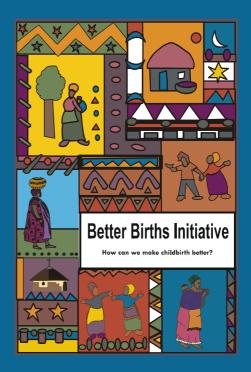
# Best evidence for practices during labour

Presentation prepared for the Better Births Initiative



In the field of health care, we need to be very careful about speaking of 'facts'. So often in the past, what we have thought were facts have turned out to be errors. Experience has shown that we will make fewer mistakes if we rely on objective evidence from clinical trials to guide our decisions, rather than expert opinion or our own feelings about what seems to work. So rather than speaking of 'facts', we should speak more cautiously of 'best available evidence'.

In recent years there has been a move towards 'evidence-based medicine' (EBM). Health care interventions or treatments should not be used simply because they seem to make sense, or have become accepted as routine practice, or because the 'experts' have promoted them. Rather, they should be subjected to careful scientific study to find out whether they are more likely to do more good than harm.

This presentation will discuss what is meant by EBM, and presents the most up to date research findings for selected procedures used during labour and delivery.



## Evidence-based medicine (EBM) is...

"...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."

Sackett et al, 1996

We will start with a a definition of evidence based medicine...."the conscientious, explicit and judicious use of current best evidence in making the decisions about the care of individual patients".

This is a rather long and complex quote, but what it basically means is...



## Evidence-based health care

- Without clinical expertise, evidence may not be applicable to or appropriate for an individual patient.
- Without current best evidence, practice will rapidly become out of date.

...that we need to integrate clinical expertise with the current best evidence.

Without clinical expertise, evidence may not be appropriate for an individual patient,

and without using the best available evidence, practice will rapidly become out of date.



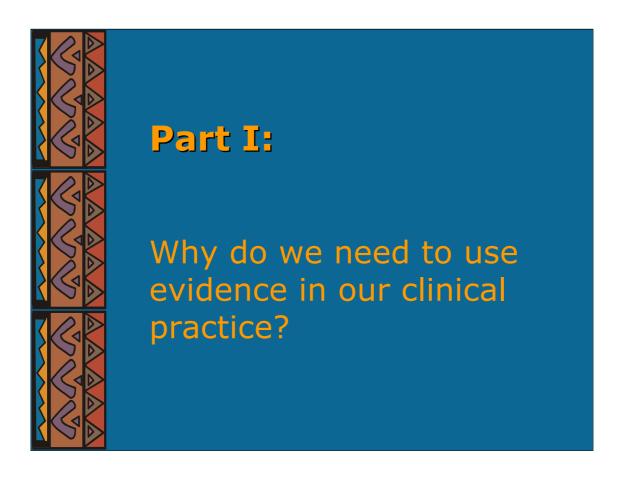
## **Principle of EBM**

In healthcare, the overall objective is to deliver interventions that:

'do more good than harm'

I think everyone agrees that the overriding objective in health care is to "do more good than harm".

Therefore, as health professionals we must ensure that our practice is always guided by the evidence, and that we always consider the benefits and harms of the interventions we use.



Why do we need to use evidence in our clinical practice?

Why should our clinical convictions be wrong?

When we have practised a certain way for many years, why must we change our practice?



## Diethylstilboestrol (DES) to prevent miscarriage

- Miscarriage is common in early pregnancy
- Using estrogen to maintain pregnancy is logical
- Women given DES seldom miscarried doctors and women were convinced it worked
- \* 1950-54: 6 non-randomised trials confirmed very low miscarriage rates with DES (no controls)

A good example of the consequences of our failure to follow 'best evidence' is the use of diethylstilboestrol (DES) in the 1950's and 60's in women at high risk of miscarriage.

Because estrogen is important for maintaining pregnancy, it seemed sensible to give estrogen to prevent miscarriage.

Doctors and women were impressed by the fact that almost all women with a history of miscarriages had successful pregnancies when treated with DES.

Several observational studies confirmed a very high pregnancy success rate with the new 'wonder' treatment. However, these studies were purely observational and had no control group with which to compare outcomes.



## Diethylstilboestrol (DES) to prevent miscarriage

- 1950-55: 5 randomised trials: women randomly allocated to receive DES or placebo
- miscarriage with DES: 83/1220 (7%)
- miscarriage with placebo: 54/1159 (5%)

Later in the 1950's five RANDOMISED control trials (RCT's) were conducted.

