infant is currently an effective way of reducing the incidence of **haemorrhagic disease of the newborn,** of which, intracranial haemorrhage is one of the most important manifestations [i].
(Health gain notation - 2 *"likely to be beneficial"*)
caveat: Reports of an association between intramuscular Vitamin K and childhood cancer [ii] have not been substantiated [i,iii]. While there is no question that Vitamin K is an important treatment for those babies at highest risk of haemorrhagic disease, further trials of the value of Vitamin K in low risk children should be encouraged.

The *evidence*

i. Brousson MA, Klein MC. Controversies surrounding the administration of Vitamin K to newborns: a review' *Canadian Medical Association Journal.* 1996; 154: 307-315
(Type I evidence - systematic review);

ii. Golding J, Greenwood R, Birmingham K, Mott M. Childhood Cancer, intramuscular Vitamin K, and pethidine given during labour *British Medical Journal* 1992; 305: 341-346
(Type IV evidence - case note study of 195 children with cancer);

iii. Klebanoff MA, Read JS, Mills JL, Shiono PH. The risk of childhood cancer after neonatal exposure to vitamin K. *New England Journal of Medicine.* 1993; 329(13): 905-908
(Type IV evidence - case control study of 48 children with cancer each matched with 5 randomly selected controls)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
21.1b. **Current professional recommendations remain** [i]: (Health gain notation - 1 "beneficial"). ■ Vitamin K is given by mouth to **all** infants on the day of birth (500µg konakion® as a single dose or 2 doses of 250µg) ■ Infants who are **breast fed** are given **further** doses of vitamin K at daily (50µg) or weekly (200µg) doses for 26 weeks; or at the 7-10 day (500µg) and 4-6 week (500µg) check. ■ If the oral route is not available or thought to be unreliable, that vitamin K is given by intramuscular injection (100µg). Oral regimens avoid the trauma of injection, the potential risk of high blood concentrations (and the unsubstantiated risk of cancer - see statement 21.1a). However, the efficacy of multiple oral doses is not well established and the only licensed oral preparation is a multidose glass ampoule [i,ii]. Further recommendations from the Department of Health are due early in 1998 [iii].	**i.** British Paediatric Association. Vitamin K prophylaxis in infancy. London: British Paediatric Association, 25 August 1992. (Type V evidence - expert opinion); **ii.** Barton JS, Tripp JH, McNinch AW. Neonatal vitamin K prophylaxis in the British Isles: Current practice and trends. *British Medical Journal.* 1995; **310**: 632-633. (Type IV evidence - questionnaire to neonatal units - 98% response rate); **iii.** As a letter from the Chief Medical and Nursing Officers; Personal communication, Department of Health.
21.1c. **Ultrasound** is effective in the diagnosis of intraventricular haemorrhage [i]. (Health gain notation - 1 "beneficial")	**i.** Koppe JG. Prevention of brain haemorrhage and ischaemic injury in premature babies. *Lancet.* 1996; **348:** 208-209 (Type V evidence - expert commentary)
21.2 The PRETERM INFANT	
21.2a. The **prophylactic administration of indomethacin** to the preterm infant significantly reduces the incidence of intraventricular haemorrhage (8% with grades 3 or 4 IVH versus 13% in the control group) and symptomatic patent ductus arteriosus in infants weighing less than 1750g at birth [i] and does not result in adverse cognitive or motor outcomes at 36 months corrected age of very low birthweight infants (600-1250g) [ii]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** An increased risk of impaired renal function and necrotizing enterocolitis has been reported [i,iii].	**i.** Fowlie PW. Prophylactic indomethacin: systematic review and meta-analysis. *Archives of Disease in Childhood.* 1996; **74(2)**: F81-F87 (Type I evidence - systematic review and meta-analysis); **ii.** Ment LA, Vohr B, Oh W et al. Neurodevelopmental outcome at 36 months' corrected age of preterm infants in the multicenter indomethacin intraventricular hemorrhage prevention trial. *Pediatrics.* 1996; **98(4)**: 714-718 (Type III evidence - randomised prospective trial of 431 neonates); **iii.** Grosfeld JL, Chaet M, Molinari F et al. Increased risk of necrotizing enterocolitis in premature infants with patent ductus arteriosus treated with indomethacin. *Annals of Surgery.* 1996; **224(3)**: 350-355 (Type III evidence - case study of 252 infants compared with 764 matched controls)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
21.2b. **Vitamin E** was initially recommended in the prevention of retinopathy of prematurity although a review of 9 randomised trials did not reveal a statistically significant reduction [i]. However, in the same treated group, a small reduction in some forms of intraventricular haemorrhage was found. The clinical value of this reduction has been questioned and further studies are needed, concerning both its value in reducing neurological handicap and retinopathy of prematurity [ii]. (Health gain notation - 4 *"unknown"*)	**i.** Law MR, Wijewardene K, Wald NJ. Is routine vitamin E administration justified in very low birthweight infants? *Developmental Medicine and Child Neurology.* 1990; **32**: 442-450 (Type I evidence - systematic review); **ii.** Wells JT, Ment LR. Prevention of intraventricular hemorrhage in preterm infants (p.222) *Early Human Development.* 1995; **42:** 209-233 (Type I evidence - systematic review)
