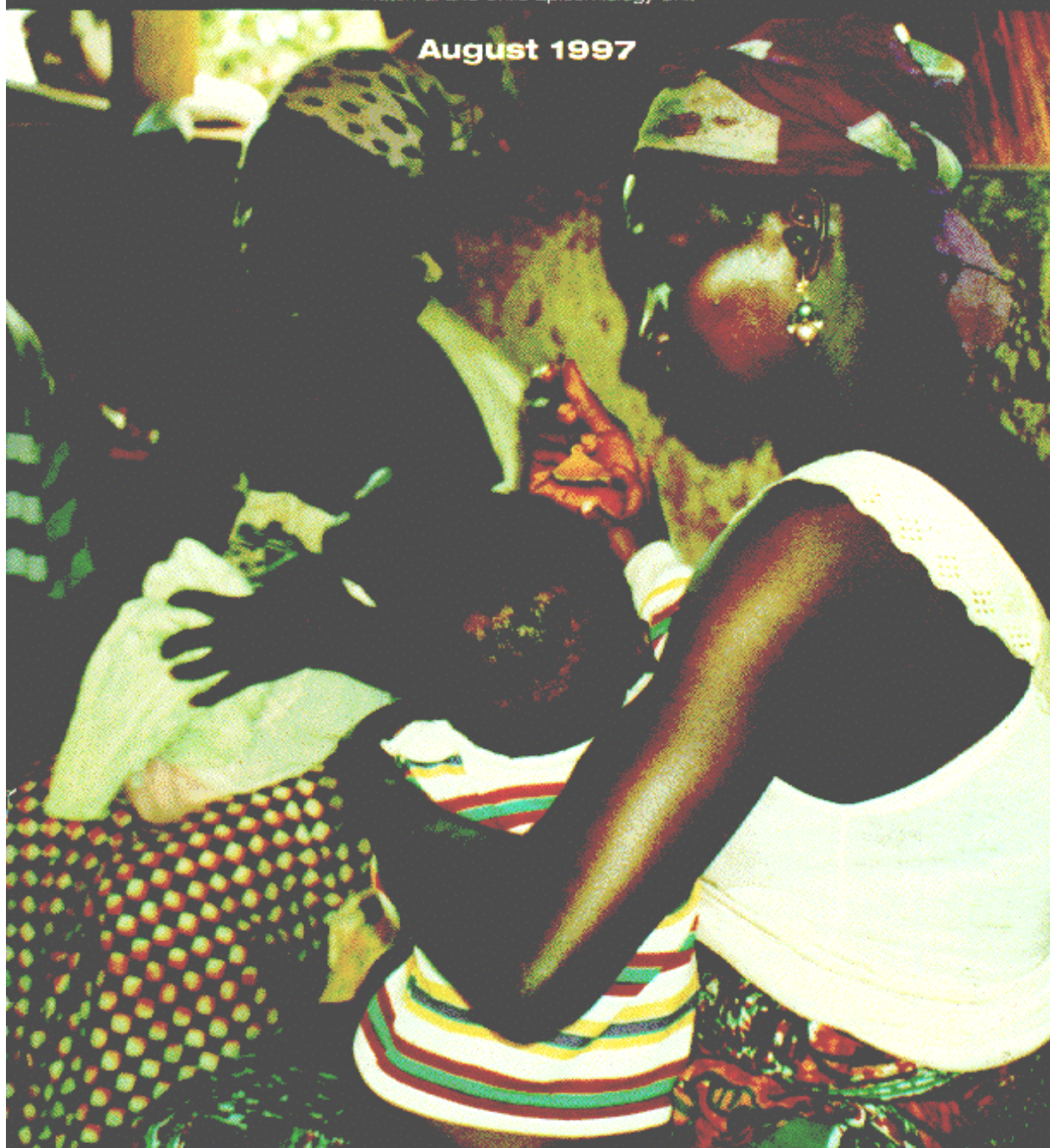


Lessons Learnt

a decade of measuring the impact of safe motherhood programmes

DFID Research Work Programme on Population and Reproductive Health
Maternal and Child Epidemiology Unit

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Ever tried. Ever failed.
No matter.
Try again. Fail again. Fail better.

Samuel Beckett

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LESSONS LEARNT:

A Decade of Measuring the Effects of Safe Motherhood Programmes

I. What is this booklet about?

A decade of programme efforts in Safe Motherhood has led to greater understanding of the possibilities and challenges involved in reducing maternal mortality. Safe Motherhood programmes now aim to have functioning first referral-level hospitals, effective referral mechanisms, an Information/Education and Communication (IEC) strategy, and provisions for community-based family planning and obstetrics (*see Box 1*). **Measuring change resulting from such Safe Motherhood programmes**, however, **presents its own challenges**. A focus of the Maternal and Child Epidemiology Unit of the London School of Hygiene and Tropical Medicine during this decade has been on monitoring and evaluating Safe Motherhood programmes. We have developed and/or tested methods for measuring maternal mortality and morbidity (health outcome indicators) and for measuring childbirth in a safe environment (process indicators). We have also addressed design issues and data sources. **The insights gained from our measurement efforts are described briefly in this booklet.** It is possible to read a summary version of the document by focussing on the bold text.

Box 1: Elements of a Safe Motherhood Programme

First referral-level facilities (district hospitals) with 24 or more beds to provide (WHO, 1991): surgical obstetrics (e.g. caesarean section); anaesthesia; medical treatment of sepsis, shock, eclampsia, etc.; blood replacement; manual procedures and monitoring labour (e.g., vacuum aspiration, partograph); management of women at high risk, specifically those who have had previous operative delivery and those at risk of obstructed labour, and family planning support, including surgical methods for men and women.

Effective referral with:

- a means (e.g. telephones, radios) of communicating between staff at the peripheral level and at the referral level for medical advice or feedback;
- a means of transporting complicated obstetrical cases to referral services, and
- a means of coordinating care among the levels of health providers (e.g. case management protocols for all levels, appropriate forms for transmitting necessary information about the woman and her newborn).

Information/Education and Communication strategy aimed at:

- increasing appropriate and timely use of services--family planning, prenatal, delivery and postpartum care;
- increasing awareness of danger signs during the maternal period, and
- mobilizing communities for transport of women with obstetrical complications.

Community-based family planning and obstetrics with trained staff (midwives) or outreach by such staff to provide:

- family planning and safe abortion management (safe services where legal, and detection and early referral of complications when unsafe abortion practised),
- case detection of complications or present medical problems, depending on the training/skills of staff,
- normal delivery, and
- obstetric first aid (e.g. initial treatment of eclampsia, skills for manual removal of the placenta).

