

MODULE 4, Tool 8

Outcomes after Pregnancy (OAP)

Version 2.0

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List of Acronyms

- Demographic and Health Surveys Non-governmental organization DHS
- NGO
- outcomes after pregnancy OAP
- WHO World Health Organization

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INTRODUCTION

Safe motherhood programmes focus on reducing maternal mortality in developing countries. Most of these deaths are caused by the inadequate care of severe complications during pregnancy, delivery or relating to unsafe abortion. Restricting the focus to maternal mortality, however, seriously underestimates the burden of disease attributable to pregnancy-related causes. For every woman who dies, at least ten survive severe obstetric complications and unsafe abortions, with potentially disabling consequences which are rarely considered.

These consequences, which we have termed 'outcomes after pregnancy' (OAP), comprise diagnosed and perceived illness or disability following pregnancy (including mental illness) and direct social and economic consequences of events related to pregnancy. Attention to these outcomes, combined with information on maternal death and acute obstetric complications, creates a more holistic and longer-term perspective on maternal health.

Public health research in developed countries has moved beyond the evaluation of 'hard' physical outcomes, such as diagnoses or deaths, and utilizes self-perceived 'health status' or even 'health-related quality of life' indicators to complement the evaluation of interventions. These findings can be useful in many ways, for example as a way to assess different programmatic options or for resource allocation. In resource-poor contexts, where public health programmes are struggling against high levels of maternal mortality, it could be argued that any other health-related considerations in relation to pregnancy are unaffordable luxuries. But by focusing on the reduction of maternal mortality as the sole benchmark for progress, programmes ignore inadvertent but undesirable effects or consequences that they may need to address.

4(8).1 What is an OAP study?

An OAP study uses an interdisciplinary approach to explore the interrelated social, psychological, physical and economic consequences of complications during pregnancy and childbirth. Research methods are primarily anthropological and epidemiological, but can also be used in conjunction with economic and clinical evaluation of outcomes.

Using the different methods of an OAP study, researchers can evaluate a broad range of consequences of near miss complications. Near miss complications are obstetric complications that require an urgent medical intervention to prevent the likely death of the woman (Ronsmans & Filippi, 2004). There is no consensus on the best criteria to identify near miss complications, which can include eclampsia, severe haemorrhage, sepsis, uterine rupture and severe anaemia. Near miss complications can occur with or without a live baby and at any time in early or late pregnancy, childbirth or the puerperium. Although outcomes after pregnancy can be both positive and negative, an OAP study focuses on the negative ones since they are frequently associated with near miss complications.

Figure 4(8).1 below shows the range of possible negative consequences associated with near miss complications for women. Our research shows that these consequences do not usually occur independently of one another, but often occur in combination or sequentially.

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Figure 4(8).1: The interrelated physical, social, economic and psychological consequences of a near miss

Results from an OAP study can be used for advocacy and programmatic purposes. The methodology presented draws primarily on lessons learned from research and evaluation activities conducted in Burkina Faso. Experience from Indonesia and the non-Immpact setting of Benin were also essential to our research.

The methodological approaches utilized within Immpact's OAP studies are as follows:

- 1. An initial ethnographic study using in-depth interviews with women, and observations in the home to explore the context, help define the outcomes and formulate questionnaire items.
- 2. An interview survey among women identified from hospital records or who report an early pregnancy loss, a birth, or a recent complication (for example complications associated with an unplanned caesarean section or a stillbirth) to document perceived physical, psychological social and economic consequences. Questions developed for the OAP survey were structured into several modules addressing infant health, women's physical health, sexual health, depression and anxiety, social relations and support, domestic violence and economic consequences. The OAP survey can either be conducted as a cohort or cross-sectional population-based study.
- 3. A full ethnographic follow-up study with a sub-set of women in the epidemiological sample, using open-ended in-depth interviews with women and their family members, as well as further observations in the home. This study is conducted in parallel with the survey (2. above).
- 4. A clinical evaluation with a sub-set of women from the survey sample. If the survey is conducted longitudinally, clinical exams can be conducted at several points after the end of pregnancy, for example 6 weeks, 6 months and 12 months. If the survey is a cross-sectional survey, the clinical evaluation might be less informative, but if used, it should be done preferably within a week of the interview.

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The OAP study could also be conducted in conjunction with an economic analysis, such as the Productivity Costs Survey or the Household Costs Survey (Tools 6 and 7 in this module), as part of one larger survey.

4(8).2 Why conduct an OAP study?

For every woman who dies, at least 10 survive severe obstetric complications and unsafe abortions with potentially disabling consequences. Demonstrating the broader implications of obstetric complications can therefore be a critical tool to advocate for investment in maternal health care. Furthermore, it allows not only the health dimensions of pregnancy complications to be highlighted, but also their social and economic impact.

Although our experience with using the OAP tools in evaluation is limited, this approach has potentially an important role to play in programmatic evaluation. It can lead to the development or use of new indicators to complement maternal mortality and process indicators in safe motherhood research and programme evaluations (Bell et al, 2007 – In Press).