21.2c There is **no evidence that the routine early use of fresh frozen plasma** (as a plasma expander in infants of gestational age <32 weeks) is effective in reducing the risk of neurological handicap [i]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Northern Neonatal Nursing Initiative Trial Group 'Randomized trial of prophylactic early fresh-frozen plasma or gelatin or glucose in preterm babies: outcome at 2 years *Lancet* 1996; **348:** 229-232 (Type II evidence - randomised controlled trial of 776 babies)
21.2d Trials of **antenatal administration of phenobarbital** have shown a minimal reduction in the incidence of intraventricular haemorrhage with an increase in the incidence of respiratory distress and a requirement for ventilation [i,ii]. (Health gain notation - 5 *"unlikely to be beneficial"*)	**i.** Horbar JD. Prevention of periventricular-intraventricular hemorrhage. In: Effective care of the newborn infant. Editors. J Sinclair and MB Bracken. Oxford: Oxford University Press, 1992 pp.565-566 (Type I evidence - systematic review); **ii.** Doyle L. Antenatal phenobarbitone and neonatal outcome. *Lancet* 1996; 348: 975-6 (Type I evidence - review including a meta-analysis and several trials)
21.2e The administration of **phenobarbital to the newborn** has shown no significant decrease in the incidence of intraventricular haemorrhage [i]. (Health gain notation - 5. *"unlikely to be beneficial"*)	**i.** Horbar JD. Prevention of periventricular-intraventricular hemorrhage. In: Effective care of the newborn infant. Editors. J Sinclair and MBBracken. Oxford: Oxford University Press, 1992 pp. 566-568 (Type I evidence - systematic review)
21.2f. **Sodium ethamsylate** is widely used to reduce capillary bleeding in surgery. A small reduction of the overall incidence of intraventricular haemorrhage has been demonstrated associated with a non-significant improvement of neurological outcome in the treated group [i]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Wells JT, Ment LR. Prevention of intraventricular hemorrhage in preterm infants *Early Human Development.* 1995; **42:** 209-233 (Type I evidence - systematic review)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
21.2g. **Antenatal steroids** have a significant effect in reducing the incidence of respiratory distress syndrome (RDS) and, in addition, have been shown to be associated with a **reduced incidence of intraventricular haemorrhage** (Odds Ratio, 0.49) [i]. This finding may be related to the reduction of RDS or a direct effect of steroids on the central nervous system [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*) **caveat:** A greater incidence of necrotizing enterocolitis was observed in several studies [i].	**i.** Wells JT, Ment LR. Prevention of intraventricular hemorrhage in preterm infants *Early Human Development.* 1995; **42:** 209-233 (Type I evidence - systematic review)
21.2h **Surfactant,** while known to be effective in the treatment of respiratory distress syndrome, has no significant effect in reducing the incidence of intraventricular haemorrhage [i]. (Health gain notation -5 *"unlikely to be beneficial"*) **caveat:** Its combined use with steroids may have benefits [i]. (Health gain notation - 4 *"unknown"*)	**i.** Wells JT, Ment LR. Prevention of intraventricular hemorrhage in preterm infants *Early Human Development.* 1995; **42:** 209-233 (Type I evidence - systematic review)
21.2i. Observational study suggests that in utero exposure to **magnesium sulphate** is associated with a lower prevalence of cerebral palsy in infants weighing < 1500g. In view of the anticipated widespread adoption of magnesium sulphate in the management of fulminating pregnancy induced hypertension, further evidence should become available [i]. (Health gain notation - 4 *"unknown"*)	**i.** Nelson KB, Grether JK. Can magnesium sulfate reduce the risk of cerebral palsy in very low birthweight infants? *Pediatrics.* 1995: **95(2):** 263-269 (Type IV evidence - observational study of 636 children)

Date of completion of this document

27.10.97

22 CONGENITAL ABNORMALITIES

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

In considering the prevalence of any congenital anomaly it is important to include not only live and stillborn infants but also spontaneous miscarriage and pregnancies terminated subsequent to antenatal diagnosis of a major abnormality which will, for many families, represent an equally great if different tragedy to the survival of a handicapped child. Antenatal diagnosis of abnormality allows parents not only the option of termination but also time to plan care for the child [i].

