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Impact of a participatory intervention with women's groups on birth outcomes in Bangladesh

Impacto de una intervención participativa con grupos de mujeres que dan a luz (nacimientos) en Bangladesh

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Abstract

Progress on neonatal survival has been slow in most countries. While there is evidence on what works to reduce newborn mortality, there is limited knowledge on how to deliver interventions effectively when health systems are weak. Cluster randomized trials have shown strong reductions in neonatal mortality using community mobilization with women's groups in rural Nepal and India. A similar trial in Bangladesh showed no impact. A main hypothesis is that this negative finding is due to the much lower coverage of women's groups in the intervention population in Bangladesh compared to India and Nepal. For evidence-based policy making it is important to examine if women's group coverage is a main determinant of their impact. The study aims to test the effect on newborn and maternal health outcomes of a participatory women's group intervention with high population coverage of women's groups. A cluster randomized trial of a participatory women's group intervention will be conducted in 3 districts of rural Bangladesh. As we aim to study a women's group intervention with high population coverage, the same 9 intervention and 9 control unions will be used as in the 2005-2007 trial. These had been randomly allocated using the districts as strata. To increase coverage, 648 new groups were formed in addition to the 162 existing groups that were part of the previous trial. An open cohort of women who are permanent residents in the union in which their delivery or death was identified, is enrolled. Women and their newborns are included after birth, or, if a woman dies during pregnancy, after her death. Excluded are women who are temporary residents in the union in which their birth or death was identified. The primary outcome is neonatal mortality in the last 24 months of the study. A low cost surveillance system will be used to record all birth outcomes and deaths to women of reproductive age in the study population. Data on home care practices and health care use are collected through interviews.

Keywords

Cluster randomized trial; neonatal mortality; community participation; Bangladesh; women's groups.

Resumen

El progreso de la sobrevivencia neonatal ha sido lento en muchos países. Aunque hay evidencia de qué funciona para reducir la mortalidad neonata, existe poco conocimiento en cuanto a cómo suministrar intervenciones cuando los sistemas de salud son endebles. Los ensayos aleatorios por grupos han demostrado reducciones significativas en la mortalidad neonatal recurriendo a una movilización comunitaria en grupos de féminas en las zonas rurales de Nepal e India. Ensayos similares en Bangladesh no reflejaron ningún impacto. Una hipótesis predominante es que este hallazgo negativo se debe a una baja cobertura de grupos femeninos en la población

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intervenida de Bangladesh en comparación con la India o Nepal. Para el diseño de políticas fundamentadas en evidencia, es vital explorar si la cobertura de grupos femeninos es un factor que determina su impacto. El estudio busca probar los efectos de un grupo participativo de intervención femenina en los resultados de la salud maternal y del infante. Se conducirán ensayos aleatorios por grupos en un grupo participativo de intervención femenina en tres distritos del Bangladesh rural. Como se intenta estudiar un grupo de intervención femenina con amplia cobertura de población, se usarán las mismas 9 intervenciones y uniones de control igual que en los ensayos del 2005-2007. Se han seleccionado aleatoriamente usando los distritos como estratos. Para ampliar la cobertura, se formaron 648 nuevos grupos además de los 162 existentes que formaron parte de los ensayos anteriores. Está involucrada una cohorte abierta de mujeres que son residentes permanentes de la unión en las cuales se identificó su alumbramiento o su muerte. Se incluyen mujeres y sus neonatos después del nacimiento, o, si una mujer fallece durante el embarazo, se incluye luego de la muerte. Se excluye las mujeres que son residentes temporales en la unión en las cuales se identificó su nacimiento o su muerte. El resultado inicial es la mortalidad neonata en los primeros 24 meses del estudio. Un sistema de vigilancia o seguimiento de bajo costo se usará para registrar todos los nacimientos y muertes en mujeres de edad reproductiva en la población bajo estudio. Se recolectan datos sobre prácticas de cuidado doméstico y el uso de la asistencia médica por medio de entrevistas.