Quantifying OAP has several methodological assets. When used in a cross-sectional survey, it is possible to use small sample sizes, since outcomes after pregnancy are likely to be common. This is in contrast to the measurement of relatively rarer outcomes, such as maternal mortality and (often) caesarean sections. It may therefore be possible to assess OAP using data from routine surveys, such as the Demographic and Health Surveys (DHS), using a specific questionnaire module.

The interdisciplinary approach used by OAP also has several methodological advantages. Collapsing analytical frameworks and combining theories and methods from different disciplines leads to a fuller understanding of women's health outcomes and of their experiences of these. The narrative approach of anthropology, for example, helps overcome some of the limitations of epidemiological methods in gathering fully textured and nuanced data. It also facilitates the definition of outcomes for epidemiological research, as well as the interpretation of epidemiological findings. This helps to ensure that women's priorities and evaluations of their own health are integrated into the study results. Conversely, the epidemiological and economic approaches help to contextualize the analysis of anthropological data from a sub-set of women within its larger epidemiological context. A further methodological advantage of an OAP study is that many medical consequences reported can be verified using medical examination or tests (for example incontinence or anaemia). The different approaches are therefore complementary and help to validate each other. It is important to note, however, that there are also significant challenges involved in combining these methods, in particular when analysing and writing up findings.

4(8).3 Limitations of an OAP study

The OAP study methodology has recently been developed and, as a consequence, requires further testing and refinement. This includes attention to how it can best be utilized within an evaluation framework. In Benin and Burkina Faso, a comprehensive set of tools and methods were used to test the hypothesis that near miss women experience a range of adverse consequences, but the methods were not used as part of a composite safe motherhood evaluation. Only sections or question items of the epidemiological questionnaire were applied in the context of the composite evaluation studies in Burkina Faso, Indonesia and Ghana. Similarly, the ethnographic component was only applied in the context of an evaluation of Indonesia's village midwife programme and the evaluation of a maternal health programme in Burkina Faso. There are still unresolved questions, therefore, on the extent to which the context or specificity of an intervention can affect the duration and the severity of an 'outcome after pregnancy', and on the research methods that are best used to capture these effects.

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The design of the methods and tools must also be considered. The instruments presented here were developed for a specific context and evaluation. Experienced demographers or epidemiologists, with a good understanding of the concept of validity, are needed to adapt our approaches and tools for capturing outcomes after pregnancy within their own settings and for their own evaluation questions.

4(8).4 Using OAP methods

This section provides a step-by-step guide to conducting an OAP study. Since the methodology will need to be designed to suit the local context, and may require further adaptation for use within a composite evaluation, this section highlights key issues for consideration.

Step 1: Prepare for and design your study

Understand the context

The local context, particularly in relation to women's status, the organization of the health system, and the social and financial implications of having a baby, is likely to shape the type of expected consequences of near miss complications. For example, in a context where fertility is highly valued, the loss of a baby might bring particularly acute social difficulties to women. Similarly, where women have to pay user fees for delivery or emergency care, there may be increased impoverishment in the postpartum period, particularly when emergency care has been used.

Understand the composite evaluation question (where applicable)

Where OAP is being used as part of a composite safe motherhood evaluation, understanding specific details about the intervention, policy or programme being evaluated might lead you to focus on certain types of adverse OAPs. For example, if an intervention or policy focuses on increasing the financial access to delivery services, you may wish to assess in detail the economic consequences of pregnancy, including any effects on poverty or debt among the beneficiaries. During the study design phase, it is therefore important to discuss the objectives of your study with policy-makers and programme managers, so as to understand which information they would find useful.

Study design

This tool presents a multi-disciplinary approach to evaluating outcomes after pregnancy. A careful study design is required to select the methods appropriate for the local context and research needs, as well as the resources available for the study. Key questions include:

- Primary outcomes: It is important to know the primary outcomes for the policy or intervention and how they will be measured: what is the intervention and what is it trying to achieve?
- Resources: What resources have been earmarked for this component of the evaluation?
- Survey design: Will the information on the selected indicator be collected from routine sources, hospital data or from special surveys? Can OAP be integrated with other surveys? Will a cohort or cross-sectional survey be conducted?
- Participant identification and selection: If a separate survey is to be conducted (as was the case with Immpact's OAP cohort study), how will women be identified? Which groups of women will be targeted for the analysis? In the Burkina Faso cohort study, near miss women and women with uncomplicated childbirth were recruited prospectively from hospitals; while in the evaluation, women with complications were identified using reports of caesarean section and perinatal deaths as proxy variables.
- Sample size: The research team will need to determine the sample sizes for both the qualitative and quantitative arms of the study. In Immpact's OAP cohort study in Burkina Faso, seven hospitals were selected for recruitment so that a sufficient number of women with near miss complications could be

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interviewed (based on estimates of the incidence of such complications in various types of facilities). Sample sizes for the survey are discussed further below. It will be helpful to seek statistical advice when determining the sample size and designing this part of the study.