Source: Campbell et al, 1995b

II. How can we show that a Safe Motherhood programme has led to a change?

A. How can we measure change?

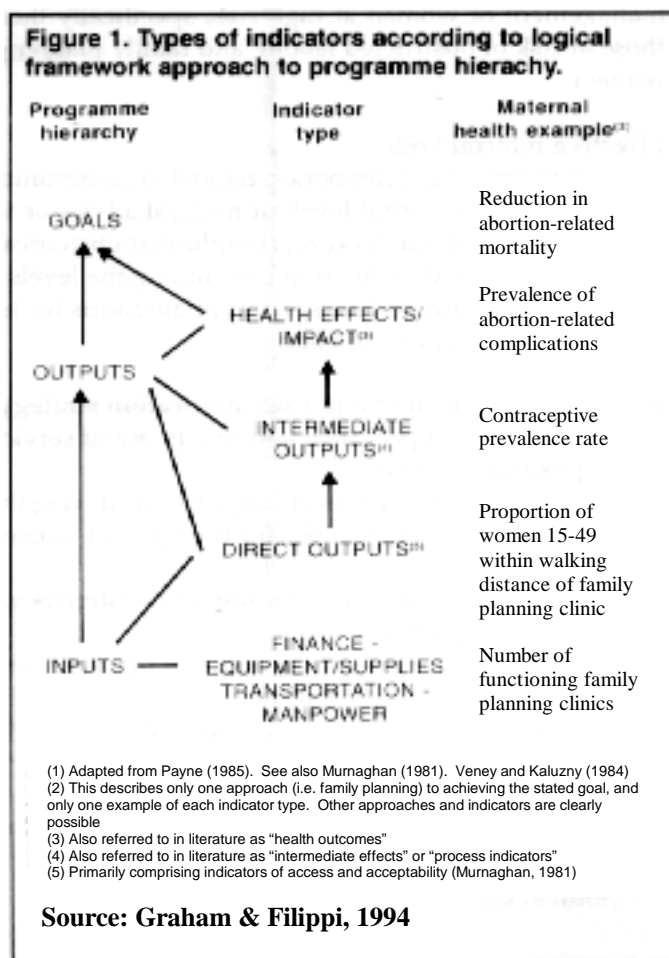
Demonstrating change involves comparing groups over time and across populations. It depends largely on how easily and accurately the preferred outputs and outcomes can be measured. Showing that such change occurred *because* of a programme or an intervention is more complicated. **An important factor in determining how convincingly a change is attributable to an intervention is the study design.**

The 'gold standard' design for testing whether an intervention has an effect is the experimental approach. In health research this is exemplified by the randomized controlled trial (RCT) or the community randomized trial (CRT). For reasons discussed below, other design approaches are more widely used in evaluation but none of these other approaches offer as definitive a standard of proof as RCTs or CRTs.

Evaluating whether a programme has resulted in change also, typically, requires the existence of feasible programme objectives, that programme inputs are delivered, that they are efficacious, and that outputs and outcomes can be measured (Graham et al., 1996; Filippi et al., 1996a). **The choice of the outputs and outcomes, and the specific indicator measures themselves, depend on:**

- **the conceptual framework**, which should specify the programme goals and causal pathways between interventions (inputs), outputs and the ultimate outcomes of interest (*see Figure 1*),
- **the ability to measure the preferred outputs and outcomes.**

How efficacious inputs are (i.e. how well they work) is another important consideration. Where efficacy is high and largely independent of either the user or provider, then short-cuts can be taken in choosing outputs and outcomes to measure. For example, tetanus toxoid immunization and tubal ligation are highly efficacious procedures which confer long-lasting protection against tetanus and pregnancy respectively. Although there is scope for error in providing these interventions, we generally assume that delivery of the inputs leads to the desired outcomes. We would therefore evaluate such interventions using the numbers of women immunized or sterilized (output measures) rather than by measuring deaths from tetanus or pregnancy rates (health outcome measures). This is not the case for other types of inputs. For example, if inputs are broader and consist of antenatal care or family planning services, it is not possible to translate use of either service into a guaranteed protection against tetanus or pregnancy. The latter situation most resembles the case of Safe Motherhood services: we can measure use of antenatal care and delivery care but cannot be certain of the degree of protection these types of service use confer.



B. What are the special features of evaluating Safe Motherhood programmes?

Specific interventions, including drugs, procedures and tools, are available for addressing most health problems leading to maternal death. There is no doubt, for example, that active management of the third stage of labour (with prophylactic oxytocics, cord clamping before placental delivery, and cord traction) reduces the incidence of post-partum haemorrhage to a third of the levels of physiologic management, or that emergency obstetric procedures such as operative delivery or blood transfusion prevent certain women from dying. The benefits of the former intervention were proven using RCTs (*see Box 2*). The latter interventions have not been evaluated using the best scientific approaches but there is nonetheless widespread consensus on their value. Safe Motherhood programmes do not require new technical solutions, rather **the question remains how to translate existing individual interventions into feasible and effective programmes, and how to show that such programmes work.**

Box 2: The Cochrane Collaboration

The Cochrane Library is a collection of databases containing reviews of the effects of health care, prepared by the Cochrane Collaboration. The Cochrane Pregnancy and Childbirth Database, provides access to systematic reviews of randomized trials in pregnancy and childbirth. The database is updated six-monthly and contains:

- reviews of over 500 interventions in childbirth and pregnancy including topics such as support from caregivers during at-risk pregnancies and routine ultrasound in early pregnancy
- the specialised register of ongoing controlled trials assembled by the Pregnancy and Childbirth Group

Address:

Cochrane Collaboration
BMJ Publishing Group
PO Box 295
London WC1H 9TE

Measuring the effects of Safe Motherhood Programmes is difficult for two main reasons:

- **the necessary interventions are usually a comprehensive package** or system (rather than a single drug or procedure), and are often **delivered to communities** not individuals. In practical terms, this limits the study design options and complicates specifying the conceptual framework (*see Section III below*).
- **it is hard to measure the preferred outcomes.** Measuring change in maternal mortality, the most popular indicator of programme achievement, has proved impractical. Measuring morbidity is unlikely to replace maternal mortality as a measure of health impact (*see Section IV below*).

The result of these two obstacles is that **Safe Motherhood programmes will need to use descriptive (observational) rather than experimental designs for evaluation, and are likely to be forced to use process indicators to measure the implementation and use of appropriate services.** While these are now seen as the most possible and likely options, **results based on these approaches will always be open to challenge.**

III. What study designs should we use to evaluate Safe Motherhood programmes?

A. Should we use experimental approaches (RCTs and CRTs)?

In health care evaluations, the most scientific approach for determining what is effective in bringing about change is usually held to be the randomised controlled trial (RCT). **The role of RCTs for evaluating single interventions, such as malaria prophylaxis for preventing severe anaemia in pregnant women in malaria endemic countries, is indisputable (see Box 3).** The main feature of the RCT is that it randomly allocates individuals to an intervention or a control group, and then measures the outcome of interest in the two groups. Random allocation ensures that there are no systematic differences between the two groups, and that any differences are due to chance. If RCTs are ‘double blind’ then neither the provider/interviewer nor the individual enrolled in the trial is aware of whether the intervention or the placebo is being administered. This removes the potential for reporting bias and bias due to Hawthorne effect (whereby people behave differently because they are under observation). RCTs *have* been designed to look at service delivery issues in Safe Motherhood: for example, several RCTs in developed countries have assessed conventional versus alternative places of delivery (Hodnett, 1997). However, RCTs are not generally useful for evaluating Safe Motherhood *programmes* because these are usually aimed at communities rather than individuals.

Box 3: Examples of RCTs on malaria and induced abortion

We are currently involved in two RCTs. One in Kilifi, Kenya is testing the effectiveness of insecticide treated bednets (ITBN) in preventing severe anaemia in pregnancy in a population randomized to having or not having ITBNs. In addition, a double-blind placebo controlled trial is examining the effectiveness of sulfadoxine-pyrimethamine in preventing severe anaemia in primigravidae in populations with and without ITBNs. The wider implications of the interventions are determined by evaluating the impact of severe anaemia on women's lives in terms of ability to perform tasks.

We have also recently completed a RCT involving a behavioural intervention: contraceptive counselling following induced abortion. This research in Fortaleza, Brazil showed that while the abortion experience increased contraceptive uptake, there was no impact of counselling on contraceptive uptake or pregnancy rates in the first year post abortion.

