A Cochrane Pocketbook: Pregnancy and Childbirth

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Foreword

The Cochrane Handbook: Pregnancy and Childbirth

For most people the day a child is born is a time of joy and celebration. It is a moment when families are afforded a brief glimpse into the future, and it is filled with hope and promise. In much of the world, however, this vision is far from reality. For women in many countries in the developing world, the day when she gives birth is a life-threatening event. For want of basic, known technologies and care over half a million women die unnecessarily in childbirth each year. The facts are stark: a woman in Sweden faces a one in 30,000 chance of dying in childbirth, while a woman in Sierra Leone faces chances of dying as high as one in six. When a mother dies, her newborn baby has much less chance of surviving the first weeks. These gross inequities underscore the fact that the right to health of childbearing women and their babies globally is far from being assured.

What does it mean, precisely, to say that health is a human right? In 2002, during my tenure as UN High Commissioner for Human Rights, I welcomed the appointment of a Special Rapporteur on the Right to Health, Paul Hunt, who has defined the right to health in the following way:

“The right to health can be understood as a right to an effective and integrated health system encompassing health care and the underlying determinants of health, which is responsive to national and local priorities, and accessible to all. In other words, the health system must encompass both health care and the underlying determinants of health, such as adequate sanitation and safe drinking water. It must be accessible to all. Not just the wealthy, but those living in poverty. Not just majority ethnic groups, but minorities and indigenous peoples too. Not just those living
in urban areas, but also remote villagers. The health system has to be accessible to all disadvantaged individuals and communities.”

To address the right to safe motherhood will require both strong political will and practical interventions based on evidence of effectiveness.

The Cochrane Pocketbook on Pregnancy and Childbirth aims to put the best evidence of effectiveness of pregnancy and childbirth interventions in the hands of those who can advocate for change—public and private decision makers, as well as health workers responsible for the care of childbearing women. The Cochrane Pocketbook authors and editors are concerned both with ensuring that health-preserving procedures are accessible to women as well as the elimination of ineffective and humiliating traditional procedures.

This book provides user-friendly access both to the Cochrane Library and to the World Health Organization Reproductive Health Library, which is distributed free of charge to health workers in low income countries globally in English, Spanish, French and Chinese.

It would be a great achievement to put these Cochrane Pocketbooks in the hands of health workers the world over. Let us join together to ensure that for every woman, anywhere in the world, the day she gives birth is one of the most hopeful days of her life.

Mary Robinson  
*President*  
Realizing Rights  
Former President of Ireland, former UN High Commissioner for Human Rights  
*December 18, 2007*
Preface

Care for pregnant women differs fundamentally from most other medical endeavours. ‘Routine’ care during pregnancy and birth interferes in the lives of healthy people, and in a process which has the potential to be an important life experience. It is difficult to measure the extent to which our efforts may, for example, disturb the development of a confident, nurturing relationship between mother and baby. The harmful effects we measure in randomised trials are limited to those we have predicted may occur. Sometimes after many years unexpected harmful effects surface only because they are relatively common, or striking in their presentation. Many unanticipated harmful effects probably never come to light.

For these reasons, interventions in pregnancy and childbirth need to be subjected to special scrutiny. Our guiding principle is to advise no interference in the process of pregnancy and childbirth unless there is compelling evidence that the intervention has worthwhile benefits for the mother and/or her baby – only then is there a good chance that benefits will outweigh both known adverse effects and those which may not have been thought of.

All pregnant women deserve the best possible care and advice founded on the best available evidence of effectiveness, applied with understanding, empathy and a philosophy of respect for the process of normal pregnancy and birth.

The Cochrane Library is the leading source of healthcare effectiveness reviews. This pocketbook provides quick access to evidence from Cochrane systematic reviews. We have arranged the contents in a logical sequence of chapters, making it easy for users to locate a topic and browse the available evidence. Users of The Cochrane Library will find it a convenient way to locate reviews of interest, and then use the ‘CD’ code provided to pick up the full electronic review in The Cochrane Library.
Where no Cochrane reviews of effectiveness are currently available, we have described, for completeness, options for care which are in common use. It is clear from the text that these measures are referred to without adequate evidence of effectiveness or hazards.

We have kept references to a minimum, as the original Cochrane reviews are extensively referenced.

Chapter introductions and linking paragraphs provide context and flow, but we have purposefully kept them brief to avoid detracting from the primary objective of the book: providing evidence summaries based on Cochrane reviews in a compact, accessible format.

The information in this book is a distillation of 3 decades of work by hundreds of collaborators from every corner of the globe. The spirit of collaboration which has made this possible has indeed been remarkable. We trust that readers will find it a valuable contribution to the personal health choices of those in their care, or themselves.
How to Use This Book

What is evidence?