Palabras clave

Nepal; mortalidad neonatal; mujeres; salud; Bangladesh

1. Background of the study

1.1 The public health importance of addressing neonatal mortality

The proportion of child deaths that occurs in the neonatal period (38% in 2000) is increasing, and the Millennium Development Goal for child survival cannot be met without substantial reductions in neonatal mortality. Every year an estimated 4 million babies die in the first 4 weeks of life (the neonatal period). A similar number are stillborn and 0.5 million mothers die from pregnancy-related causes. Three-quarters of neonatal deaths happen in the first week—the highest risk of death is on the first day of life. Almost all (99%) neonatal deaths arise in low-income and middle-income countries, yet most epidemiological and other research focuses on the 1% of deaths in rich countries. The highest numbers of neonatal deaths are in south-central Asian countries and the highest rates are generally in sub-Saharan Africa. The countries in these regions (with some exceptions) have made little progress in reducing such deaths in the past 10–15 years. Globally, the main direct causes of neonatal death are estimated to be preterm birth (28%), severe infections (26%), and asphyxia (23%). Neonatal tetanus accounts for a smaller proportion of deaths (7%), but is easily preventable. Low birth weight is an important indirect cause of death. Maternal complications in labor carry a high risk of neonatal death, and poverty is strongly associated with an increased risk. Preventing deaths in newborn babies has not been a focus of child survival or safe motherhood plans. While we neglect these challenges, 450 newborn children die every hour, mainly from preventable causes, which is unconscionable in the 21st century.

1.2 Newborn health in Bangladesh

The neonatal mortality rate in Bangladesh is relatively high (41 per 1,000 live births in 2003), with most of the estimated 170,000 annual deaths occurring due to infections, birth asphyxia, and complications of prematurity and low birth-weight (LBW). This figure has shown an extremely slow decline over the years. In the time period ranging from 1995 to 1999, the neonatal mortality rate in Bangladesh was 42 per 1,000 live births, from 1992 to 1996 it was 48 per 1,000 live births, and from 1989 to 1993 it was 52 per 1,000 live births. More than 90% of births and neonatal deaths occur at home, generally with little-to-no involvement of the formal healthcare system. Traditional birth attendants (TBAs) attend 75.6%, relatives predominantly attend 10.8%, and medically-trained personnel attend 11.6% of deliveries. Most neonatal deaths can be avoided through simple, affordable interventions, especially in areas with weak health systems and high rates of neonatal mortality. Outreach and family-community care, health education to improve home-care practices, recognition of danger signs, generation of demand for skilled care, and increased health-seeking behavior can lead to significant reductions in neonatal mortality. A plan executed under the five-year Health and Population Sector Plan (HPSP) of the Government of Bangladesh which concentrated on reproductive- and child-health services, limited curative care, and behavior change communication showed a significant reduction in neonatal mortality from 36.8 per 1,000 live births in 1999 to 15.1 per 1,000 live births in 2002. Given this context, understanding the domiciliary newborn-care practices and care-seeking for illness are of paramount importance for developing strategies, including behavior change communications, to prevent these deaths.

Formative research on community newborn-care practices and care-seeking behavior is required to provide the foundation on which behavior change-communication plans can be designed and implemented. Such research will need to address the practices of the mother, her nuclear family, TBAs, traditional healers, and formal health providers and facilities. It also must explore the various social, cultural, religious, and economic factors that influence such practices. The Saving Newborn Lives Initiative (SNLI) of Save the Children-USA undertook a review of maternal and newborn-healthcare practices, specifically: (a) Domiciliary practices: Current maternal and newborn-care practices and behaviors at the community and household levels that directly affect newborn health; (b) Attitudes and beliefs: Behavioral determinants of newborn-care practices, including a review of socio cultural and religious beliefs, and economic determinants behind particular practices; (c) Decision-making: Roles of various individuals (mother, father, mother-in-law, extended family members, neighbors) involved in decision-making about the care of a newborn, including decisions about routine care of a well newborn and decisions relating to the care of a sick newborn. The primary influences, which impact the decision-making process, were also delineated; and (d) Health-seeking behavior: We sought

information on characteristics of those families who elect to use the formal health sector and those who do not. The types of conditions or illnesses that would lead a family to seek care and the type of care they would seek (e.g. formal healthcare sector, traditional healers, private sector) were determined. Various pathways a family uses to seek care for their newborns, and logistical, economic and cultural factors that influence health-seeking behavior were also considered.