That means, women were randomly allocated to receive DES or placebo (identical-looking tablets).

As we can see from the results, those who received DES had excellent results (only 7% miscarriage rate).

However, those who received the placebos also had very similar results (only 5% miscarriage).

This is what we mean by 'objective evidence of effectiveness'. Using a placebo group to compare, it was obvious that DES was not beneficial at all.



## Diethylstilboestrol (DES) to prevent miscarriage

- Conclusive proof that DES was ineffective
- Experience of doctors and women so positive that use continued
- ▶ >2 million women treated up to 1970
- Does this matter?
  - The doctors were happy
  - The women were happy
  - There were no known side-effects

So, the RCT's provided conclusive evidence that DES was ineffective.

However, doctors and women were so impressed with their personal experience that they ignored the objective evidence. Doctors continued prescribing DES to over 2 million women over the next 20 years.

The question is, does this matter?

The women were happy that something was done to help them, the doctors felt good about the successful pregnancies, and there seemed to be no side-effects. Why should we bother with objective evidence?

Well the story doesn't end there.



## Diethylstilboestrol (DES) to prevent miscarriage (2)

- \* 1970: rare vaginal adenocarcinoma in 7 young women traced to DES in utero
- Follow-up of randomised trial cohorts: DES offspring had significant excess of:
  - · uterine anomalies, vaginal adenosis
  - miscarriages, perinatal losses, infertility
  - testicular hypotrophy, unmarried men
  - · dramatic excess of psychiatric problems

Around 1970 a few cases of vaginal cancer or adenocarcinoma occurred in young women in the Boston area. Only because this is an almost unheard of occurrence in young women, a search was mounted for a cause, and it was discovered that all their mothers had received DES during their pregnancies.

There was an intensive investigation of the offspring of DES-treated women. Compared with those whose mothers had received placebo treatment in the original randomised trials, those exposed to DES in utero had a significant increase in health problems, including uterine anomalies, vaginal adenosis (in 90% of the female offspring), miscarriages, perinatal losses, testicular hypotrophy, infertility, unmarried men, and a dramatic excess of psychiatric problems.

No link between these problems and DES would ever have been suspected had it not been for the occurrence of as rare a tumour as vaginal adenocarcinoma. The lesson to be learned from this is that all interventions may have adverse effects that we can't measure, because we can't predict them. All we can do is to ensure that we never use interventions without good evidence that they are effective. Then at least there is a chance of doing more good than harm.



## Why do we need objective evidence of effectiveness?

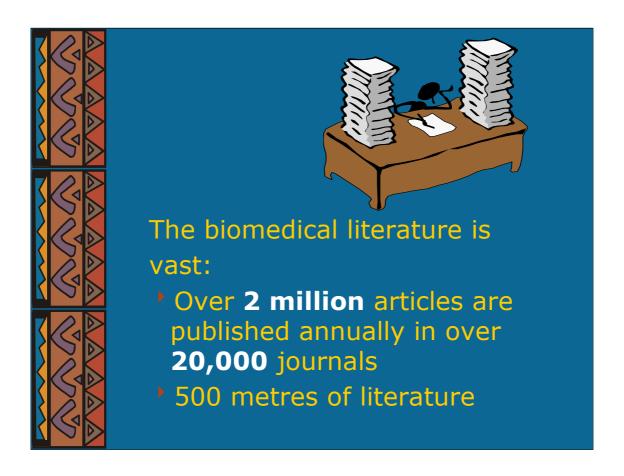
- Our understanding of human biology is full of gaps - we can't predict effectiveness
- Subjective clinical impressions are misleading (tend to overestimate the effectiveness of care - placebo effect)
- Adverse effects are often difficult to identify because they are unexpected

The DES episode is one of many examples of why we need objective evidence of effectiveness.

Firstly, our clinical convictions may be wrong simply because current scientific understanding is imperfect.

Secondly, we may underestimate the power of the placebo effect. We assume that because most patients we treat in a certain way feel better, that the treatment must be effective. It is only through double-blind, placebo-controlled trials that we have come to realise that people treated with placebo also get better. For a treatment to' work' is not good enough. It must be shown to work better than placebo.

And thirdly we need objective evidence of effectiveness because all treatments have the possibility of unexpected adverse effects.



How do we keep up to date with the evidence?

There are over 2 million articles published each year, which amounts to 500 metres of literature!

We all have very busy schedules, and keeping up to date with the latest research evidence is very difficult indeed.