Then Daniel said to the steward.... “test your servants for ten days; let us be given vegetables to eat and water to drink. Then let our appearance and the appearance of the youths who eat the king’s rich food be observed by you....” So he hearkened to them in this matter, and tested them for ten days. At the end of ten days it was seen that they were better in appearance and fatter in flesh than all the youths who ate the king’s rich food. Daniel 1: 11–15.

The results of David’s experiment were impressive. However, the well-being of those eating vegetables and water may have been due to factors other than their diet. This uncertainty could have been reduced by allocating the alternative diets at random rather than to a preselected group.

Random allocation is the only known method of ensuring that different outcomes in groups of women receiving a particular treatment are the result of the treatment, rather than some pre-existing characteristic.

The focus of this pocketbook is the effect of interventions on the health and wellbeing of pregnant women and their babies, derived from Cochrane systematic reviews. These are based almost entirely on evidence from randomised controlled trials (RCTs). Our purpose is not to recommend specific methods of care, but to provide easy access to high-quality evidence which can contribute to clinical decision-making and the development of management guidelines and protocols.

We have taken care to ensure the quality of information in this book. However, the responsibility for use of this information for clinical care or other purposes rests with the reader.
The Cochrane Pregnancy and Childbirth Group

The foundations upon which the Cochrane Collaboration is based were laid by Iain Chalmers and colleagues in Oxford in the late 1970s. These incorporated the following principles:

- Randomisation is the most reliable method of evaluating alternative forms of care.
- To avoid bias, reviews of randomised trials must follow a pre-specified protocol and include all trials on the topic conducted globally which meet quality criteria specified in the protocol.
- Reviews need to be updated regularly and disseminated quickly.
- Global collaboration is necessary to achieve these goals.

Handsearching of journals to identify all randomised trials was an essential basis for this work, and was commenced with a grant from WHO in 1978. Some subsequent landmarks were:

- A classified bibliography of more than 3000 trials, prepared by the National Perinatal Epidemiology Unit in Oxford, was published in 1985. This formed the basis for an electronic database, the ‘Oxford Database of Perinatal Trials’.
- In 1995, the administrative base of the Pregnancy and Childbirth Review Group, led by Jim Neilson, moved from Oxford to Liverpool. The administrative support is ably led by Sonja Henderson. The Group’s systematic reviews are published in The Cochrane Library.
- Current editors are: Jim Neilson (UK), Zarko Alfırevic (UK), Caroline Crowther (Australia), Lelia Duley (UK), Metin Gulmezoglu (Switzerland), Ellen Hodnett (Canada) and Justus Hofmeyr (South Africa).
- Selected reviews with commentaries providing a low-income country context and video teaching aids are published in parallel in the World Health Organization ‘Reproductive Health Library’ and distributed globally in English, Spanish, French and Chinese (RHL@who.int; http://www.rhlibrary.com).
Scope of this book

The focus of this book is care, based on best evidence. For more details of aetiology, pathophysiology, diagnosis and epidemiology, please consult the background sections of the relevant Cochrane reviews, and standard textbooks. We have included the abstracts of Cochrane reviews relevant to the care of women and their babies before, during and after pregnancy. These include the Cochrane Pregnancy and Childbirth Group’s reviews, as well as selected reviews from the following Cochrane Review Groups: Anaesthesia; Consumers and Communication; Depression, Anxiety and Neurosis; Developmental, Psychosocial and Learning Problems; Drugs and Alcohol; Effective Practice and Organisation of Care; Epilepsy; Fertility Regulation; Gynaecological Cancer; HIV/AIDS; Infectious Diseases; Neonatal; Oral Health; Schizophrenia; and Wounds. We acknowledge with thanks the contribution of these Cochrane Review Groups.

Methods for the Cochrane Pregnancy and Childbirth Group reviews

The Cochrane Pregnancy and Childbirth Group assembles, maintains and administers a register of trials, containing more than 12,000 reports of controlled trials relevant to the care of pregnant women and their babies. About 800 new records are added annually. Review authors conduct additional searches such as electronic searches, reference lists in key papers, and by personal contact with experts in the field.

Review authors set the quality criteria for inclusion of trials in the review (limited to randomised and sometimes quasi-randomised trials) and follow the methods described in the Cochrane Handbook of Systematic Reviews of Interventions (http://www.cochrane.org/resources/handbook/) and additional methods advised by the Review Group as described in the ‘Methods used in reviews’ section of the information about the Pregnancy and Childbirth Group in The Cochrane Library. The authors pre-specify outcomes in the protocol. They extract data and analyse them using Review Manager software. Generally, for dichotomous outcomes, they use relative risks (risk ratios) and sometimes odds ratios, with 95% confidence intervals. For continuous outcomes, they use weighted mean difference or standardised mean difference, with 95% confidence intervals.
For more detail, please consult the Cochrane Pregnancy and Childbirth Group’s section in ‘About the Cochrane Collaboration (About; Cochrane Groups)’ in The Cochrane Library. An explanation of common statistical terms appears on page xxi.