1.3 Community interventions and the need for further research

Substantial reductions in neonatal mortality can be achieved, even in contexts where health care systems are very weak, as has been shown in cluster randomized trials of community mobilization with women's groups in rural Nepal and rural tribal areas in India. These interventions were modeled on a before-and-after study in remote rural Bolivia, which used a participatory learning and action cycle with women's groups to improve home care practices and health care use. The women's groups, under the guidance of a facilitator, went through a cycle of meetings, in which they identified and prioritized maternal and newborn health problems, and subsequently developed implemented and evaluated strategies to address these problems, with the support of the entire community. The studies in Nepal and India showed a 30% and 45% reduction in neonatal mortality respectively. There are indications that such participatory strategies for behavior change are more effective than one-to-one health education. There are still questions about the factors that influence the impact of women's group interventions on newborn mortality. The intensity and coverage of community mobilization might be two such factors. A women's group trial running between 2005 and 2007 in rural Bangladesh, of similar high intensity as in Nepal and India also showed no impact on neonatal mortality, or on most home care practices and health behaviors. A main hypothesis is that this was due to the much lower coverage of women's groups in the Bangladesh 2005-2007 trial (1 women's group per 1414 population) compared to Nepal (1:756) and India (1:468). The potential of women's groups to reduce newborn mortality is high and the costs are low. Their scalability in the Bangladesh context, with its numerous women's groups involved in a variety of activities such as micro-credit, is high. This study will examine whether coverage is an important factor influencing the effect of women's groups on neonatal mortality. It will test the effect on neonatal mortality of an intensive women's group intervention with high population coverage.

2. Objective of the study

To test the effect on newborn and maternal health outcomes of a participatory women's group intervention with a high coverage of women's groups in the population.

2.1 Primary research question

What is the effect of a participatory women's group intervention with a high coverage of women's groups on the neonatal mortality rate?

2.2 Ancillary questions

What is the effect of a participatory women's group intervention with a high coverage of women's groups on:

1. Early and late neonatal mortality, stillbirth rate, pregnancy-related mortality ratio, maternal mortality ratio;
2. Maternal and newborn home care practices;
3. Maternal and newborn health service utilization.

3. Methodology

3.1 Trial design overview

The intervention will be evaluated using a cluster randomized trial design. The rationale is that the intervention is applied to the entire community, involving both regular women's group meetings as well as direct involvement of the wider community. Unions, the lowest administrative level in Bangladesh, are randomized into intervention or control. Because of the nature of the intervention, allocation is not masked. Eighteen unions, 9 intervention and 9 control, with a population of around 28,400 each, are included. The entire study population is around 512,000 people. We have set up a prospective surveillance system in which all live births, stillbirths, neonatal deaths and deaths to women of reproductive age in the study population are recorded and combined with data on home care practices and health care use collected through an interview 6 weeks post-partum.

3.2 Setting

The study areas are located in three rural districts of Bangladesh, representing the country's different geographical features. Moulvibazar district in the northeast is hilly, making travel difficult, and contains socio-economically more deprived tea garden estates with tea garden workers. Faridpur district, to the south of Dhaka, is characterized by large rivers, regularly causing floods and making some unions inaccessible. The study areas in the northern district of Bogra are quite scattered, and recruitment and retention of project staff is comparatively difficult. Data from our surveillance system show that over 80% of the population in the study areas is Muslim, with nearly all the remainder being Hindu. About half of the women giving birth in the study areas have received no formal education or only primary

education. The vast majority of women deliver at home, without professional assistance. In 2007, neonatal mortality was around 35/1,000 in both intervention and control unions. In Bangladesh, primary care is provided at Union Health and Family Welfare Centers and at Community Clinics. In- and out-patient services, including emergency obstetric care, are provided at sub-district (*upazilla*) health complexes and hospitals, and tertiary care is provided at district hospitals and medical college hospitals. In practice, both availability and quality of health care, including maternity care, are important problems in our study areas, due to a lack of facilities and trained health care providers, short supplies of medicines and low responsiveness of services.