And that's assuming everyone has access to journals and databases!



### What are reviews?

- Many RCT's have been conducted
- Unwise to make decisions based on information from a single trial
- Clinicians, managers, researchers and users depend on summaries of research
- These are usually published in journals and textbooks

Many randomised controlled trials (RCT's) have been conducted and it is always unwise to make decisions based on just one trial.

Therefore we often rely on summaries of research published in journals and textbooks.



### **Traditional reviews**

- No methods section
- Not rigorous or replicable
- Conclusions based on clinical opinion
- Usually inaccurate and out of date
- As a result, clinicians are poorly informed and interventions used may do more harm than good.

However, these summaries and reviews of research often:

have no methods section - we don't know how they were conducted and how the evidence was selected

are not replicable

the conclusions are usually based on opinion

and can be inaccurate and out of date (especially if published in textbooks which take years to complete)

This can lead to mis-information and we may end up doing more harm than good.



## Systematic review

- Scientific methodology for synthesising the results of trials
- A reliable and less biased summary of data that address focussed clinical questions
- Continually updated as new trials become available

A systematic review is a more scientific way of reviewing the evidence from RCT's.

It is a distinct methodology for synthesising results of lots of different trials.

Systematic reviewing uses rigorous techniques to assess the eligibility and quality of trials, therefore reducing bias.

Reviews are continually updated as new evidence emerges.



#### The Cochrane Collaboration

- 1970's: Archie Cochrane, British epidemiologist, recognised that health professionals lacked access to reliable reviews of medical evidence
- 1980's: the Oxford database of Perinatal Trials was developed
- 1993: Cochrane Collaboration has extended this process to other fields of health care.
- The Cochrane Collaboration is an international organisation dedicated to producing systematic reviews and making them available to health workers and consumers. This information is published electronically every 3 months in the Cochrane Library

Systematic reviewing has a long history. In the 1970's Archie Cochrane, a British epidemiologist, recognised that health professionals lacked access to reliable reviews of medical evidence.

This challenge was taken up by Iain Chalmers and his colleagues in Oxford, and in the 1980's the Oxford Database of Perinatal Trials was developed, including reviews of care during pregnancy, childbirth and the neonatal period.

In 1993, the Cochrane Collaboration was established to extended systematic reviewing to other areas of health care.

The reviews are published electronically every 3 months in the Cochrane Library.



## The WHO Reproductive Health Library

- Selection of systematic reviews from the Cochrane Library
- Commentaries on relevance to a developing country environment
- Distributed free of charge:
  - WHO HRP, CH 1211 Geneva 27, Switzerland
  - Fax: 0941 22 791 -4171/ Tel -3380
    (J Khanna)
  - Email: RHL@who.ch

For health workers in developing countries, the Cochrane Library may be unaffordable.

To address this problem in the field of reproductive health, several researchers from developing countries have collaborated with the World Health Organisation to produce the Reproductive Health Library.

This is a collection of Cochrane reviews of particular relevance to reproductive health problems in developing countries, with commentaries written by authors with experience of developing country conditions.

Health workers from developing countries can receive the annual issues free of charge by sending their postal address by letter, fax or email to WHO.



The next section presents the most recent evidence for procedures used during childbirth. Most of the evidence is from systematic reviews conducted by the Cochrane Pregnancy and Childbirth group.



### **Background**

- In developing countries many women give birth in state maternity facilities
- Surveys show that women have negative experiences

In developing countries, many women now give birth in state maternity facilities. Surveys of postnatal women in Zimbabwe, Zambia, China, India and South Africa have shown that women find the hospital practices unpleasant, and will often try to avoid giving birth in a hospital or clinic.

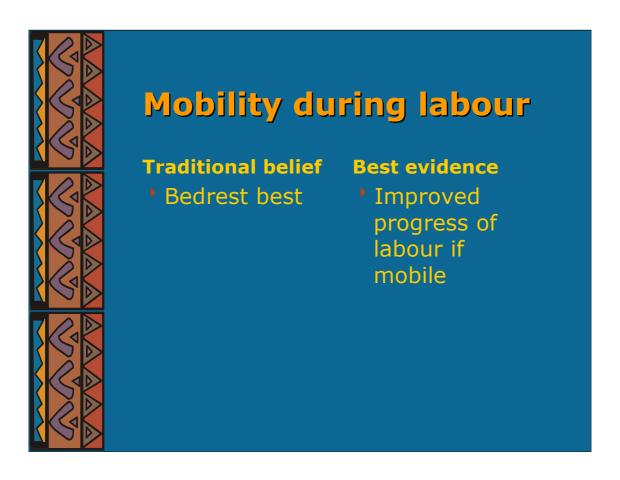




## Best evidence versus traditional 'beliefs'

Are our traditional obstetric practices based on evidence of effectiveness?