When deciding on the survey methods, there are several key considerations. OAP was originally designed as a cohort study to document the range of adverse consequences experienced by women after a pregnancy, primarily for advocacy purposes. This approach allows for a long-term investigation into outcomes after pregnancy, including how long they last, whether they get better or worse over time, what factors trigger recovery or worsening, or what is an appropriate time to try and help women who are suffering from adverse outcomes. A cross-sectional survey, on the other hand, is suited for an evaluation context and is usually conducted before the intervention, and likely to be repeated after.

In Immpact's cohort study in Burkina Faso, the consequences of severe obstetric complications were identified and compared among four groups of women:

- women with a near miss complication associated with a live birth
- women with a near miss complication associated with a perinatal death before discharge
- women with a near miss complication associated with an early pregnancy loss
- women with an uncomplicated childbirth

In addition to these groups, the researchers would also now recommend including a fifth group, based on Immpact's experiences with OAP studies:

• women with a stillbirth or perinatal death associated with an uncomplicated childbirth.

Step 2: Obtain permissions and train research team

Seek permissions from the Ethics Committees of collaborating institutions, from the regional health administrations in the country, and from the participating hospitals and health centres. In order to ensure that your study will have the highest impact, it is a good idea to inform high-level authorities that the study is taking place, and to receive their support from an early stage.

Both the qualitative and quantitative components of the OAP study are likely to involve women who have experienced acute problems or complications related to a pregnancy. Interviews conducted during the study may lead to a greater recognition of these problems by the woman herself and possibly raise expectations of treatment or help.

Some sensitive topics may also be discussed during the interviews, such as marital disharmony, which could be associated with violence. It is important that the interviewers are trained on how to handle this in the field. Useful ethical and training advice on conducting this kind of sensitive research is available from the WHO.

(see: http://www.who.int/entity/gender/violence/en/womenfirtseng.pdf)

Interviewers must also be trained to respond to indications of depression identified by the questionnaires. For example, if the questionnaire module indicates that a woman appears at risk of mild depression, the interviewer should, in the first instance, reassure her that these feelings are natural and should encourage her to speak to a close friend, family member, priest, or other person she feels she could confide in. Referrals should also be made for women with a high score for depression. Research should be conducted prior to the interviews to ascertain what resources are available to women in these areas (such as NGOs), and to gain their permission to refer women there.

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Resource allocations for the research should take these referral needs into consideration (see section 4(8).5). This includes referral to clinical, mental health and social care. The study group should also develop a screening policy to help them decide who should be eligible to access funds or resources, as the amount of suffering in the community can be large.

Step 4: Conduct initial ethnographic study

The main aims of this initial ethnographic study are to understand women's concerns and perspectives in order to identify the various possible consequences of near miss complications that have or have not been anticipated, as well as to develop an understanding of and documentation of the study context.

While the interview guide can be applied by a good qualitative interviewer, an experienced anthropologist is needed to design the interview guide, and to analyse the data with sufficient depth and reflection.

Qualitative interviews using an unstructured study guide should be conducted both with women who have had a severe complication at their last delivery or during an abortion, or a serious adverse consequence from pregnancy or delivery such as vesico-vaginal fistula, as well as with women who have had a normal delivery or abortion without a complication (as a comparison). Qualitative interviews with women who have had a complication can help identify the range of possible consequences experienced, while interviewing women with sequelae can help enhance our understanding of specific disabilities or adverse effects associated with the pregnancy or delivery. Qualitative interviews also help researchers to identify appropriate terminology that can be used in the survey instrument. The comparison group was used in Immpact's cohort study to try to discern how a woman's experience of pregnancy and childbirth might be expected to look compared with the experiences of women who had complications.

The sample can be identified with the help of health care providers or from hospital records. Women with direct obstetric complications cannot be identified easily from the community as the validity of these self-reported complications in retrospective interview surveys is generally poor. In Burkina Faso, 30 women were interviewed for this initial qualitative study since a comparison group was also involved. In anthropological research, the quality and depth of the interviews and observations is more important than the quantity of interviews: this depends on the rapport developed between the interviewer and the interviewee, as well as on linguistic and other practical factors.

After the ethnographic study, the research team need to construct a conceptual framework of the ways in which possible consequences of pregnancy-related complications relate to each other, focusing on the interplay between social, economic and health-related issues. This conceptual framework and the potentially measurable 'outcomes' implied by the framework can help to inform the design of the questionnaire (see below), taking into account the type of intervention and primary outcomes to be evaluated, as discussed in Step 1. The findings can also help ensure that questions are adapted and framed in a way that makes sense to the women. It is important to take into account the fact that many of the consequences identified through ethnographic fieldwork may not be easily amenable to quantification and may, therefore, not easily be incorporated into a survey instrument. This demonstrates the need for an ethnographic study to be nested with the cohort study.

Step 5: Design the questionnaire

Review existing instruments and tools, including Immpact tools

The OAP survey questionnaire was developed partly by using pre-existing questionnaires, and partly by developing new questions. Using questions from other surveys helps to increase the comparability of the findings, in particular when these have been validated. A similar review of existing survey instruments can be

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conducted by those planning an OAP study in their country. However, one should remain aware that when questions are changed or adapted the validity also changes. Conversely, using questions without making changes in a culturally different context may also reduce validity and meaning. Comparisons with other studies may be severely limited because of such contextual differences. New questions in the OAP survey were developed based on a literature review, and on the initial ethnographic fieldwork and analysis. Any research team wanting to use the modules from Immpact's OAP survey as a base would need to adapt or redesign the questionnaire in the same way (see below).