For more information contact Caroline Shulman or Chizuru Misago respectively.

Where interventions are delivered to communities, CRTs are the most scientific approach.

CRTs are large-scale undertakings where a community may be the catchment area of a hospital, or of a health centre. Typically twelve or more communities will be required, divided equally, and randomly, into intervention and control. This scale of operation, and its requirement for skilled research personnel, makes the cost high.

Other points which make CRTs difficult or less desirable are:

- Randomized trials of interventions involving service delivery are context-specific and the cost may be prohibitive when measured against the benefit, if the intervention cannot be generalized beyond this immediate context.

- Randomized trials cannot be used to evaluate interventions that have already been put into place, or where the evaluators cannot influence which communities do and do not receive the intervention.
- CRTs are not always fully 'controlled' since it may be difficult to maintain a strict separation between intervention and control communities particularly when the intervention involves communication strategies (i.e. IEC).
- The scale of operation may preclude carrying out a CRT at all. For example, if the intervention includes components targeted at hospitals providing essential obstetric care (EOC) for entire districts, there may not be 12 hospitals available to randomize.

By contrast, the essential advantage of CRTs is that they lead to conclusions that remain true even if the complex processes leading to the outcome cannot be fully measured, are not fully understood or do not fully follow their expected path. **It is possible to justify a CRT if the results have a commensurate importance to the cost.** A CRT is most justified when the results are of general importance and of wide applicability, rather than being context-specific (*for example, see Box 4*).

Box 4: When are CRTs worth doing?

A recent example of a CRT is the Mwanza trial of the impact of syndromic management of STDs on HIV prevalence (Grosskurth et al, 1995). This trial was expensive, but answered an important, generalizable biological question which could not be answered convincingly by previous observational studies, because of concerns about residual confounding. The question, 'are STDs implicated in the causal pathway of HIV transmission?' was answered with a 'yes'. The trial also showed that syndromic management reduced HIV transmission in Tanzania. This second finding is more context-specific and its generalizability depends on the prevalence of HIV and STDs in the setting being studied, the percentage of STDs which are asymptomatic, the population's willingness to seek care for STD symptoms, the percentage of partners which are treated, the types of antibiotics used, and the skills and training of health workers in syndromic management. Because these factors may not hold outside Mwanza, it cannot be assumed that syndromic management will work in other countries.

If the second (service delivery) question was the only research issue, should the CRT have been conducted? The answer depends on the value of the results. If many countries have profiles resembling Tanzania, then CRTs would certainly be worthwhile. If not, it is questionable whether equivalent resources could be spent to answer the question for each country. The more unique, privileged or sophisticated a country's conditions are, or the more advantageous they are to showing a positive effect of the intervention, the less likely are results able to be generalized to poorer, more disadvantaged settings. Resource rich countries do, of course, conduct context-specific trials.

In the case of Safe Motherhood, CRTs would be worthwhile for services which can be delivered through a minimal health infrastructure, preferably through lay persons. For example, the efficacy of new technologies which might be delivered by TBAs or relatives delivering women, without the need for extensive training, would be worthwhile testing.

B. What are the alternatives to RCTs and CRTs?

Countries which now have low levels of maternal mortality did not design and evaluate their programmes using CRTs. Equally, current programme efforts in Safe Motherhood are not based on evidence from CRTs but from accumulated knowledge and experience, including historical review, previous programmes, and rational interpretation of the expected benefits of the specific components of a programme based mainly on clinical knowledge or ‘common-sense’ (**Box 5**). For example, the now accepted need for access to skilled obstetric care at health facilities, as a prerequisite to averting maternal deaths, draws mostly on the analysis of historical trends in maternal mortality in western countries and on clinical knowledge.

Box 5: What evidence are Safe Motherhood programmes currently based on?

Single treatments or interventions

These are based on:

Oxford Data Base of Perinatal Trials/Cochrane Pregnancy and Childbirth database (Chalmers et al, 1991; Neilson et al, 1997). For example, the RCT of which anticonvulsant to use for eclampsia included developing country settings (The Eclampsia Trial Collaborative Group, 1995).

Clinical experience and non-experimental (observational) studies.

Programmes

Current Safe Motherhood programme planning is based on **historical precedent**, namely the **pattern of MMR decline in England & Wales, the USA and other western countries** in the 20th century, which is:

Ascribed to availability of antibiotics, blood transfusion and better management of hypertensive disorders of pregnancy (Loudon, 1992; Maine, 1991)

Contrasted with pattern of infant mortality which is ascribed to socioeconomic improvements (Maine, 1991)

Strengthened by high maternal mortality among US women refusing medical care (Kaunitz et al, 1984)

Alternatively ascribed to conduct of medical audits/confidential enquiries (Speert, 1980) and political awareness (De Brouwere, 1997).

Programmes are not based on the **19th century pattern of decline in Scandinavia**, which is ascribed to home-based midwifery, antiseptic technique and political commitment (Hogberg et al, 1986; Hogberg and Wall, 1986; De Brouwere, 1997).

Programmes are also based on ‘**thought experiments**’ (logical reasoning and ‘common-sense’). These include the following ideas:

TBA skills are poor vis à vis ability to manage life-threatening complications (Campbell et al, 1995)

Except for hypertensive diseases of pregnancy and, possibly anaemia, there is not a strong association between morbidities treatable antenatally and causes of maternal mortality (Rooney, 1992)

Antenatal high risk screening tools lack predictive power (Vanneste and Ronsmans, 1997).

Source: Campbell, 1995

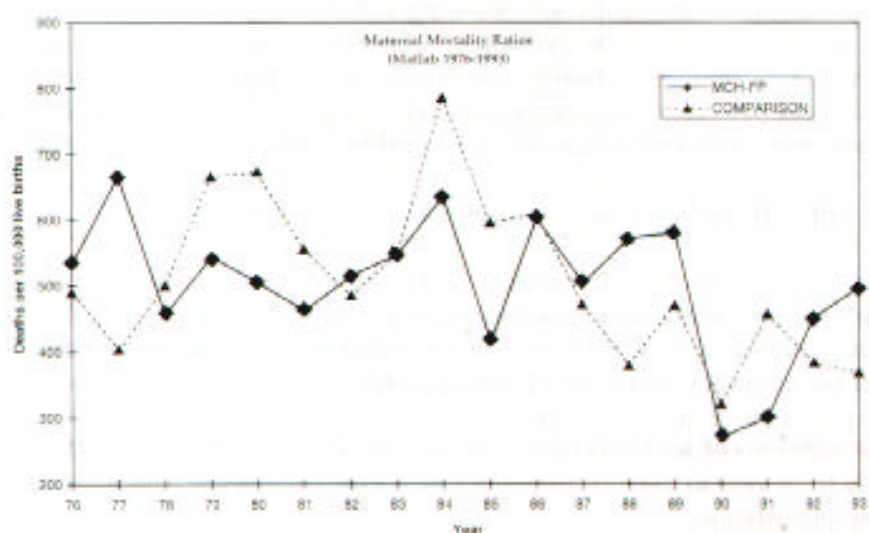
Save in exceptional circumstances, evaluation efforts in Safe Motherhood should be descriptive rather than analytical. This is not to say there is no need for accurate quantitative measurement of indicators; quite the contrary. These descriptive efforts should use quantitative and qualitative data to elaborate not only the intervention taking place, but also the wider context, whilst guarding against the trend to seek single technical solutions for complex problems such as maternal health. The presence of change can be interpreted, provided relevant data to confirm or refute the role of the intervention are collected. Typically, relevant data will include information on the timing and coverage of the intervention, the potential outside influences such as the presence of other projects in the area, the existence of a specific policy environment, the coverage/use of existing services on which the intervention relies (e.g. presence of an obstetrician in a district hospital), and the factors which are known to affect maternal health (e.g. levels of fertility, clients' attitudes towards the services, etc.).