Reported prevalence rates (underestimates based on a voluntary notification scheme of live births and terminations) are:

All congenital malformations - 84.9 per 10000 (1993) [ii];

Major structural abnormality - 18 per 10000(1993) [ii];

Down's syndrome - 0.92 per 1000 (1993) [iii];

Neural tube defects - 0.8 per 1000 (1992) [iv];

Heart malformations - 4.7 per 1000 live births (1985-1990) [v].

i. The OPCS monitoring scheme for congenital malformations. Occasional paper 43. London: HMSO, 1995 (Type V evidence - expert opinion)

ii. Office for National Statistics. Congenital malformation statistics: notifications 1993. Series MB3 No. 9 London: HMSO, 1996;

iii. Alberman E, Mutton D, Ide R, Nicholson A, Borrow M. Down's syndrome births and pregnancy terminations in 1989-1993: preliminary findings. British Journal of Obstetrics and Gynaecology. 1995; 102: 445-447;

iv. Hey K, O'Donnell M, Murphy M, Jones N, Botting B. Use of local neural tube defect registers to interpret national trends. Archives of disease in childhood. 1991; 71: F198-F202;

v. Abu-Harb M, Hey E, Wren C. Death in infancy from unrecognised congenital heart disease. Archives of disease in children. 1994; 71: 3-7 (nos. ii-v : Type IV evidence - statistical information)

The *statements*	The *evidence*
22a. **Population screening** is conventionally offered for chromosome abnormalities and neural tube defects. The potential benefits and adverse effects of serum testing and/or ultrasound should be available for parents, verbally and with the help of literature, so that informed decisions can be made [i]. (Health gain notation - 3 *"trade-off between beneficial and adverse effects"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. pp. 45-51 (Type V evidence - expert opinion)
22b. All professionals who offer antenatal screening require **education** and ongoing training in a rapidly changing field [i]. (Health gain notation - 2 *"Likely to be beneficial"*)	**i.** Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press, 1995. pp. 46-47 (Type V evidence - expert opinion)

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*	The *evidence*
22c. **Ultrasound** is likely to identify the majority of major abnormalities [i,ii]. Recent developments in technique and technology mean that trials only a few years old are out of date. All new techniques such as the use of markers (nuchal thickness) for first trimester diagnosis of chromosomal abnormality should be the subject of controlled trial before adoption into practice [ii]. (Health gain notation - 2 *"likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989 p. 372 (Type IV evidence - observational studies. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth. 2nd ed. Oxford: Oxford University Press. 1995. p. 47-48); **ii.** Royal College of Obstetricians and Gynaecologists. Report of the working party on ultrasound screening for fetal abnormalities. Consultation document. London: RCOG, March 1997 (Type V evidence - expert opinion)
22d. Adoption of **population screening** by an **18-20 week scan** for structural abnormality has been widely debated [i]. (Health gain notation - 4 *"unknown"*)	**i.** Royal College of Obstetricians and Gynaecologists. Report of the working party on ultrasound screening for fetal abnormalities. Consultation document. London: RCOG, March 1997 (Type I evidence - systematic review)
22e. It is *beneficial* to provide pre- and peri-conceptual **folic acid supplementation** to prevent recurrent neural tube defects [i]. (Health gain notation - 1 *"beneficial"*)	**i.** MRC Vitamin Study Research Group. Prevention of neural tube defects: Results of the Medical Research Council vitamin study. *Lancet.* 1991; **338:** 131-137 (Type II evidence - randomised controlled trial, 1817 women)
22f. The evidence indicates that **rubella vaccination** in the early postpartum period for seronegative women is safe and effective. The opportunity for immunization should not be missed [i]. (Health gain notation - 2 *"Likely to be beneficial"*)	**i.** Chalmers I, Enkin M, Keirse MJNC. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989. pp. 541-542 (Type I evidence - systematic review. Summary in Enkin M, Keirse MJNC, Renfrew M, Neilson J. A guide to effective care in pregnancy and childbirth 2nd ed. Oxford:Oxford University Press, 1995. pp. 117-119)
22g. Recommendations for the optimum performance of **amniocentesis** are available [i,ii]. (Health gain notation - 2 *"Likely to be beneficial"*)	**i.** Royal College of Obstetricians and Gynaecologists. Amniocentesis. Guideline No.8. London: Royal College of Obstetricians and Gynaecologists, 1996 (Type V evidence - expert opinon); **ii.** Benbow A, Semple D, Maresh M. Royal College of Obstetricians and Gynaecologists Clinical Audit Unit. Effective procedures in maternity care suitable for audit. London: Royal College of Obstetricians and Gynaecologists, June 1997. pp. 11-14 (Review of effective procedures, classified according to evidence type)

Date of completion of this document

23.6.97

23 SUDDEN INFANT DEATH SYNDROME

Users are advised to consult the supporting evidence for a consideration of all the implications of a recommendation.