Questionnaires adapted from other sources included WHO's questionnaire on domestic violence (physical, mental and sexual violence); the World Bank/DHS ownership of assets index; a questionnaire from the Medical Outcomes Study on social support; and the K10 questionnaire on risk of depression and anxiety. The K10 is an instrument used in the WHO's Mental Health Survey, designed to detect individuals at risk of depressive disorder, and was included because Immpact was particularly interested in the long-term risk of postpartum depression (see Baggaley et al, 2007 – In Press, for further information). Also, it is quick and easy to administer, has been developed through a systematic process, and while it is relatively new, it has been extensively tested and validated in various regions. All questionnaires added to the OAP tool were adapted, translated and back-translated.

Validity indicates whether a tool is measuring what it is intended to measure. There are different forms of validity, including content face, construct and criterion validity (Bowling, 2001). When there is a gold standard and criterion validity can be assessed (as is the case with morbidity data, such as depression), the two key parameters in defining the utility of a screening tool such as the K10 are its sensitivity and specificity. Sensitivity is the ability of the test to correctly identify individuals with the condition; specificity is the ability to correctly identify those without. There is usually a trade off between the two. For a screening test in a medical setting of an industrialized country, the priority is usually to identify all those with early or asymptomatic disease at the expense of including some false positives, so specificity can be low. However, the use of tools in surveys does not require this level of sensitivity, and specificity becomes more important. Indeed, the specificity must be very high when the outcome of interest is relatively rare (below 10 percent), otherwise there is a risk of overestimating its prevalence (Ronsmans, 1996). It is recommended that screening or diagnostic tools used are validated, ideally within the same setting/context, though this is not always possible. The less effective a tool is at correctly classifying subjects, the more individuals will be misclassified and any differences between groups will be underestimated.

Design the questionnaire

The questionnaire modules used in Immpact's OAP studies are currently being refined and revised and therefore have not been included in this module. Copies of the modules can be obtained from Immpact (info@immpact-international.org) or the researchers at the London School of Hygiene & Tropical Medicine (see section 4(8).6).

Since outcomes after pregnancy are dependent on the context in which people live, it will be important to adapt any existing questionnaire, and include questions that are relevant to the local context. This design process can also support local researchers to take ownership of the survey instruments. New and relevant questions will usually be based on findings from the initial ethnographic study.

In Burkina Faso, for example, we developed a set of questions on women's relationships with family members (including husbands, extended family and children), perceived stigmatization and isolation, negotiation of payment of health-related costs, perceived poverty, perceived disability and long-term morbidity, impact of health state on daily activities and factors perceived to affect recovery from pregnancy-related health problems. Since the anthropological work had indicated to us that these factors were important in explaining women's (lack of) recovery from their initial complications and current consequences, and since no standard questionnaires had been developed in these areas, these questions were developed by Immpact for the study. It is important to

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emphasise, however, that ongoing qualitative work to investigate the social and ecological dimensions of the study needs to be conducted in parallel to the survey to ensure the validity of the questions.

Pre-test and pilot

The main objective of the pre-test is to check that the questions are meaningful to women, are likely to provide useful information, and that the flow of the questionnaire is correct. Ideally the pre-test should be conducted with women who have had a range of experiences at the end of their last pregnancy, from a complication related to an early pregnancy loss or delivery to a normal delivery. For reasons explained above, you might need to approach providers or use hospital records to identify this sample. It is useful to use a pre-test questionnaire to collect information on the results of the pre-test. Any new or revised questionnaire conducted later in the study (for example at 3, 6 or 12 months) must also be pre-tested. An example of the pre-test question guide from Burkina Faso is included in section 4(8).6 below. Once the survey questionnaire has been revised after the pre-test, a pilot study can be conducted to test the logistics of the survey.

In Burkina Faso, all instruments were translated into French and into two local languages, and back-translated by translation specialists.

Step 6a: Carry out the quantitative survey

Cohort and cross-sectional surveys involve distinct approaches to data collection which are discussed further below. In all cases, interviewers will need to be trained to carry out the survey. A cross-sectional survey would ideally use lay interviewers (non-health professionals), preferably women of reproductive age or even older. In a cohort study, it is possible to employ lay interviewers or midwives; the latter are slightly more costly but may be better able to elicit detailed and interesting responses on some sensitive issues such as violence and mental health problems, so long as respondents' perception of them as health care providers does not work against this. As with other population-based surveys, interviewers will need to be trained in survey skills, as well as maternal health, in order to understand the questions being asked. Immpact's training programme in Burkina Faso lasted two weeks (with an additional two days for training on the K10 questionnaire).