The trial is implemented by the Perinatal Care Project (PCP) with technical assistance from the University College London (UCL) Centre for International Health and Development. PCP was established in 2002 as collaboration between the Diabetic Association of Bangladesh (BADAS), the UCL Centre for International Health and Development (UK), and Women and Children First (UK). In the same study areas, PCP also implemented the 2005-2007 women's group trial, of which the current study is a follow-up.

3.3 Study population

In the intervention areas, the target group for the women's group meetings is permanent residents of reproductive age, in particular pregnant and newly married women. However, other women, such as older in-laws and adolescent girls are also welcome. Community health workers sometimes also participate. Men are allowed, but rarely do attend. The wider community, including both men and women, is involved through, among others, community meetings. The study population is an open cohort of women, living in the study area, who are permanent residents of the union in which their delivery or death was identified. Women and their newborn infants are included after birth, or, if a woman dies during pregnancy, after her death. A woman is considered a permanent resident of a union if the house she normally lives in is in that union. Excluded are women who are registered as temporary residents in the union in which their delivery or death was identified. These are predominantly women who temporarily move to their parents' house in a different union to give birth, after which they return to their husband's house. On the basis of data from our ongoing surveillance system, we expect 15% of births to occur to women who temporarily move into the PCP study area to give birth and 6% of births to occur to women who temporarily move to a different union within the PCP study area. Given that 75% of newborn deaths occur during the first week of life, and given the nature of the intervention, in which women's group membership is open to permanent residents and in which entire communities are mobilized to take action during pregnancy, delivery and the newborn period, we expect to see mainly an effect among women who are permanent residents in the union in which they give birth.

3.3 Community mobilization through women's groups

The intervention to be evaluated is a participatory learning and action cycle with women's groups. Facilitators, who are local women of reproductive age with at least a high school degree, recruited, trained and paid by PCP; convene monthly women's group meetings. As we aim to study the effect of a women's group intervention with high population coverage, 648 new groups were formed by newly recruited facilitators and started to meet from January 2009 onwards, in addition to the 162 women's groups that were already set up in the intervention areas as part of the 2005-2007 trial. These 'old' groups have continued to meet on a monthly basis from late 2004 onwards. The 648 new groups will go through a cycle of monthly meetings on maternal and newborn health (Cycle 1), while from April 2010 the 162 'old' groups will proceed to a cycle of meetings on under-5 and women's health (Cycle 2) and periodically review maternal and newborn health issues. Membership of the 'old' groups has been relatively stable. The combined 810 women's groups constitute coverage of 1 group per 300 populations, compared to 1 per 1414 in the 2005-2007 trial. Each facilitator is responsible for 18 groups. She guides the groups through a four-phased community action cycle, in which she activates and supports the groups to identify and prioritize maternal and newborn (cycle 1), or child and women's (cycle 2), health problems (phase 1), plan strategies to address these problems (phase 2), and implement (phase 3) and evaluate (phase 4) these strategies. At the end of phase 2 and at the start of phase 4 community meetings will be held to engage the wider community in the development and implementation of the strategies. The facilitator uses picture cards and a flip chart as means to stimulate discussion. Facilitators received training in participatory communication methods and in basic maternal and newborn (Cycle 1) and child and women's health (Cycle 2) issues. Except for the paid facilitator and tools, no resources are provided to the groups. The groups meet on a monthly basis throughout the intervention period. We expect occasional interruptions of the meeting schedule, for example during the monsoon and Ramadan. Within the 21/2 year period, we expect all groups to have held at least 20 meetings. The 2005-2007 intervention has been adapted to increase participation of pregnant women in the women's groups. Pregnant women in the community are now identified by facilitators, traditional birth attendants (TBAs), community health workers and women's group members, and are encouraged to attend the groups. Facilitators visit pregnant women and their families to explain the benefits of attending the women's and they keep a record of the number of pregnant women attending the groups.

3.4 Health systems strengthening

Both intervention and control clusters will receive health system strengthening activities. The reason to include a health systems strengthening component in our study is twofold. First, there is the ethical imperative to ensure that also the control areas benefit from

the study. Second, we expect some degree of a functioning local health system to be necessary for the success of a women's group intervention. The health systems strengthening strategy contains four components: sensitization of community health committees (set up by the Ministry of Health and Family Welfare) to maternal and newborn health issues; basic training of traditional birth attendants in essential newborn care; financial and organizational support of training of doctors; and provision of weighing scales and sphygmomanometers to the 44 community clinics operating in the study area.