Abridgement of the Cochrane Pregnancy and Childbirth abstracts in this book

To avoid repetition, we have abridged the methods of the abstracts as described by the authors of the individual reviews. The following elements are common to many abstracts:

‘Search strategy
We searched the Cochrane Pregnancy and Childbirth Group’s Trials Register [date].

Selection criteria
Randomised trials of [the study interventions].

Data collection and analysis
We independently assessed trial quality and extracted data. We performed double-data entry. If necessary, we contacted study authors to request additional information.’

In this book we have abridged the above three headings and descriptions as:

‘Methods: ‘Standard PCG methods (see page xvii). Search date ....’
(This is followed, if necessary, by additional methods specific to the review).

Systematic review protocols

We have included abridged background and objectives of protocols published in The Cochrane Library for reviews which are still in progress. Please consult The Cochrane Library (using the CD number to search), as these reviews may have been completed since going to press with this book.
Effectiveness icons

To highlight reviews with clear evidence of benefit or harm, we have adapted the system of icons used by the WOMBAT collaboration (www.wombatcollaboration.net).

😊 - Benefits likely to outweigh harms in at least some circumstances
😊 - Likely to be ineffective or harmful
😊 - Benefits versus harms equivocal

How to locate the original review

In The Cochrane Library:
Each review or protocol has a ‘CD’ number. Enter the ‘CD…….’ number in the search window of The Cochrane Library and ‘Search all text’, to get directly to the review or protocol.

The Cochrane Library is available on CD-ROM, as well as online through Wiley InterScience at http://www.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME or through the Cochrane Collaboration’s website at http://www.cochrane.org/index.htm.

In the WHO Reproductive Health Library:
If the ‘CD’ number is followed by ‘(in RHL11)’, the review is also available in the WHO Reproductive Health Library issue 11. Search the RHL using the title, or part of it. Subsequent issues of the RHL will include additional reviews (RHL@who.int; http://www.rhlibrary.com).
A brief guide to the format of results in Cochrane reviews

- This figure shows the rates of pre-eclampsia in all the included trials comparing calcium supplementation during pregnancy with placebo.
- In the trial by Crowther et al (1999), pre-eclampsia occurred in 10 out of 227 women who received calcium, compared with 23 out of 223 who received placebo.
- In this trial the **relative risk** (RR) of developing pre-eclampsia in the calcium group compared with the placebo group was (10/227 ÷ 23/229) = 0.44 (44%). This is a **risk reduction** of (1 – 0.44) = 56%.
- We are 95% certain that the “true” relative risk lies somewhere between 0.21 and 0.90 (the 95% **confidence interval** (CI)).
- The whole range of the 95% confidence interval is <1. The bar representing the CI does not cross the “no effect” line (RR = 1 = no effect). This indicates that the reduction in pre-eclampsia with calcium is statistically significant.

![Figure 1: Displaying categorical data](image-url)
This figure shows the average haematocrit of preterm babies randomly allocated to early cord clamping, compared with delayed cord clamping.

In the trial by McDonnell (1997), 23 babies with early cord clamping had an average haematocrit of 52.9% (standard deviation 7.1); another 23 who received delayed cord clamping had an average haematocrit of 55.0% (standard deviation 7.7).

The difference between these means (early minus delayed) was –2.1%.

There was no heterogeneity between the trials ($I^2 = 0\%$).

Thus the trials were combined using a fixed-effects model.

The combined difference between the means for all three trials, weighted for the trial sizes, was –3.21%.

We can be 95% certain that the true difference in the means lies somewhere between –5.62 and –0.80.

As the whole range of the 95% confidence interval lies in the same direction (–ve) (the diamond representing the confidence interval does not cross the zero or no effect line), this difference is statistically significant at the 5% level.

Figure 2: Continuous data (measurements, as opposed to either–or outcomes)

Notes on the orientation of the analysis figures

Which intervention is chosen as the ‘treatment’ intervention?

The ‘treatment’ or experimental intervention is listed in the first columns (to the left). In the example above, it may be argued that since early clamping of the umbilical cord is current routine practice, delayed clamping should be regarded as the experimental intervention. However, we prefer to regard the intervention which deviates most from the ‘normal’ as the experimental one, consistent with the philosophy that in childbirth any deviation from the normal requires justification.
How is the outcome defined?

Where possible, we prefer to define the outcome as an adverse health event. Thus beneficial effects of the experimental intervention will appear to the left of the ‘no effect’ line, and harms to the right. In some cases, this may result in somewhat cumbersome outcomes. For example, in reviews of methods of labour induction, the simpler outcome ‘vaginal delivery in 24 hours’ is rather presented as the reciprocal ‘vaginal delivery not achieved in 24 hours’.
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