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Evaluating health and education outcomes in children following death of a mother in pregnancy or child birth: A Prospective Cohort Study (Study Proposal)

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Introduction

Pregnancy and delivery complications rank among the leading causes of death and disability amongst women of reproductive age. Worldwide it has been estimated that 529,000 women die during pregnancy or childbirth every year, the vast majority in developing countries[1]. It has been estimated that maternal conditions account for three out of the ten leading causes of disease burden in women of reproductive age worldwide. In developing regions, five out the ten leading causes of Disability Adjusted Life Years (DALYs) are related to reproductive ill-health for women of reproductive age[2]. Tragic an event as maternal mortality is, it casts even longer shadows in terms of its impact on children and families. Child health and family well-being are directly related to the health and survival of the mother. Data from Matlab, (an area in Bangladesh where the population is being followed longitudinally for nearly thirty years) reveal that the death of a mother was associated with a 200% increase in mortality for her sons and 350% for her daughters aged less than ten years[3].

In addition to its impact on the survival of offspring, a mother being a primary care giver in most settings, her death is likely to result in poor health outcomes for the children who survive her. A study of Indonesian children showed that a mother's death tends to increase the incidence of malnutrition in her surviving children[4]. The impact of a woman's death on food and nutrition security of households with particular reference to children has been seen in studies that attribute the latter to a women's management of household budget to ensure better food security for their families[5].

Additionally, possibly due to certain social and sociological constraints, elder children may drop out of school and younger ones may not initiate schooling, either due to financial constraints or because they have taken over the caregiver's role for their younger siblings[6], affecting their life course in turn. Maternal loss may thus result in an intergenerational cycle of poverty and deprivation

Local context

Pakistan is a low income developing country with poor health and economic indicators. Maternal mortality is high as is the lifetime risk of maternal death (500 per 100, 000 live births and 1 in 31 respectively) [1,7], even within the developing country

context. Hospital based figures of maternal mortality are as high as 2736 per 100,000[8]. While the issue of maternal and child health has received tremendous attention recently, thanks mainly to renewed donor interest in sponsoring and supporting research on the issue, progress is slow.

Child health indicators are also poor with a high prevalence of malnutrition and relatively low vaccination coverage. Under-five mortality is 103 per 1000 live births; of these 81 are children who do not survive to their first birthday[9]. School enrollment is low, coupled with high dropout rates. The Gender Parity Index for schooling is also heavily tilted in favor of males[10].

The proposed study aims to evaluate how within this already dismal backdrop, the death of the primary caregiver affects her surviving children. To date there has been no local study on the issue. It is hoped that if implemented the proposed project will allow a better evaluation of health outcomes for children of these mothers and will enable recommendations to be made for health interventions targeted specifically at maternal orphans.

There is a paucity of literature on outcomes for children following the death of their mother during pregnancy and childbirth. Most of the studies have been conducted in Africa within the backdrop of the HIV/AIDS epidemic and some of the socio-cultural factors confounding the findings in these settings (poverty as a consequence of prolonged parental illness, social stigmas, psychological impact of acting as a caregiver to a parent) may potentially be absent in cases of maternal mortality.

General objective

To assess the impact that loss of a mother (as a consequence of maternal mortality) has on the survival, health and well being of children who survive her.

Specific objectives

1. To assess the incidence of mortality in children under 10, following a maternal death relative to a comparable cohort with surviving mothers
2. To assess the incidence of malnutrition (specifically under nutrition) in children up to five years of age following a maternal death relative to a comparable cohort with surviving mothers

3. To assess the vaccination coverage in these children (with reference to National Immunization guidelines) relative to a comparable cohort with surviving mothers
4. To assess the incidence of episodes of illness (requiring hospitalization) relative to a comparable cohort with surviving mothers
5. To assess the incidence of episodes of serious illness (requiring hospitalization)
6. To assess school enrollment rates and school drop out rates for these children
7. To examine the gender differentials for all the above parameters.

Hypothesis to be tested

The primary hypothesis is that proportion of mortality in children whose mothers have died is greater than that in children whose mothers are alive

Setting

The project will be carried out in Karachi. Karachi is Pakistan's largest city with a population of over 9.3 million**,** of which approximately 45% live in squatter settlements dotted all over the city[11]. Despite this, literacy and health indicators are better when compared to other parts of Pakistan, but in general fall far short of satisfactory. The city has three large teaching hospitals in the public sector which cater for the greater majority of individuals unable to afford health care. These hospitals also serve as a referral center from primary and secondary health care units as well as from smaller private sector facilities.

Study design

The study is planned as a prospective cohort, which will enable an evaluation of multiple outcomes in the study population.

Sampling frame and sample selection

Selection of the cohort

All cases of maternal mortality, as per the ICD-10 definition[12] that occur/are brought to the three public sector tertiary care hospitals will be identified via hospital records. All cases of maternal deaths identified during the period between August 2005-December 2006 will, depending on consent be eligible to be included in the study. The family of the deceased woman will then be traced via the contact information available on patient records. Following an explanation of the rationale and

methodology etc. and subject to the consent of the father (or other care giver qualified to give consent on behalf of the child) all children of the deceased woman who meet the selection criteria will be enrolled into the study.

Selection of the comparison group

Women who delivered in the same hospital(s) during the same period and were discharged safely following delivery will be contacted. The comparison group for evaluating differences in outcomes will be the children of these women who survived pregnancy and childbirth

Sample size estimation

Sample size calculation will be made using an acceptable alpha of 0.05, a beta of 20%. Assuming the proportion of mortality in the cohort of maternal orphans to be 0.206 (twice that of the under five mortality rate of 103/1000) and an effect size of 0.1 between the proportion mortality experiences in the children in the two groups (using the lower limit of a 2 fold increase in mortality among children losing their mothers). To accommodate the attrition that is expected in a follow-up study, the final sample will be calculated with an allowance for approximately 10% loss to follow up.