Such descriptive designs, which are usually termed **before-and-after designs**, will not prove that the association between the intervention and the observed change was causal; rather, the different elements will be pieced together to present a plausible argument as to why/ how the intervention contributed to change. We prefer to term these **before-during-and-after designs** to emphasize that **it is not sufficient to measure a single indicator at two points in time.**

C. Does having a control group help?

One or more control areas can help indicate whether the observed change is part of an existing trend, unrelated to the programme. Such controls can be historical (i.e. trends before the introduction of the programme) or external (i.e. communities not receiving the intervention). Use of control areas can also counteract the Hawthorne effect. However, non-randomly selected control groups are likely to be systematically different from the intervention area and an apparent effect of the programme may be due to these initial differences. **Since it can never be assumed that the comparison groups are similar, it remains necessary to exclude alternative causes for the observed trends** and the efforts to document outside influences in the control groups need to match those made in the intervention groups. **This limits the use of control groups (Figure 2).**

Figure 2. Interpretation of a non-randomly allocated control area



The difficulties of interpreting findings from non randomly-selected control groups is illustrated in the studies from Matlab, Bangladesh. Maternal mortality ratios (MMRs) were found to differ significantly between intervention and control areas within a larger area receiving maternity care and family planning interventions (MCH-FP area), suggesting the intervention (including community-based midwives) was effective (Fauveau et al 1991). However, MMRs in a third area not receiving such inputs (Comparison area) were *not* different from the MCH-FP area. Analyses of more recent trends in the MCH-FP and Comparison areas confirm these findings and indicate the difficulties of relying entirely on one outcome (Ronsmans et al, 1997a).

D. Can individual components of programmes be evaluated?

Donors and governments often want to know which component of a multi-faceted programme worked best or was the most cost-effective. In most cases it is not possible to evaluate the specific contribution of individual elements of complex packages of services typical of Safe Motherhood programmes, particularly if the inputs are expected to affect the same outcome. If the expected and measurable results are highly specific to the intervention, (for example for improved knowledge after an IEC campaign), it may be possible to get a sense of the contribution of a single component.

IV. What types of health outcome and process indicators should we measure to evaluate programmes?

Evaluating Safe Motherhood programmes requires the ability to measure change using our preferred indicators. We have devoted considerable efforts to understanding the options for measuring maternal health outcome indicators. To a lesser extent, we have also gained some experience in measuring process indicators and outputs related to birth in a safe environment. This section describes our experience with specific indicators.

Numerous groups have derived lists of indicators for use in monitoring and evaluating Safe Motherhood programmes, including WHO, UNICEF, USAID, and UNFPA (*see Box 6*). Although we acknowledge the relevance of some of these indicators for global monitoring of progress, **individual programmes will typically have to collect many** more input, output and, where possible, outcome **indicators** to build a convincing case that attributable change has occurred. **These indicators need to be programme specific.**

A. What have we learnt about measuring health outcome indicators?

For most Safe Motherhood programmes, showing a decline in maternal mortality is the most desirable result, since this is the goal most usually set. Showing a change in potentially life-threatening maternal morbidity seems an equally acceptable alternative. This is because policy makers and donors are more likely to be convinced by changes in health outcome indicators than by process indicators. The main question is whether we can get this information, and if so how? We argue that **in most cases, health outcome measures (mortality and direct obstetric morbidity) are too costly or difficult to obtain.**

A.1 Can we get population-based measures of maternal mortality easily?

Reducing maternal mortality should continue to be the goal of Safe Motherhood programmes in developing countries, as this maintains the focus on the complications which kill 585,000 pregnant or recently delivered women each year. Moreover, **a rough estimate of the maternal mortality ratio (MMR) is useful for advocacy and even planning purposes.** For example a MMR of, say, 50-250 per 100,000 points to problems of quality of care for labour/delivery, while higher MMRs (say, MMR>250) suggest there are problems of access as well. By contrast, specific MMRs (say, MMR=426) are likely to vary considerably from year to year, and should not be used for determining service programme plans or changes in implementation.

Box 6: Outcome and process indicators proposed by various agencies for monitoring maternal health goals			
BROAD INDICATORS	USAID(1)	WHO (2)	UNFPA(3)
HEALTH OUTCOME			
- Maternal mortality ratio (MMR) and/or rate	✓	✓	✓
- Annual number of maternal deaths		✓	
- Case fatality rate (CFR) - all complications	✓		
PROCESS			
- Proportion of women with prenatal care by trained personnel	✓	✓	✓
- Percentage of pregnant women with tetanus toxoid immuniz.	✓		✓
- Proportion of births attended by trained health personnel	✓	✓	✓
- Percentage of adults knowing about maternal complications	✓		
ESSENTIAL OBSTETRIC CARE (EOC)			
- Number of EOC facilities per 500,000 population	✓	✓	
- Percentage of district hospitals with c-section and blood transfusion			✓
- Percentage of population within 1 hour travel time of EOC		✓	
- C-sections as a proportion of all births in the population	✓	✓	✓
- Proportion of expected complicated cases managed at EOC facilities (Met need for EmOC)	✓	✓	✓
- Admission-to-treatment time interval	✓		
SPECIAL TOPICS			
- Anaemia (prevalence and/or supplementation)		✓	✓
- Abortion	✓		✓
- Syphilis screening		✓	✓
- Policy environment	✓		✓
- Client satisfaction with maternal health services			✓
- In-service training for health personnel			✓

Note: (1) Based on shortlist of suggested indicators; (2) Based on minimal monitoring list; and (3) Based on core list of suggested indicators

Source: Koblinsky et al, 1995; UNFPA, 1996; WHO, 1994.

UNFPA (1997) Indicators for assessing the performance of reproductive health programmes: a discussion paper. April 1997. New York: UNFPA.

Fortunately, even in the absence of complete and accurate vital registration, there are two ways to obtain a rough national (or a large population aggregate) estimate:

- **The sisterhood method**, an indirect demographic technique that relies on relatively small sample sizes and hence is comparatively inexpensive. (Graham et al, 1989; Danel et al, 1996)
- **The WHO/UNICEF models**, which predict the MMR based on a country's general fertility rate (GFR), and the percentage of births delivered by a trained attendant. These models were built using data from countries with good estimates of maternal mortality (WHO, 1996)

Other methods for obtaining accurate population-based estimates are usually costly and research intensive (Campbell and Graham, 1990 and 1996).

Measuring change in the maternal mortality ratio over time is not feasible given the usual project/programme periods of three to five years (Graham et al, 1996).

Neither of the two approaches described above, the sisterhood method nor the UNICEF/WHO models, can be used for monitoring change. The reasons are as follows:

- the sisterhood method yields a retrospective estimate (for the past 10-12 years) rather than a current one, and its confidence intervals are generally wide; and
- the WHO/UNICEF models will only show change as a result of changes in the model inputs of GFR and the percentage of births delivered by trained attendants, rather than by observed changes in MMR.