In the Burkina Faso cohort study, participants were recruited prospectively in hospitals, since near miss events cannot be identified retrospectively at the community level with sufficient accuracy (Filippi et al., 2000; Ronsmans & Filippi, 2004; Stewart & Festin, 1995; Ronsmans et al. 1997; Seoane et al., 1998). Women were recruited at hospitals if their medical records indicated that their pregnancy ended in a near miss obstetric event. Near miss events were defined as cases where a woman's survival was unlikely without acute obstetric care. Cases were classified as such if they had signs of extreme clinical severity, for example symptoms of shock or a major obstetric intervention such as hysterectomy for haemorrhage. These women can be assumed to be representative of women experiencing these complications in the community. A control group of women with uncomplicated deliveries was also recruited, defined as a vaginal delivery with a live birth that did not require major obstetric intervention, but who gave birth in the same facilities. However, where skilled birth attendance is low, the selection of controls in the health service settings can be a source of bias, and it is important to collect information on all women's health and socio-economic status during pregnancy at their first interview after discharge, in order to control for confounders during the analysis. It may also be useful to recruit these controls in health centres rather than hospital and to add an additional set of controls of neighbouring women who have delivered around the same time as the case. Since follow-up interviews needed to be conducted in women's homes, a further inclusion criterion was residence within 30 km of one of the hospitals.

Cohort study

A cohort of 1014 women was identified for the Burkina Faso study, including 337 who had experienced near miss events and 677 who had uncomplicated deliveries.

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The structured questionnaire was administered in women's houses at specific intervals after the end of the pregnancy, the first questionnaire 3 days after the end of pregnancy, with follow-up questionnaires 3, 6 and 12 months later. It was found that even longer follow-up would have been beneficial to the study results; however this would cause the costs of the study to increase. Based on this experience, Immpact would recommend questionnaires at 3 days, 6 weeks, 3 months, 6 months and 12 months after the end of pregnancy.

It is important to keep the loss to follow-up as small as possible to avoid bias. A good way to reduce this is to try to use the same interviewer for the same woman and provide incentives to the women. Extra arrangements must be made to ensure women can be traced to their homes for follow-up interviews. Although women were recruited in hospitals, a fieldworker accompanied them home to ensure their locations were adequately documented.

Cross-sectional survey

The recall period will depend on the main outcome of interest, but typically the survey will be done among women who have had a birth in the past 12 months. However, if infertility is an outcome of interest, a longer recall period is required since it can be diagnosed only after two years of attempted conception.

The sample size will also depend on the primary outcomes of interest. However, as long as the primary outcomes are not rare events, an adequate sample size would be in the range of 500 to1500 women.

Clinical follow-up examinations

Follow-up clinical examinations by gynaecologists were conducted in the Immpact Burkina Faso study at the 6 and 12 month interviews, to diagnose specific physical outcomes after pregnancy. Women were invited to the hospital for a clinical examination (with transport costs provided). The protocol for the medical exam is available on request from Immpact. The exam enables the identification of a range of conditions such as obstetric fistula, hyptertension, prolapse, urinary tract infection, anaemia and weight loss.

Step 6b: Carry out in-depth interviews and observations

In-depth interviews may be conducted concurrently with the cohort study with a sub-sample of survey participants. In other words, an ethnographic study is 'nested' within the cohort study. Interviews with women can be repeated a number of times during the year-long follow-up period. The specific approach adopted for this ethnographic component should be adapted to the local context and study requirements and objectives.

In Burkina Faso, 82 women were selected, which was less than 10 percent of the total cohort size. 18 of these women had an uncomplicated delivery (control) and 64 had experienced near miss events. This large qualitative sample was selected in order to ensure that the qualitative component could be analysed according to the woman's pregnancy outcome (see analysis section below). Women from each of the four groups of interest were selected for inclusion in the sample.

In-depth interviews are conducted by female anthropologists with the woman in her home, between one week and one month following discharge from the health facility, followed by a second interview about six months later. In line with anthropological approaches, the interview guide should be designed following the initial ethnographic study, and then adapted for each woman. Interviews should explore women's reproductive histories, healthcare seeking behaviour, aetiological frameworks, perceived health and recovery, social relationships and everyday lives. Interviews must be conducted in local languages or dialects, recorded, transcribed and translated (if required). Where possible, interviews should also be conducted with women's husbands and family members.

Observations during informal visits to women's homes should also be conducted throughout the duration of the study. Observations allow researchers to become immersed in the social environment of the women in the study

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population. They involve repeated contacts with women in this context (usually in her home), talking to other members of the household informally, and taking into account the environment in which the more 'formal' interview was being carried out, for example noting whether people were present that may have shaped how the woman was talking. Observations play an important role in the interpretation of the qualitative interview data. Researchers undertaking observations should be fully trained in ethnographic research.

Step 7: Analyse the data

One of the main challenges with an OAP study is to reflect the multi-disciplinary nature of the work in the analysis and give equal weight or importance to the different disciplines involved. An essential step is to examine and test the initial hypotheses (that were expected before the study was undertaken) for both the qualitative and quantitative studies, plus additional hypotheses that emerge during and from the anthropological field work. Forming additional hypotheses in the course of data analysis runs the risk of a false 'lead' emerging that cannot be statistically supported. But this stress on hypotheses will help lead to the main conclusions of the report and to see if results from the two types of study are coherent or complement each other, thus strengthening the conclusions. Divergences in findings between the two components are also important as they may reveal a more complex picture than any of the tools could have found on their own.