If our labour wards are to provide a service that is effective and efficient, and offers good quality care for women, we need to ask the question, 'are our traditional obstetric practices based on evidence of effectiveness?'



Many women cope better with the pain of labour, and the labour may progress more efficiently, when they are able to move about freely rather than being confined to bed. No position is comfortable for a

long period of time. Being upright also removes the risk of supine hypotension. Encourage women to walk around and choose more comfortable positions.



## Different positions for birth

#### Traditional belief Best evidence

- Supine position best access for attendant
- Supine safest position
- Supine -progressive acidosis of baby, slower progress
- Other positions
  (lateral tilt, upright,
  squatting) less pain,
  less vaginal trauma,
  improved fetal
  outcome

Women are often expected to lie flat on their backs during the delivery.

This has been shown to be the worst possible position, as pressure of the uterus on the woman's main blood vessels may cause her blood pressure to fall, and reduce the flow of blood to the placenta. The baby becomes progressively more distressed.

It is also difficult to bear down in this position. Other positions, such as lying on her side or being tilted to the side, or being upright (crouching, sitting or kneeling), are preferable.

Encourage women to adopt the position they find most comfortable. Labour ward staff will need to become familiar with other positions for delivery, and be willing to attend women who prefer an upright, or squatting, position.



## Fluids and food during labour

#### **Traditional belief**

- Risk of inhalation if general anaesthetic needed
- Keep everyone nil per mouth

#### **Best evidence**

- No difference in anaesthetic risk
- Dehydration → acidosis, fetal distress
- Nil per mouth only for specific reason

Women are often forbidden to eat or drink during labour. The main reason for this is the fear that, should a Caesarean section with general anaesthesia become necessary, the woman might vomit and inhale stomach contents, causing aspiration pneumonitis. Women who do not drink fluids, become dehydrated and acidotic. It's like trying to run a marathon without drinking any fluid. They usually need to be rehydrated with intravenous fluids, which have their own risks. Their babies may become distressed.

Does starvation in fact reduce the risk of complications from general anaesthesia? Studies have shown that it does not. Even with starvation, a woman's stomach does not empty during labour. Special precautions are therefore routinely taken if a general anaesthetic is needed (which is rare, as spinal anaesthesia is the safest method for Caesarean section). Unless there is a medical reason to prohibit oral fluids, women should be encouraged to drink at least 250 ml of fluids hourly throughout labour. At Coronation Hospital it was found that most women enjoy an iced lemon rooibos tea with sugar, made by the kitchen staff at a cost of about 10 SA cents per glass. Four rooibos teabags, 4 sliced lemons and 400g sugar are boiled in 10 litres of water. The tea is strained, cooled and supplied to the labour ward in used plastic1 litre sterile water bottles from theatre. Even plain water is better than nothing.

Some women may not want to eat during labour, but most will need to drink. Women are able to monitor their own intake, and will intuitively avoid heavy meals. Avoid interfering with women's wish for food and drink during labour.



## Encourage childbirth companionship

#### **Traditional belief**

- Companions discouraged
  - Worries about infection
  - Get in the way
  - Lack of privacy
  - Staffoverworked

#### **Best evidence**

- Better progress of labour
- Fewer Caesarean sections
- Less pain
- More self-esteem
- Better relationship with baby
- More breast-feeding
- Less depression

When women traditionally gave birth at home, they were supported by family members and other women. During labour and delivery in hospital, women are often left alone.

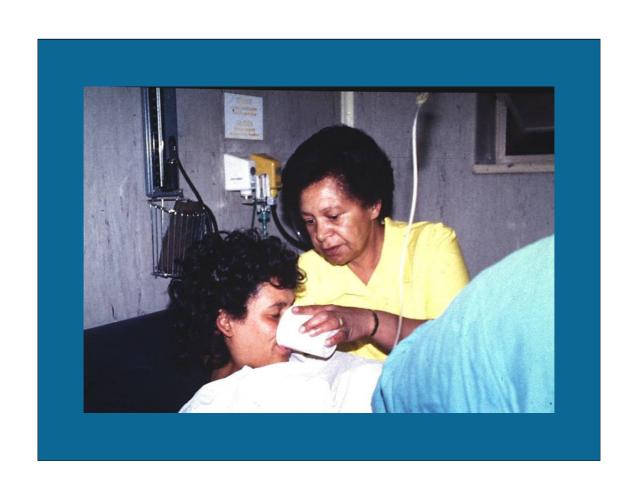
Companions have been discouraged from labour wards due to worries about infection, lack of privacy, and fear that they will disrupt staff routine.