Statistically, maternal mortality is a rare event even where the risk is high. Moreover, it is difficult to sample and is usually under reported. Establishing a reliable baseline level of maternal mortality, let alone demonstrating changes, requires a very large sample size and is costly. Except where the vast majority of deaths occur in hospital or vital registration is very good, few countries have the means to evaluate using maternal mortality as an outcome indicator, so it will remain in the domain of special studies.

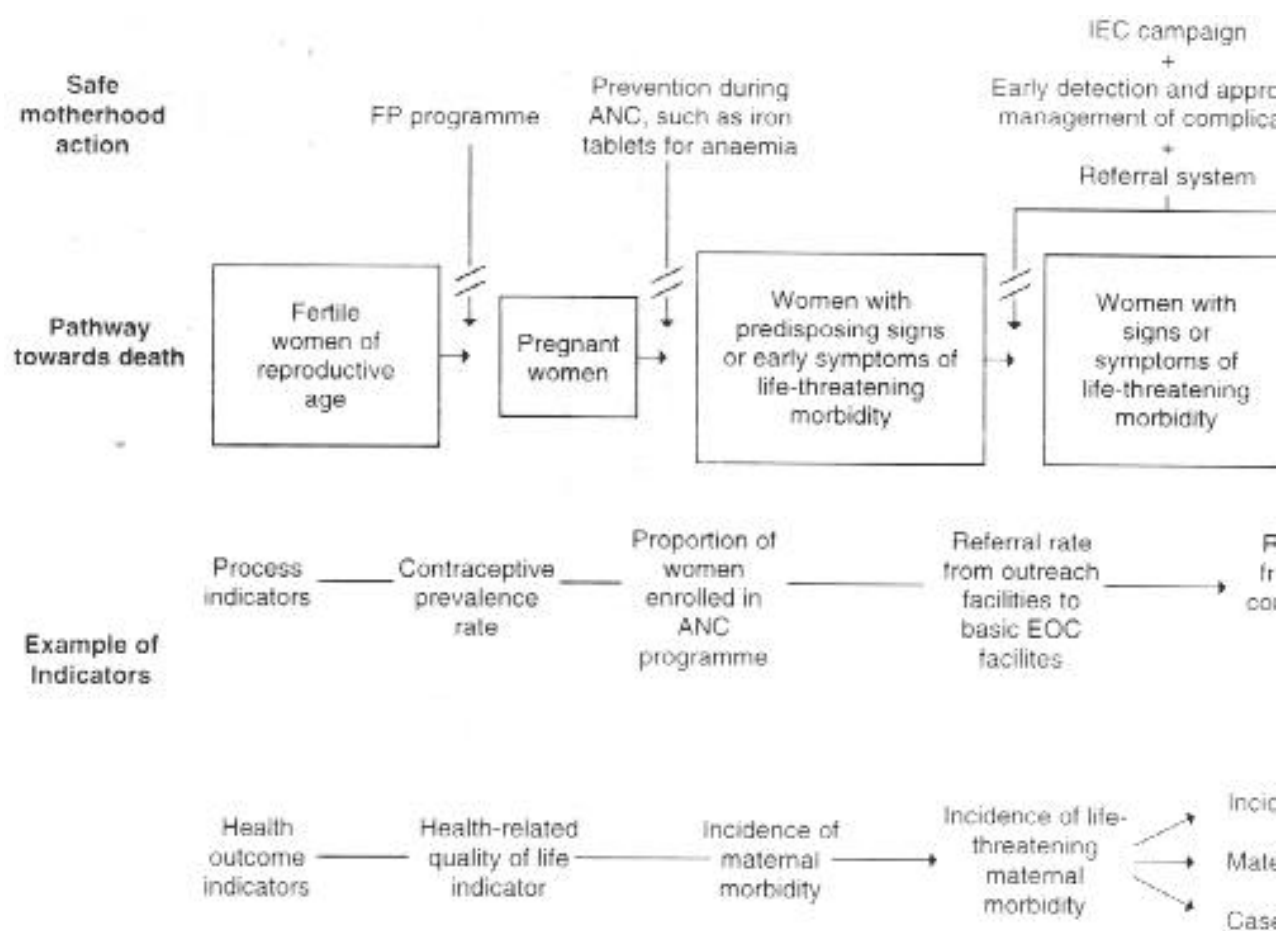
A.2 What about using population-based figures of direct obstetric morbidity as an alternative?

Although maternal morbidity is more common than mortality, **the major direct complications known to lead directly to maternal death are unlikely to replace maternal mortality as an indicator of progress.**

Interpreting associations between morbidity trends and programme inputs are not as conceptually straightforward as for mortality. Most Safe Motherhood interventions aim at preventing complications from becoming severe or leading to death (secondary prevention), rather than at preventing complications per se (primary prevention) (*see Figure 3*). Thus Safe Motherhood programmes may reduce mortality without reducing the incidence of obstetric morbidity. Indeed the incidence of chronic conditions following complicated childbirth could even increase, as women with chronic sequelae survive. Only programmes aimed at preventing pregnancy complications would be expected to reduce the incidence of morbidity and mortality.

Measurement problems compound the interpretational obstacles of morbidity data. Death is an unambiguous outcome, even to those not trained medically. Morbidity is not, even to those trained medically. Minor and major illnesses can thus easily be misclassified. Interview data collected in national surveys to estimate the population prevalence of prolonged labour, haemorrhage, eclampsia and sepsis, have not yielded biomedically valid or reliable results (i.e. accurate when comparing self-report with medical records or diagnoses) (Task Force Meeting on Validation of Women's Reporting of Obstetric Complications in National Surveys, 1997). Other research has shown that household survey approaches to determine the prevalence of induced abortion are similarly flawed (Baretto et al, 1992).

Figure 3. Conceptual framework for evaluation of Safe Motherhood programmes and indicators



Source: Filippi et al, 1996b

Even though complications are more frequent than maternal deaths, their numbers are small compared to 'healthy pregnancies'. In such circumstances, **even small numbers of false positives (where women report complications they do not appear to have clinically) lead to overestimating the prevalence of complications**(Ronsmans, 1996; Ronsmans et al, 1997b). **The resultant prevalences should be interpreted primarily as perceptions, rather than as accurate determinations of biomedically valid morbidity.**

It is sometimes argued that disagreement between reported and medically-defined morbidity should not discourage us from using estimates of self-reported morbidity in surveys, since adjustments can be made if the sensitivity and specificity of self-reported symptoms are known. However, the sensitivity and specificity of survey questions are so context-specific and variable that values derived in one population can only be used to correct estimates for a very similar population.

Estimates of maternal morbidity based on data from in-depth, more focused studies may be more accurate if considerable efforts are made to determine the appropriate wording of questions (see for example Goodburn et al, 1995). In a small-scale intensive validation study in Benin (Filippi et al, 1997a), the following results were found:

- Questions on acute complications such as prolonged labour, bleeding during delivery, and fever, which are at an extreme end of a continuum, performed poorly.
- Very good results were achieved for antepartum and acute events (bleeding before labour and eclampsia) in terms of clinical validity.

It is, of course, reasonable to want to measure perceived complications(Graham et al, 1995). Such questions are perhaps best used in the context of understanding health care seeking behaviour. Models of behaviour seek to understand the intent to use services in relation to actual use when the perceived need arises. Thus a woman can be asked, for example, whether a woman with antepartum bleeding should seek care, whether she herself experienced antepartum bleeding, and if so whether she actually sought care for this antepartum bleeding.

A.3 What about our ability to get other population-based indicators of maternal health?