In Immpact's OAP study in Burkina Faso, data analysis compared the 4 groups of women involved in the study (women with a near miss complication associated with a live birth, women with a near miss complication associated with a perinatal death before discharge, women with a near miss complication associated with an early pregnancy loss, and women with an uncomplicated childbirth).

Survey data were analysed using standard software, presenting both adjusted and unadjusted results. Since some of the statistical analysis of the longitudinal data is quite complex, it is important to work with a good epidemiologist or statistician. The adjusted analysis took into account the socio-economic status of women, enabling the identification of consequences more directly related to the complications.

The anthropological data were analysed in parallel with the survey data, using thematic analysis of in-depth interview transcripts. This included the identification of common themes from interview transcripts and a comparison between women's representations with those of their family members and also with the anthropologist's observations. Since the analysis was carried out in parallel with the epidemiological analysis, this allowed the quantitative analysis to take into account differences according to the type of near miss/pregnancy outcome and other analytical categories that emerged as important, such as marital status and parity.

Step 8: Disseminate findings and recommendations

It is important to report the study's findings and recommendations to women, their partners, the local community, as well as to programme managers and policy-makers. The study results may have implications for a wide range of social policy interventions, including health care and social support mechanisms. So far, one of the main recommendations from Immpact's OAP studies relates to the catastrophic costs of pregnancy outcomes, and how to avoid these or counterbalance their effects. In Burkina Faso, since many women and men in the local population were illiterate, the results of the cohort study were disseminated in a local theatre show with the help of local actors, and through radio shows.

If OAP is being applied as part of a broader evaluation on the quality of maternal health care, the findings from this arm of the evaluation should be integrated with other study results.

4(8).5 Budget implications of using OAP

The table on the following page shows the costs associated with the development of OAP. This information should not be taken as representative of the likely costs of usage. Among other costs, the table also includes the costs associated with payment for referrals and treatment for women who discover problems through the research (see 'Other' row below). It is also important to bear in mind that the logistic implications will be increased during a cohort study, with additional resources required for tracking and following-up women in the community.

Table 4(8).1 shows the resources that were required for the OAP cohort study in Burkina Faso (sample size of 1014 women) (resources required may vary at other sites and with varying study designs):

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	Quantity	Time
Supplies	 Medical supplies for clinical examinations Computing equipment 	Not applicable.
Personnel	1 clinical research fellow	Full time for duration of data collection (about 18 Months + at least 3 months for preparation and analysis)
	1 epidemiologist (coordinator)	Full-time for at least 21 months, but usually 24 months.
	2 experienced social scientists*	Full-time for 21–24 months.
	Data manager	Usually working part-time (20%) for duration of data collection (15 months) + 2 months
	2 Data entry clerks	Part-time (25%) for 15 months
	Administrator	Full-time for 21 months
	10 interviewers	14 months full-time
	OB/GYN	Dedicated hours for medical examinations for survey participants (1014 women)
	Midwives or other health workers	Approximately 1 hour per day for 3 months during recruitment
Travel and communication	 Vehicle to travel to interview sites and to health facilities. Travel reimbursements, per diems and lodging Phone calls, emails. 	Not applicable.
Building operation and maintenance	Shared premises with other researchers. Office equipment (including computers for transcription and analysis)	Over a period of 21–24 months.
Other	 Planning and interim workshop costs Training workshop Gifts/incentives for visits Payment of initial care for women identified as having severe sequelae of complications, such as vesico-vaginal fistula Referral to appropriate health and social care for women and babies identified as having medical problems, mental illness, or suffering from serious social problems (such as domestic violence or living in extreme poverty) Dissemination costs Software for analysis (STATA, Nvivo for qualitative analysis) 	– 1 week – 2 weeks

Table 4(8).1: OAP resource requirements

^{*} In Burkina Faso, a third experienced anthropologist was recruited to provide support to the other two social scientists working on the qualitative components of the study. This expert worked part-time (25%) during the study.

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Further support on OAP

Further support on the design of an OAP study can be obtained by the following researchers at the London School of Hygiene and Tropical Medicine:

- Dr. Veronique Filippi (survey design): veronique.filippi@lshtm.ac.uk
- Ms. Katerini Storeng (qualitative components): katerini.storeng@lshtm.ac.uk
- Dr. Tom Marshall (sample design and statistical support): tom.marshall@lshtm.ac.uk

4(8).6 OAP data collection instruments

The following pages include key OAP research instruments:

- 1. Ethnographic data collection guide: example from Burkina Faso and Benin
- 2. Pre-test questionnaire: example from Burkina Faso

As noted above, copies of the OAP survey instrument can be obtained from Immpact or from the researchers listed above.

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1. Ethnographic data collection guide

Example from the longitudinal study on consequences of obstetric complications in Benin & Burkina Faso

NOTE: This is an interview guide used for an initial ethnographic study. For the follow-up interviews with women, individualized interview guides were written based on the transcripts and our observations from the previous interview.