The *statements*

23a. The risk of SIDS is **increased** by a **prone or side sleeping position** and loose bedding which can slip over the baby's head. A sleeping position on the back is recommended [i,ii,iii].
(Health gain notation - 1 *"beneficial"*)

The *evidence*

i. Flemming PJ *et al.* Environment of infant during sleep and risk of the sudden infant death syndrome; results of 1993-5 case-control study for confidential enquiry into stillbirths and deaths in infancy. *British Medical Journa*l 1996;**313:**191-5
(Type IV evidence - case control study);

ii. Guntheroth MD, Spiers PS. Sleeping prone and the risk of sudden infant death syndrome. *Journal of the American Medical Association* 1992; **267:** 2359-62
(Type IV evidence - review of observational studies);

iii. Confidential Enquiry into Stillbirths and Deaths in Infancy 1 Jan-31 December 1994. London: Department of Health, 1996. Chapters 4-9.
(Type IV evidence - statistical information)

23b Exposure of babies to **tobacco smoke** from other members of the household before or after birth increases the risk of death: the greater the exposure the higher the risk [i,ii]. 62.6% of mothers with babies who died from sudden infant death smoked as compared to 25.1% of mothers in the case-matched control group [i].
(Health gain notation - 6 *"likely to be harmful"*)

i. Blair PS, Fleming PJ, Bensley D *et al.* Smoking and the sudden infant death syndrome. *British Medical Journal* 1996;**313:**195-8
(Type IV evidence - case matched control of 195 babies who died and 780 case-matched controls);

ii. Poets CF, Schlaud M, Kleemann QJ *et al*. Sudden infant death and maternal cigarette smoking: results from the Lower Saxony Perinatal Working Group. *European Journal of Paediatrics* 1995;**154**:326-9
(Type IV evidence - statistical information)

23c. **Health promotion campaigns** directed towards the reduction of sudden infant death syndrome should be aimed specifically at more socially deprived families who do not share in the general fall in the incidence of this condition [i].
(Health gain notation - 2 *"likely to be beneficial"*)

i. Confidential Enquiry into Stillbirths and Deaths in Infancy. 1 January - 31 December 1994. London: Department of Health, 1996. p. 119
(Type IV evidence - statistical information)

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27.10.97

APPENDIX I: STATISTICAL INFORMATION SOURCES & AUDIT

The purpose of **clinical information** is in the assessment and analysis of health status and needs of the population served, outcome measures and the application of resources. The importance and the relative paucity of maternal and perinatal data have been stressed by several influential groups [1-3].

Data on every registrable birth to women resident in Wales is currently available from the Welsh Office and the Office of National Statistics (ONS, previously OPCS). The ONS publishes data taken from birth notifications and registration of deaths relating to district of residence, including outcome and birthweight [4]. Both the Welsh Office and ONS publish other useful summary information [5-9].

Birth notification initiates a child's record on the **Child Health Computer Database.** The Child Health System (CHS), established in 1977 to manage the childhood immunisation and vaccination programme, also collects data on child health surveillance and for children with special needs [10]. There are plans to upgrade the system to make the valuable data it contains more easily accessible to all professional users. It has been shown to be capable, even on its current configuration, of producing a minimal maternity and perinatal data set for Wales.

Detailed analysis on mortality is available through reports on maternal deaths [2] and the All Wales Perinatal Survey [11] and CESDI [3] which report a detailed analysis of all fetal and infant deaths from 20 weeks gestation to 1 year of age.

Denominator and morbidity data are more difficult to obtain. The Patient Episode Database for Wales (PEDW) provides only limited information on hospital episodes [12] as do the National and Welsh Morbidity Studies of General Practice activity [13-14].