Underlying maternal morbidities such as **anaemia, malaria, syphilis, UTIs, high blood pressure and long-term disabilities such as uterine prolapse, fistulas, and female genital mutilation** are often chronic or long-lasting conditions (Koblinsky et al, 1992). Because they are less acute than direct obstetric complications, **they can be measured using population-based health examination survey methods** (with clinical, anthropometric, and laboratory diagnosis).

Our experience is largely with anaemia (see below), prolapse, UTIs, and RTIs (*see Box 7*). However, most of these morbidities, with the possible exception of anaemia and malaria, are not implicated in maternal death.

Anaemia in pregnant women, defined as a haemoglobin of less than 11g/d, is estimated to affect more than half of pregnant women in developing countries. Causes include a mixture of reduced dietary iron or folate, malaria, hookworm and schistosomiasis. Haemoglobin concentration in the blood can be measured in the field using a battery run device called a Hemocue and a few drops of blood. Our field experience in Malawi and Burkina Faso suggests this technique is acceptable; women get a reading immediately and can be treated, or referred, appropriately. In Malawi, this instrument, along with standard household survey techniques, is being used to estimate the prevalence of anaemia before and after an intervention (for more information contact Linda Williams).

Box 7: Measuring Prolapse, UTIs and RTIs in Turkey

In a study of reproductive morbidity in Istanbul, a sample of parous women were asked a series of questions relating to specific types of morbidity by a lay interviewer, and also examined medically for the same morbidities. The prevalence by the two means of ascertainment were not the same. For example, the self-reported prevalence of prolapse (indicated by incontinence or sensation of pelvic organs being down) and of urinary tract infections (UTI - indicated by incontinence with burning pain when passing water), were both 19%, whereas the prevalence of the same conditions medically diagnosed were 27% and 7%. Similarly, the self-reported prevalence of reproductive tract infections (RTI - indicated by abnormal vaginal discharge) was 43% while the medically diagnosed prevalence was 20%.

Women in this community under-perceived signs of prolapse but over-perceived symptoms of RTI and UTI, in so far as these symptoms reflect the conditions. Also, fewer women were both diagnosed and perceived the signs of morbidity; this occurred in only 10% of the sample for prolapse and RTIs, and in less than 1% for UTI. For this reason we recommend using surveys with clinical and laboratory components to measure medically defined UTIs, RTIs and prolapse.

Source: Bulut et al, 1997; Filippi et al, 1997b.

A.4. Can facility-based data be substituted for population-based data collection?

It may be possible to collect useful data on maternal mortality and morbidity from health facilities using facility-based and /or provider-based records and registers and in-depth reviews of case records (see for example, Malle et al, 1994).

The potential for facility- or provider-based records and registers to measure progress in Safe Motherhood activities is greater than for population-based surveys. These records and registers have the potential to provide:

- a record of biomedically valid morbidity and mortality
- a record of outcomes following treatment

These data are not population-based but if we are prepared to assume a certain proportion of women require obstetric procedures in specialised hands to treat serious complications, then health facility register data can be used to derive (indirectly) population-based estimates of the proportion of women with severe obstetric complications who deliver with a medically trained attendant (see section IV.B.1 below).

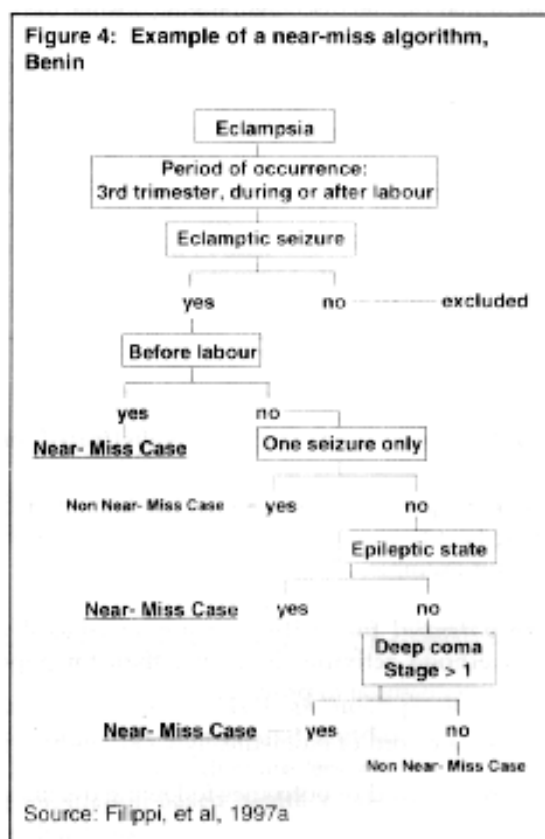
To our knowledge, no studies of maternal health services in developing countries have shown that record-keeping can be sufficiently improved for the duration of programme implementation. Such efforts, presently on-going in a number of countries, should not be underestimated in terms of time, resources and intensity of programme effort required. Also, while we suggest that records may provide biomedically valid data on morbidity, it is important to recognize that clinical diagnoses and treatments may be wrong. Clinical diagnoses often show serious misclassification when compared to laboratory tests and autopsies.

Retrospective reviews of existing facility or provider-based records and registers are not a practical tool for measuring maternal morbidities in many settings where we have worked. Records are often missing information or have illegible writing. A ‘broad diagnosis’ may be available but without confirmatory information (e.g., prolonged labour without a partograph report). A treatment (e.g., antibiotics) may be recorded but only have been given as advice to the patient rather than supplied to the patient. For example, in Assiut, Egypt we found that among women who had delivered in hospital, 93%, 92% and 95% of patient records listed parity, sex of the infant and presence of abnormalities respectively, but only 20%, 1% and 1% recorded problems with the pregnancy, birth weight of the infant, or APGAR scores respectively (Abdullah et al, 1995).

Complications at the severe end of the morbidity spectrum, such as near-miss death events, are potentially useful health outcomes that can be measured in health facilities. A near-miss death event is a severe life-threatening complication necessitating an urgent medical intervention in order to prevent the likely death of the mother (Filippi et al, 1996b).

The advantage of near-miss death events over complications is that near-misses are a better proxy for maternal deaths, while still occurring in large enough numbers for statistical analysis. The main requirements are:

- the definition of ‘severity’ must be agreed upon (some were tested in Benin(see **Figure 4**) and are available from Veronique Filippi).
- protocols to identify near-miss death events must be developed. These should be site-specific especially when retrospective data or treatment information are used.



B. What lessons have been learnt about measuring process indicators

Given the difficulties of measuring health outcome indicators, and the recommendation that detailed descriptive designs are used in evaluation, the importance of process indicators is increased. However, **our experience with these process indicators is more limited** as our main focus had been on measuring health outcomes. This section discusses the advantages and limitations of the few process indicators which we have measured. **These include several promising indicators for measuring use/coverage of services (among all women, and among those experiencing certain complications) and less practical indicators of quality of services.** Our overall assessment is that while many process indicators may prove useful, they usually cannot be interpreted on their own and may need to be disaggregated for various sub-populations.

B.1 How can we measure service use/coverage?

Information on service use/coverage by all women and by those with complications is important for evaluating programmes.