Methodology

- Themes not questions: This is a data-collection guide, based on a list of themes and subtopics that need to be explored with each woman throughout the course of the research. Specific questions are outlined only as a way of providing examples of how to broach a topic and not as a recommendation that must be followed. The fieldworker should use these and any other questions that seem appropriate for the specific woman being interviewed, since the strength of the ethnography is to adapt the data-collection tools according to specific contexts and according to personal characteristics of the interviewee, and to adapt the interview process to unexpected topics, factors and narratives.
- <u>Unstructured ordering of themes to explore</u>: There is no specific order in which themes should be explored; in general, it is best to begin neutral topics and general questions, but if the woman wants to begin speaking about more sensitive aspects of life, it is best to let her do so when she wishes.
- Explore unexpected issues: Using this guide does not preclude the discovery of new themes and issues that arise over the course the research; indeed, this is only a draft. New themes and topics, issues, *should* arise as we come to know each woman in the study. As you explore these themes, try to keep the main research questions below in mind, but be aware that these research questions can also change or lose importance depending on results we obtain throughout the research.
- <u>Try to use a mix of methods</u>: Since each woman will be visited multiple times, any topic that can be explored through participant-observation (such as, for example, marital relations, quality of the relationship with her children, etc...) as well as informal interviewing, should be done so; fieldwork notes written regarding these observations in the woman's main file along with all other interview material.
- Interviewing family members and/or support persons where possible: Although the focus of the interviewing and participant observation will lie predominantly with the woman, take advantage of any opportunity to interview family members as well, even if only for 10–15 minutes and informally. This might include husbands, sisters, mothers, mothers-in-laws, and significant friends. Criteria for selecting such additional informants include availability, willingness, and perhaps most importantly, the extent to which they have been involved in supporting women through their pregnancies and births. We will aim to interview additional family members in at least half of the whole qualitative sample.
- Repeated visiting and longitudinal design: it is important to capitalize on the fact that this is a longitudinal design which aims to actually observe changes in women's lives as they happen, rather than to rely on retrospective data, or women telling us about their experiences. Being able to conduct repeated visits with the same women is more important for quality of the data than having a large qualitative sample.
- <u>Individualized interview guides</u>: It would be ideal to be able to transcribe interviews with women quickly enough so that we can read them and draw up an individualized interview guide for subsequent visits, based on what is already known of each woman's situation and experiences. This should be feasible for most of the sample, given the relatively long intervals between one visit and the next.
- <u>Sampling</u>: Sampling should be based on quotas, and then, within each quota, sampling should be random. Initial quotas should be based on type of near miss.

Research questions to keep in mind while conducting the fieldwork:

1. How do women define and perceive the 'negative' and 'positive' aspects of various pregnancy outcomes they have experienced. Outcomes can include but are not limited to such things as the birth of a child, consolidation of a marriage, a near miss, induced abortion, loss of a child, loss of reproductive ability, general ill-health, fear of infertility.

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- 2. How might these positive and negative experiences impact upon the social, emotional, marital, economic and reproductive future of a woman's life, and the life of her family, including her children and her husband, in both negative and positive ways? (<u>NOTE:</u> it is important to be open to the possibility that even a negative reproductive health experience can have positive consequences, and positive experience can have negative consequences.) This includes consequences that women themselves can consciously identify and consequences that we, by virtue of coming to know a woman's life history, identify as being linked to their reproductive events. This research question can be answered by:
 - a. conducting a life-history with all the women in the sample, to explore the role of past reproductive events in determining a woman's current life situation;
 - b. exploring how the social, health and economic aspects of women's lives change over the course of the post-partum period, and comparing these changes between women who had a negative reproductive health experience in their last pregnancy with those who did not have a negative experience;
 - c. asking women to reflect on recent changes in their life that have ensued since and <u>due to</u> their last pregnancy.
- 3. What personal, social and economic resources do women and their families use to reverse or counter the potential negative consequences of their reproductive experiences? Of those who have had a negative experience, who improved significantly and who did not, and what might be the reasons for this difference?

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Ethnographic interview guide

1. General characteristics

- Migration history
- Romantic history
- Family composition
- Education
- Professional life
- Ethnicity

2. General perceptions on reproductive health

- What is 'normal' childbirth?
- An abnormal delivery and negative consequences of pregnancy
- What a woman can do to ensure that her pregnancy and delivery go well; what should she refrain from doing?
- Pregnancy and delivery: normal or pathological?
- Ideal number of children
- Changes in a woman's life following the birth of a child
- The importance of fecundity in a woman's life
- The consequences of not having a child

3. Pregnancy and delivery (index pregnancy and previous experiences)

- Narrative of the most recent pregnancy (development, expectations, sex of the child, difficulties, use of health care etc.)
- Comparison with other pregnancy and delivery experiences
- Pregnancy history (use of contraceptives, interval between the initiation of sexual activities and the first pregnancy, account of the pregnancies, their development, illness experiences associated with pregnancy
- Perceived reasons for illnesses (social, economic, medical, emotional, physical, sorcery etc.)
- Emotional life (before the onset of pregnancy)
- Health of the baby
- The birth of the most recent baby and relationship with other children
- Desire for future pregnancies and husband's opinion
- The gap between wishes and reality
- What to do in the case of infertility

4. Negotiation of payment for treatment of pregnancy and delivery

- Sum paid for treatment (during pregnancy, delivery and the post-partum period)
- How the family managed the payment (debt, savings, cut-backs, selling assets etc.)