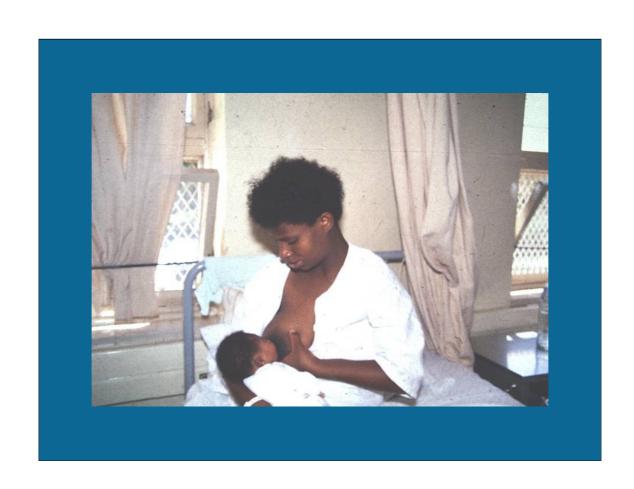
However, there is evidence from randomised trials around the world that women who are supported throughout labour by a partner, friend, relative or carer enjoy many important benefits.

The challenge we face as health workers, is how to overcome the difficulties to ensure that women during labour receive the companionship they need.

Providing a private room for each women to deliver may not be possible, but female supporters can usually be accommodated with minimal disruption.









### **Enemas in labour**

#### **Traditional belief**

- Necessary to avoid soiling
- Use routinely

#### **Best evidence**

- No difference in soiling (more liquid)
- Use only if requested

The main reason for routinely giving women enemas in labour is to reduce soiling during the birth. Studies have shown that this is not the case, and in fact liquid stool may be more difficult than solids to remove during the birth. In addition, enemas can be uncomfortable for women, and they are expensive.

An enema should only be offered if a woman requests it, or feels uncomfortable because of constipation.



## Stop shaving for labour

## Shaving advocated:

- To facilitate suturing
- To reduce infection

#### **Problems:**

- Painful, embarrassing
- Re-growth uncomfortable
- Microabrasions cause infection
- No benefits shown
- Risk of HIV transmission

It also seemed logical that perineal shaving would reduce the risk of infection during delivery.

However, several studies have shown that shaving before birth or surgery causes microabrasions of the skin, and actually increases the risk of infection. Some women find the procedure embarrassing, and the re-growth painful.

In addition, there is a risk of HIV transmission if shaving is done with a non-sterile blade.



## Avoid episiotomy

#### Traditional belief Best

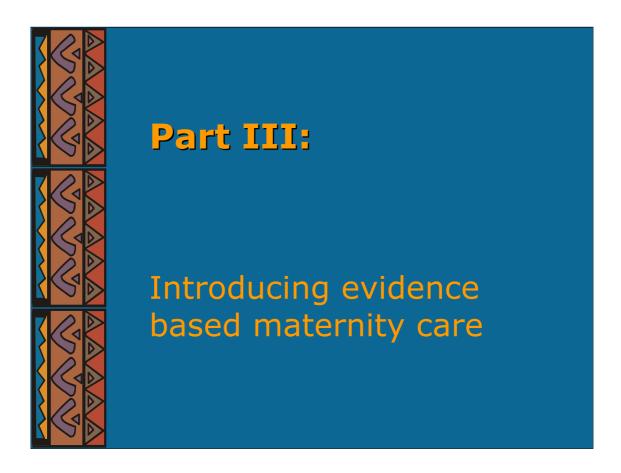
- Clean incision easier to repair
- Heals better
- Fewer 3° tears
- Use routinely

- **Best evidence**
- More perineal trauma
- More suturing needed
- More complications
- Use only when absolutely necessary

In 1920, Jos De Lee, the American obstetrician, proposed that all women giving birth for the first time, and most multiparas, should routinely have an episiotomy cut. It seemed logical that a clean surgical incision would be easier to repair and heal better than a ragged tear.