B.1.1. We can readily obtain information on who delivers women and on where they are delivered. There is increasing experience collecting such data from women in large-scale household surveys. This information is critical to determining and understanding the constraints within which a Safe Motherhood programme works. **Key requirements include**

- **carefully specifying the nature of the delivery attendant.** It is important to distinguish between trained Traditional Birth Attendants (TBAs) who have a limited scope for delivering emergency obstetric care, and medically trained providers such as doctors or midwives, who should be better able to recognize complications, provide emergency first aid, and access the referral system. It is also useful, though sometimes difficult, to discern between TBAs and relatives/other persons. Women who deliver in a medical context cannot always determine the qualification of their providers.
- **distinguishing between hospitals and health clinics/small maternities** (rather than lumping them together as 'health facilities') and between private and public sector providers/facilities.
- **cross-tabulating results** so that it can be understood both who is doing deliveries and where they are taking place.

B.1.2. How can we measure service use/coverage by women with complications? It is possible to measure use/coverage by counting the women with complications who use health facilities By making some assumptions we can translate this number into a potentially useful indicator. The options all assume that the potential outcome for some obstetric complications is much better when care is provided in a district hospital than at lower levels of care. Women and their babies with these complications who do not present at a district hospital (or similar institution) are taken to have received inadequate care. The number of complications observed in health facilities (usually the district hospital) is recorded. An expected number of complications is derived using one of three possible options: 1) a standard 'guesstimate' of 15% of all deliveries in a geographic catchment area (sometimes termed a 'met-need' indicator) (Koblinsky et al, 1995; WHO, 1994); 2) a specific prevalence of complications based on the literature (Pittrof, 1997), or 3) a figure based on women's reported prevalence of complications in the population under study. The first approach, promoted by UNICEF, has been tried in India (Nirupam and Yuster, 1995) and Bangladesh. We have experience with the latter two approaches.

The second approach, termed *Observed Versus Expected Ratio (OVER)*, seeks to assess conditions which are distinct and obvious, easy to diagnose, and difficult to misclassify (Pittrof, 1997). Breech presentation and twin pregnancy at delivery and, to a lesser extent, management of a pregnancy complicated by placenta previa or placental abruption fulfill these conditions. The *OVER* method requires that each chosen condition has a biologically determined incidence within a population of pregnant women which is largely independent of the knowledge, skills or management preferences of the health service providers. These criteria hold for breech presentation in labour, twin pregnancy, placenta praevia and placental abruption, so the *OVER* is expected to provide robust estimates of the use of appropriate care. The *OVER* for placenta praevia and placental abruption assesses coverage for emergencies requiring rapid management (such as Caesarean section for antepartum haemorrhage) while the *OVER* for twins and breech assesses coverage for conditions which can be diagnosed antenatally or during early labour (i.e. before the emergency condition arises). These conditions are routinely recorded in delivery registers or annual statistics of many institutions thereby minimizing the required workload (see **Box 8**).

Box 8. Use of *OVER* in Zimbabwe

The *OVER* method was tried in Zimbabwe. Reference incidences for pregnancy complications were established using data from settings in the USA, Rhodesia and South Africa where most women deliver within institutions. The number of deliveries in the catchment area was estimated by multiplying the estimated population by the estimated crude birth rate. The number of deliveries was in turn multiplied by the reference incidences. This resulted in an expected number of complications, which was compared to the observed number. The resulting ratio provides information on use of health care facilities.

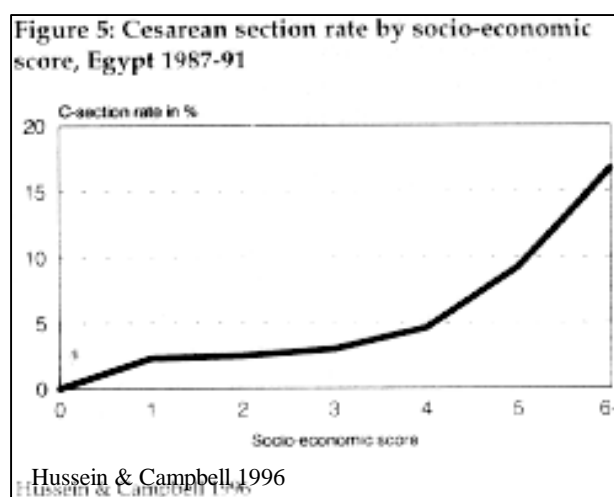
Obstetric complication	Source	Reference incidence	Expected number	Observed number	OVER
Breech at delivery	Clinch (1989); USA, urban black population	31.7/1000 deliveries	246	90	0.37
Twin pregnancy	Bulmer (1970); Rhodesia, urban black population	28.4/1000 deliveries	220	122	0.55
Placental abruption	Green-Thompson (1982); South Africa, Durban, mainly urban black population	10.0/1000 deliveries	77	5	0.06
Placenta praevia		3.0/1000 deliveries	23	2	0.09

Total number of deliveries in Makoni district in 1992: 7768 (Central Statistical Office, Census 1992, Harare, Zimbabwe, 1992).

Source: Pittrof, 1997.

Implementing the third approach should be possible by using the prevalence of complications women report from survey data to calculate an 'expected number of complications'. Such data are provided by our survey data in Indonesia, but we do not recommend this approach because of the over-estimates produced by women's reports of rare events (see section IV.A above).

B.1.3. Can the Caesarean section rate be used as a measure of use/coverage of emergency services? The Caesarean section rate provides another potential indicator of use/coverage of emergency services, and has also been proposed as a measure of unmet need (WHO, 1994; De Brouwere et al, 1996). The rationale is that a Caesarean section rate below a certain level (usually 5%) suggests too few women are getting this potentially life-saving service (although rates over certain levels, usually 15%, indicate over-medicalization).



- **We feel this indicator needs to be interpreted with caution** Caesarean section prevalence rates can be extremely misleading and mask very differing rates among different sub-populations (Campbell et al 1991; Hussein and Campbell, 1996). Analysis of PAPCHILD data in Egypt showed that even though the national Caesarean section rate was 5%, when we stratified women by socio-economic status, the poorest women had no Caesarean sections while better off women experienced rates over 15%(see *Figure 5*).
- If data on Caesarean sections are collated from hospital log-books rather than survey data, it is not possible to examine data in socio-economic sub-populations (as described above).

B.2. What indicators can we use to measure quality of care?

In the absence of health outcome indicators, process indicators on use/coverage of services can only give a limited picture of what is happening vis a vis Safe Motherhood programmes. If however, these are complemented by information on the quality of care provided by services, a more complete picture can be built up. We define quality of care as having many aspects (see Box 9). However, our experience with quality of care indicators is limited to case-fatality.

Case fatality is an instinctively appealing facility-based indicator of health impact and quality of care. However:

Box 9: Definition of Quality of Care:

We define quality of care as the provision of a minimum level of care to all pregnant women and their newborn babies, and a higher level of care to those who need it, while obtaining the best possible clinical and emotional outcome. This includes using a transparent managerial system (standards or guidelines), providing care which satisfies users and providers, maintaining sound financial performance, and developing existing services so as to raise the standards of care provided to all women.

- **Case fatality shares the problem of rarity** that affects the measurement of maternal mortality. Even hospitals with a large volume of deliveries may have few deaths (less than 10). In district hospitals, the numbers of deaths can be even smaller. It is also unclear how much case fatality is sensitive to changes in quality of care or to the case-mix of patients. Case fatality should be interpreted with caution. A successful community programme could even cause it to rise if more women with complications use facilities.
- **The definition of the denominator is problematic** The best choice of case fatality rates is cause-specific (for example, a case fatality rate for postpartum haemorrhage), but these limit the numerator even further. Moreover, it may be difficult to define the denominators: (for example, women with the complication of postpartum haemorrhage). If an alternative all-cause case fatality rate is used, the rate will vary immensely between settings depending on how broadly or loosely 'complications' are defined. Defined most broadly, the all-cause case fatality rate becomes a facility-based maternal mortality ratio, with all births as the denominator.