Inclusion criteria

- Children under 10 years of age at the time of enrollment into the study
- Living in a household that includes their biological father (to enable a better isolation of the effect of maternal death)
- Not suffering from any chronic disease at the initiation of the study
- Informed consent for participation given by a caregiver
- Residents of Karachi

Exclusion criteria

- Children aged more than 10 years at the time of enrollment
- Living within an extended family setting that does not include their biological father
- Suffering from chronic disease or grade 3 malnutrition at the time of enrollment
- Non-residents of Karachi

Methodology

Following consent, each child will be examined for any pre-existing health conditions as well as a recording of anthropometric measurements. Children with any signs of chronic disease or severe malnutrition (below -3 z scores of age appropriate anthropometric indices)[13] will be dropped from enrollment. These individuals will however receive all the available counseling and referral services. The health worker will then note the ages, anthropometric measurements and vaccination status of each child. A detailed history of each child (particularly those under five) with reference to nutrition, previous illnesses and schooling will be recorded on a structured questionnaire.

Plan for follow up visits

Frequency of visits

The frequency of visits will depend upon the age(s) of children in the household. For families where there is a child under one year of age, visits will be made at four month intervals till the child's first birthday. For households with older children visits will be made at six month intervals.

"Content" of each visit

At each visit, the health care worker will enquire about the number of episodes of diarrhea, acute respiratory infections and other infectious diseases in each child. Enquiries will also be made about any episode of hospitalization since the previous visit. The caregiver will be asked about the child's vaccination status. For children whose vaccination status is not appropriate for age, the required vaccine will be given at the end of the visit. While this will probably result in marked underestimation of the percentage of unvaccinated children in the study group, it was considered unethical to withhold a potentially protective and beneficial intervention especially where a health care worker is visiting the household regularly. The health care worker will also enquire about the schooling status of each child. If feasible, recent report cards will be used to verify whether the child is attending school.

Anthropometric measurements to be made at each visit

- Length/height
- Weight
- Head circumference (for children under 3)
- Triceps skinfold thickness

- Mid- Upper Arm Circumference (MUAC)

Study endpoints

The study end points will be considered to have been reached in case of:

- Mortality
- Child reaching his/her tenth birthday
- At the end of the study period (tentatively five years)

Outcome variables

Primary outcome

- Incidence of mortality in both groups

Secondary outcomes

- Wasting or low weight-for-height (cut-offs <-3 and <-2 SD)
- Stunting or low height-for-age (cut-offs <-3 and <-2 SD)
- Underweight or low weight-for-age (cut-offs <-3 and <-2 SD)
- Body Mass Index (in children older than 5)
- Mean MUAC (stratified by age categories)
- Mean number of episodes of acute illness (stratified by age categories)
- Mean number of hospitalization episodes (stratified by age categories)
- Percentage of children with AFA (appropriate for age) vaccination at each visit- this indicator is for children under 3.
- Percentage of children attending school
- Percentage of children dropping out of school
- Male: female ratio of school attendance

Duration of the study

The study is tentatively planned to last a total of five years from initiation of enrollment of subjects to final follow up.

Potential sources of bias/problems

- The fact that the households will be visited regularly may serve as a potential source of bias, both in terms of the adopted health behaviors and better health outcomes and also in terms of improved care that the children receive when compared with care they may have received otherwise.
- Reconstitution of households may also serve as a potential confounder

- Children living in extended households vs. nuclear families.
- Attrition and characteristics of the participants lost to follow up

Ethical considerations

Consent procedures

A detailed explanation of the study, its purpose and the contents of each visit will be given prior to obtaining consent from the child's caregiver. It will specially be emphasized that a decision not to participate will not result in any "penalization" of the family in terms of access to health care and of the benefits to which they may otherwise be entitled. The investigators will also ensure that each care giver understands the completely voluntary nature of their child/children's participation and the freedom to withdraw at any time they choose to.

Interventions/service provision

This being a longitudinal study, it was difficult deciding exactly when and to what extent a health care worker visiting the household can "intervene" without altering the normal sequence of events. However where the risk to the child was potentially great (as in for example not receiving vaccination), it was decided that a health provider would intervene with the intervention being adjusted to and being mentioned at the analysis stage.

Monitoring and supervision

To ensure a standardization of techniques, all workers involved in data collection in the field will be trained in interview techniques and anthropometry prior to initiation of field work.

A random 10% sample of the data collection forms will be verified by field supervisors.

Data analysis plan

Data will be double entered to ensure integrity. Data will be analyzed using SPSS Version 9. Exploratory data analysis will involve the use of frequencies for categorical data and means for numerical data. Following preliminary analysis data will be stratified by age and gender and analyzed to observe statistical differences on the outcomes variables between the groups. Potential confounders will be controlled for by adjustment and stratification. Survival Analysis will be used to detect difference in primary outcomes between the two groups

To ensure a priori decisions regarding data analysis, dummy tables will be form part of the finalized study protocol.

Collaborating institutions/organizations

1. Civil Hospital, Karachi
2. Jinnah Post graduate Medical Center, Karachi
3. Abbasi Shaheed Hospital, Karachi

Dissemination

1. The study results will be published in peer reviewed journals
2. Dissemination through presentation of findings at national conferences $
3. Publication of findings in newsletters related to maternal and child health
4. Through national press.

Appendices

1. Time line for activities(to be developed)
2. Budget (to be developed)
3. Dummy tables for data analysis (to be developed)
4. References

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