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- Feelings associated with being a financial burden to the family
- Feeling of social debt? Vis-à-vis who?
- Personal contribution to the management of costs?
- Support from the family circle and from the husband

5. Physical recuperation during and after the post-partum

- Management of the post-partum period: problems encountered, nature and cause of the problem, who helped her, utilization of medical care, reactions and behaviours or the family circle, how problems were resolved, decisions taken to change the situation
- Perceptions of positive and negative events following the end of pregnancy (disruption of marital relations, consolidation of relationship with husband, loss of fertility, loss of ability to work etc.)
- Strategies used to speed recovery
- Changes to daily life patterns following the end of pregnancy
- Persons involved in the management of the woman's health following the end of pregnancy (emotional and material support)
- Sufficiency of rest period, appropriate rest duration, function of rest etc.
- Activities performed before the pregnancy that have since been terminated
- Resumption of income-generating activities or salaried work?
- Duration of the period required to regain health
- What facilitates recovery from difficult childbearing?
- Comparison between recovery from index pregnancy and previous pregnancies
- Sadness or despondency following the end of the pregnancy

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2. Pre-test questionnaire: example from Burkina Faso





Information form to pre-test the first exit interview questionnaire

3. Interview number:
 4. Characteristic of the woman: Near miss or complicationrelated to an abortion or an extra-uterine pregnancy Near miss or complication of the third trimester, of delivery or during the post-partum Near miss or complication plus still birth Normal delivery 5. Language of the interview:
Near miss or complicationrelated to an abortion or an extra-uterine pregnancy Near miss or complication of the third trimester, of delivery or during the post-partum Near miss or complication plus still birth Normal delivery still birth 5. Language of the interview: 6. Did you need to use an interpreter? 7. Informed consent form : a. Quality of the interaction with the woman (bad, average, good, very good): b. If a bad interaction, explain why:
 Near miss or complication of the third trimester, of delivery or during the post-partum Near miss or complication plus still birth Normal delivery Language of the interview:
 partum Near miss or complication plus still birth Normal delivery 5. Language of the interview: 6. Did you need to use an interpreter? 7. Informed consent form : a. Quality of the interaction with the woman (bad, average, good, very good): b. If a bad interaction, explain why:
 Normal delivery 5. Language of the interview: 6. Did you need to use an interpreter? 7. Informed consent form : a. Quality of the interaction with the woman (bad, average, good, very good): b. If a bad interaction, explain why:
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 6. Did you need to use an interpreter? 7. Informed consent form : a. Quality of the interaction with the woman (bad, average, good, very good): b. If a bad interaction, explain why:
 7. Informed consent form : a. Quality of the interaction with the woman (bad, average, good, very good): b. If a bad interaction, explain why:
a. Quality of the interaction with the woman (bad, average, good, very good):b. If a bad interaction, explain why:
b. If a bad interaction, explain why:
c. Did the woman have guestions on the information sheet?
d. If yes, what questions?
e. Was the woman able to sign the consent form herself, or was it necessary to obtain a witness?
f If so did you have difficulties in finding a witness?
f. If so, did you have difficulties in finding a witness?

-	ere interfere		-	-					
	of the conse			the time tak	en to introdu	uce yourself	to the		
8. Addres	s identifica	ation form (sections A	and B)					
					ge, good, ve	ery good):			
	interaction,								
c. Did the	woman hav	e questions	about the a	address ide	ntification fo	rm?			
•	vhat questio								
f. How lon	g did it take	to complete	e the form ?		(m	inutes)			
9. Exit int	erview (wo	men with n	o abortion):					
a. Length	of the interv	iew		(hours	3)	(m	ninutes)		
•				•	ge, good, ve	ery good) :			
	interaction,								
	have proble re were prol			es for the fo	llowing ques	stions (circle	the numbe	r of the que	stion
D3	D9	D21	E11	F7	G2				
c. Which c	other questic	ons was it h	ard to ask, o	or hard for t	he woman te	o respond to	?:		
Question _		_: Explain	:						
Question _		_: Explain	:						
Question _		_: Explain	:						
Question _		_: Explain	:						
Question _		_: Explain	:						
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e. Was the woman embarassed or ashamed to respond to the following questions ? (circle the number of the question to which she was embarrased or ashamed to respond)

Section B:	B13	B15	B16								
Section C:	C26										
Section D:	D2	D10a	D10b	D10c	D26	D27	D28				
	D29	D30									
Section F :	F1	F2	F4	F6	F9	F10					
Section G :	G1	G2									
Section H :	H3										
section H : H3 f. Did the woman hesitate or refuse to respond to certain questions? g. If yes, which? h. Did you note any errors in the skips? i. If yes, which? j. If you could make any changes to this questionnaire based on the experience of this interview, what would your changes be? 10. Exit interview (women with abortion):											

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