V. Where do we go from here to improve our knowledge of measuring quality of care?

Although our experience with process indicators is limited, we have developed and tested tools for assessing various aspects of maternal health programmes, including auditing deaths, near-miss death events, and the processes of providing a high-quality health care service. These tools provided data which can in turn generate numerous indicators. As experience with these tools and indicators grows, it will be possible to select the better ones to evaluate programmes using the 'before-during-and-after' designs described above.

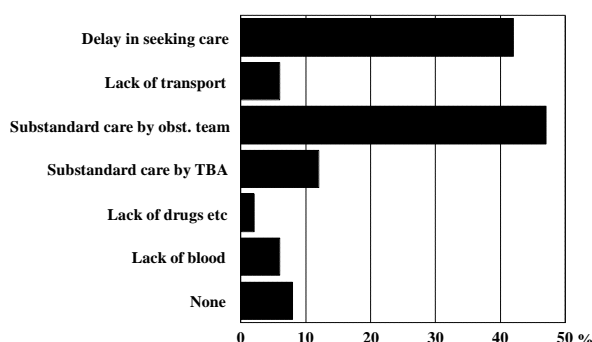
A. What tools do we have for measuring processes related to mortality?

Determining factors contributing to maternal death is useful for programme planning and implementation. Maternal death audits (or confidential enquiries) can be conducted in facilities where deaths take place, as well as in the community. Verbal autopsy tools exist for determining the biomedical causes of death (Campbell and Ronsmans, 1994), although reliability may be poor (Ronsmans et al, 1997c). Investigating the processes and avoidable factors leading to the maternal deaths may provide valuable clues to access or quality of care problems amenable to intervention (see Box 10).

Box 10: Audits of maternal mortality in Egypt

A nationally representative sample of maternal deaths, identified through the vital registration system, was reviewed by medical specialists at governorate and central level in Egypt. Among the leading avoidable factors contributing to the deaths, was sub-standard care by the obstetrician teams (47%) and delay in seeking care (42%).

Avoidable factors contributing to maternal deaths, Egypt 1992-3



Source: MOH, 1994; Campbell et al, 1995

MOH Egypt, 1994

B. What tools do we have for measuring processes related to morbidity?

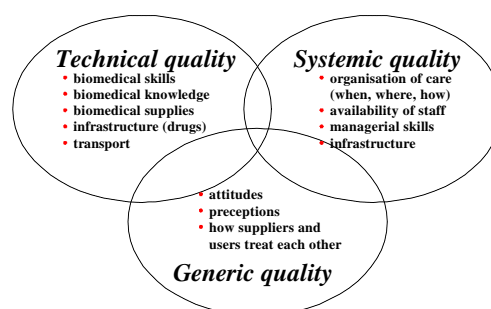
Audits can also be done for near-misses. In the context of audits, near-miss enquiries may be less threatening to service providers than death enquiries, since guilt feelings are reduced, thus making for a more productive debate. Women with morbidity can also be interviewed themselves, thereby providing complementary information on quality of care from the patient's point of view. If near-misses, or deaths for that matter, are used as an initiating point for confidential enquiries or audits, the definition of the elements of quality of obstetric care and substandard care within the local resource environment should be determined in advance.

C. What tools do we have for assessing quality of care other than those which focus on health outcomes?

Some experience exists in assessing the inputs into maternal health care (e.g. checklists for minimum equipment) but less is known about how best to assess most aspects of quality of care and how to determine priorities for improvement. One particular difficulty is how to assess skills in treating obstetric complications. The incidence of the most common serious complication, postpartum haemorrhage, is less than 20%, so more than five births would have to be observed to witness the management of one haemorrhage.

Figure 6. Aspects of quality of care

Quality Assessment Tool



This makes it necessary to develop instruments to assess the correct use of tools and procedures without observing the provision of care. We have developed and tested instruments to assess all aspects of care (i.e. *generic quality* (interaction between users and providers or among providers, and structures and processes affecting the psychological/emotional aspects of care); *systemic quality* (managerial structures, processes and outcomes); and *technical quality* (biomedical structures, processes and outcomes))(see **Figure 6 and Box 11**).

Box 11: Measuring quality of care in five hospitals in Egypt

Work in progress and results of quality assessment in 5 hospitals in upper Egypt showed that:

- Adjusting assessment tools developed by others (for example by WHO (1995) or our group) to local conditions is possible.
- Enquiries into quality of care provided is threatening to care providers and managers.
- Collaboration with local care providers and managers and confidentiality of the evaluation process are extremely important.
- It may be possible to assess communication by measuring the agreement between and within types of providers and managers.
- Senior and junior doctors, managers, nurses and midwives often have different priorities for quality improvement. We did not measure user's priorities but expect these would differ as well.
- No two hospitals assessed had the same quality limiting factors ("bottle necks"). Blanket interventions for all hospitals are therefore likely to be ineffective.
- Quality assessment may stimulate some local providers and planners to initiate change.
- Ranking facilities according to quality of care provided is extremely difficult (this would require adjustment for case mix - and there are no simple methods to do this!).

For more information contact Rüdiger Pittrof.

VI What are our conclusions?

The summary of our main findings to date are shown in Box 12.

Evaluation is a valuable tool for improving health programmes and using resources wisely. The obstacles faced in evaluating programmes are not unique to Safe Motherhood; they are shared by many other areas of health. Even if programmes are not amenable to experimental approaches, it is possible to design effective packages and to evaluate them. Many countries have created successful programmes (resulting in low MMRs) using observational evidence.

Moreover, the difficulties of measuring the MMR should not be interpreted to mean that maternal mortality is not a problem. Special studies throughout this past decade have shown that the burden of maternal ill-health is high, and is amenable to reduction. Such studies of maternal mortality and severe morbidity remain valuable tools for advocacy and maintaining political commitment.

Maternal mortality does not appear to be preventable with 'quick technological fixes'. Rather it appears to require services that integrate several levels of care from the community to the district hospital. Sustained efforts are needed to provide this. Health care providers, policy makers, and donors should not hide behind methodological problems to justify inaction.

Box 12: Summary of main findings

Safe Motherhood programmes are difficult to evaluate because: a) the interventions are usually a comprehensive package delivered to communities not individuals, and b) it is impractical to measure the preferred health outcomes of mortality or morbidity. These two points affect a) the study design used for evaluation and b) the indicators chosen

Design. Descriptive (before and after) rather than experimental (RCTs and CRTs) study designs should be used for evaluation unless the intervention can be generalized broadly to many settings.

Indicators. In most settings, Safe Motherhood programmes are forced to use process indicators to measure the implementation and use of appropriate services, possibly supplemented by facility-based data on morbidity and mortality.

Health outcome indicators

- we can obtain rough population-based estimates of maternal mortality but cannot measure change.
- we cannot easily obtain population-based estimates of direct obstetric morbidity using interviews, but may be able to substitute facility-based information for some of this.
- we can measure underlying (chronic) maternal morbidity with health examination surveys.
- we can measure perceived morbidity of all types.

Process indicators:

- we can measure use/coverage of services among all women, and among those experiencing complications
- we have yet to develop or identify good indicators or approaches for measuring quality of care. We need considerable work and documentation in this area.

Tools. We are developing tools for auditing maternal deaths, near-misses, and the processes involved in providing high quality care. These instruments generate many indicators. The best of these may ultimately enable us to assess quality of maternal health services.

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