However, randomised trials have shown that a policy of routine episiotomy results in more trauma and complications than a policy of trying to avoid episiotomy.

In general, the risk of perineal tearing is better than routine episiotomy, which should be used only for specific situations such as prolonged second stage of labour and fetal distress.



There is now a lot of evidence available about the benefits and harms of procedures used during labour and delivery; the challenge is how to begin to use this evidence in practice.

This will involve making changes to the way we practice.



## Changing practice

- Obstacles to changing practice are daunting
- If initial apprehension of staff is overcome, benefits will become self-evident
- With commitment from staff, change can be achieved

So, how can we begin to change our practice so that it is consistent with the evidence? When we have been doing something in a certain way for a long time it is hard to change. But it is possible - with a lot of time, energy and commitment. Also, with the support of all colleagues, and the attitude that change is necessary, it can be achieved.



### The Better Births Initiative

This is a global initiative that promotes humane and evidence based care for women during childbirth.

The 'Better Births' initiative is an international collaboration of researchers, health workers and others committed to promoting the use of research findings in practice and improving women's experiences of childbirth.



### The 'Better Births' Principles

Humanity: women treated

with respect

**Benefit:** care that is

based on the best available

evidence

**Commitment:** health professionals

committed to improving care

**Action:** effective strategies

to change current

practice

Over the last 2 years, researchers working in Zimbabwe, India, China, Zambia and South Africa have confirmed that many women, particularly those from poor communities, experience unpleasant, unnecessary procedures during labour.

The BBI is based on four main principles: Humanity, Benefit, Commitment, and Action. The most important is the commitment of health professionals to improving care, and developing effective strategies to help initiate change in practice.

This comprehensive programme is being developed to help improve the quality of care and make it more humane, and more rewarding for caregivers.



### **BBI** standards

- Use procedures that are effective and beneficial:
  - Mobility during labour
  - Different positions for birth
  - Companionship

The BBI standards are focussed, practical methods based on the best available evidence, and can be implemented using existing resources.

The BBI encourages:

the use of obstetric procedures that are effective and beneficial to women. These include: mobility, other positions for birth, and companionship.



The BBI discourages the use of procedures that have no benefit. These include: Supine position, witholding fluids and food, enemas, and shaving.



### **BBI** standards

- Avoid making interventions routine when there is no evidence of benefit:
  - Routine episiotomy
  - Routine suction of neonates without meconium exposure
  - Routine artificial rupture of membranes

The BBI also advocates that interventions with no evidence of benefit in all cases, should not be routine. This includes: episiotomy, suction of neonates without meconium exposure, and artificial rupture of membranes.



#### **BBI** standards

- Identify other priority areas, and take steps to bring about change:
  - Magnesium sulphate for eclampsia
  - Oxytocin in third stage
  - Strategies to reduce MTCT of HIV
  - Steroids for preterm delivery
  - Antibiotics for Caesarean section
  - Use of the partogram

The BBI focuses on issues that are important to women, and those which will improve the experience of birth in a hospital setting. They are also changes that can be made without additional resources.

In your setting, there may be other procedures (with good evidence) that need to be addressed urgently. The BBI cannot cover all important topic areas, but encourages labour ward staff to consider the potential benefits and harms of other procedures used or not used.

Other priorities may include: MgSO4 for eclampsia, oxytocin during third stage, strategies to reduce MTCT of HIV, steroids for preterm delivery, antibiotics for Caesarean section, or use of the partogram.



## Change is never easy

- Moving towards 'Better Births' will take a lot of time, energy and commitment.
- The 'Better Births Initiative' provides the materials to bring about real change for the better.
- It's up to each one of us to take up the challenge.

During the last century, much effort went into strategies to make childbirth safe. The challenge for the new century is for us to make childbirth not only safe, but humane as well.





### More information

- Wits EBM website:
  - http://www.wits.ac.za/fac/med/medfac.html
- The Cochrane Library: (In all SA Med School libraries)
  - http://www.update-software.com
  - Subscription: SA Cochrane Centre, MRC, Tygerberg 7505, SA; <u>jimmy.volmink@mrc.ac.za</u>.
- The WHO Reproductive Health Library:
  - Free subscription: RHL@who.ch
- Cochrane Systematic Review workshops:
  - Learn Systematic Review techniques (eg for Mmed thesis)
  - Contact SA Cochrane Centre

If you would like more information about evidence based practice, here are some useful contact details.