1. Clinical Standards Advisory Group. Women in normal labour. Report of a CSAG Committee. Tindall VR (Chair). London: HMSO, 1995;
2. Department of Health and Others. Report on Confidential Enquiries into Maternal Deaths in the United Kingdom. 1991-1993. London: HMSO, 1996
3. Departments of Health. National Advisory Body. Confidential enquiry into stillbirths and deaths in infancy. Annual report for 1 January - 31 December 1993. Part II. London: Department of Health, 1996;
4. Office for National Statistics. *Monitor Population and Health.* DH3 - Annual Publications. London: Office for National Statistics;
5. Office for National Statistics. *Key Population and Vital Statistics: Local and Health Authority Areas.* 1996; *Mortality Statistics*. See 4.;
6. Central Statistical Office. *Annual Abstracts of Statistics. London*: HMSO;
7. Office for National Statistics. *Regional Trends.* See 4.;
8. Botting B, Crawley R. The health of our children. Dicennial supplement. London: HMSO, 1995;
9. Government Statistical Services. *Health Statistics Wales.* Cardiff: Welsh Office, 1995;
10. Welsh Health Common Services Authority. Report on maternity data/information aspects of the Child Health Data System. Cardiff: WCHSA, 1996;
11. Cartlidge PHT. All Wales perinatal survey and confidential enquiry into stillbirths and deaths in infancy. Annual Report 1995. Cardiff: Welsh Office, 1996
12. WCHSA Information Group. Patient Episode Database for Wales. Cardiff: WCHSA, 1996;
13. McCormick A, OPCS. Morbidity Statistics from General Practice. Fourth National Study 1991-1992 London: Office of Population Censuses and Surveys, 1995;
14. Rogers C, Evans E. Personal Communication regarding the General Practice Morbidity Database;

Other local or limited data sets do exist, or are being developed, and may be taken as models for other developments:

a) All Wales Congenital Anomaly Service - a register of all congenital anomalies and of ante-natal screening used in diagnosis - to be linked with the existing Eurocat register and with the ONS congenital abnormality register [15-16].

b) Audit of Cerebral Palsy Wales [17].

c) Follow up of preterm infants (1500 g or less). The importance of this study relates to both the high investment of resources and the potential for handicap among these children. This problem has been reviewed by a working group of the NPEU [18-21].

d) Sudden Infant Death: Wales has been part of the case ascertainment of the national CESDI study.

e) Detailed population based maternity/perinatal data are currently available in parts of Wales, in West and South Glamorgan and in West Wales. Each of these Trusts are in the process of revising or upgrading their computer platforms.

Certain principles relate to all data collection [22]:

- It must have relevance to those who provide the information and should, wherever possible, be obtained as a by-product of clinical, operational IT systems.
- It must be timely
- It must be population based - This is especially relevant in the field of maternity and perinatal care where changing practice and more emphasis on home based care, require ongoing assessment
- It must be complete to prevent bias
- Data sources should use common definitions
- It should be possible to transfer information between systems

AUDIT

Recommendations for audit in maternity care are summarised in a document from the Royal College of Obstetricians and Gynaecologists Clinical Audit Unit [23].

15. OPCS. Working Group of Registrar General's Advisory Committee. Chair: Professor Alberman. The OPCS monitoring scheme for congenital malformations: a review by a working group of the Registrar General's Medical Advisory Group. Occasional paper No. 43 London: Office of Population Censuses and Surveys, 1995;

16. Cotter M, Elder S, Lawrence M. Wales' participation in the Eurocat surveillance of congenital malformations. Cardiff: WCHSA, 1996

17. Penny L, Sibert J. Audit of cerebral palsy for children in Wales. Final Report. December 1994;

18. National Perinatal Epidemiology Unit, Working Groups convened by NPEU and Oxford Regional Health Authority. Disability and perinatal care - measurement of health status at two years. Oxford: NPEU, March 1994;

19. Cartlidge PHT, Stewart JH. Survival of very low birthweight and very preterm infants in a geographically defined population. *Acta Paediatrics.* 1997; **86:** 105-110.

20. Tin W, Wariyau U, Hey E, Northern Neonatal Network. Changing prognosis for babies of less than 28 weeks gestation in the North of England between 1983 and 1994. *British Medical Journa*l 1997; **314:** 107-111;

21. Escobar GJ, Littenberg B, Petitti DB. Outcome among surviving very low birth weight infants: a meta-analysis. *Archives of Disease in Childhoo*d. 1991; **66**: 204-211

22. Accepted good practice; and see Mason A, Morrison V. Walk don't run. A collection of essays on information issues published to honour Mrs Edith Körner CBE; Chairman of the NHS/DHSS Health Service Information Steering Group 1980-1984. London: King Edward's Hospital Fund, 1985

23. Benbow A, Semple D, Maresh M. Royal College of Obstetricians and Gynaecologists Clinical Audit Unit. Effective procedures in maternity care suitable for audit. London: Royal College of Obstetricians and Gynaecologists, June 1997.

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