3.5 Randomization

The same intervention and control unions were used as for the 2005-2007 trial. The randomization for that trial was as follows: the three study districts, Bogra, Faridpur and Moulvibazar, were purposefully sampled on the basis of having active Diabetic Association of Bangladesh (BADAS) offices. In each of these districts, 2 upazillas (sub-districts), and within each upazilla 3 unions were purposefully sampled on the basis of recommendations from BADAS representatives, using perceived limited access to perinatal health care and a feasible travelling distance by motorbike from BADAS district headquarters as the main criteria. The 18 unions were randomly allocated to either intervention or control (9 intervention and 9 control), with each district constituting one stratum, in the presence of four project staff (including the project director and project manager) and two people external to the study team (Dr. Nazmun Nahar, Department of Paediatrics, Dhaka Medical College, Dhaka, and Dr. Azad Khan, BADAS, Dhaka). For each district, cluster names were written on pieces of paper, which were folded and placed in a bottle. The project manager then drew the papers from the bottle. The first three cluster names drawn were allocated to the intervention group and the remaining three to control. The allocation sequence had been decided upon by the project team before drawing the papers.

3.6 Reducing contamination

We expect little contamination from the intervention to the control areas. The intervention and control clusters are mostly geographically far apart, though in the few adjacent intervention and control unions, a small number of women from the control areas do participate in the women's group meetings. Mobility, in particular of women of reproductive age, is socially restricted, and opportunities for social mixing between unions are limited. However, a substantial proportion of women temporarily move to their parents' house for delivery. From our previous trial we know these are mostly women arriving from outside the study area. Our study population excludes women that are temporary residents in the union in which their delivery or death was identified.

3.7 Sample size

Sample size was determined following equations from Hayes and Bennett and Hayes and Moulton, using Microsoft Excel 2003. The trial, with two treatment arms, includes 9 intervention and 9 control areas with an average population of 28,400. The clusters are unmatched. We used 2005-2008 data from our ongoing surveillance system to come to conservative estimates of the number of live births among permanent residents per cluster per year (445), the baseline neonatal mortality rate (34/1,000), and the between-cluster coefficient of variation for neonatal mortality ($k = 0.099$), assuming an equal k in intervention and control areas. We assume a 6-month time lag in effect on the basis of findings of similar trials. The study will have between 86% to 90% power to detect a 30% difference in neonatal mortality between the intervention and control arm during the last 24 months of the study.

3.8 Impact evaluation

The primary outcome of our study is the neonatal mortality rate (number of deaths in the first 28 complete days after birth per 1,000 live births) in the last 24 months of the study. Secondary outcomes are early and late neonatal mortality rate, stillbirth rate, perinatal mortality rate, pregnancy-related mortality ratio, maternal mortality ratio, and health care use and home care practices during pregnancy, delivery and the neonatal period.

3.9 Data collection and management

A low-cost prospective surveillance system will be used to record all deaths during pregnancy up to 6 weeks post-partum and all births and their outcomes (live birth, stillbirth, neonatal death). This system has been in place in the study areas since 2005, and will be maintained throughout the study period. Data are collected using the following steps. 500 key identifiers, all TBAs, are responsible for identifying all women that have given birth and all deaths to women of reproductive age. Each key identifier covers a geographical area of around 200 households. TBAs conduct the majority of deliveries in our study area, and are in a good position to identify births, irrespective of whether they attended them. They are mostly middle-aged women, who are less restricted in movement than newly married women. A full-time salaried monitor (37 monitors work in the study area) meets with the key identifier twice per month to collect the list of identifications. The monitor visits the household to verify the births and deaths, and, for deaths to women of reproductive age, asks if the death occurred during pregnancy up to 6 weeks post partum. The monitor pays the key identifier Tk100 (€1.08, December 2010) for each accurate identification and makes an appointment for the interview. The monitor conducts the interview, which covers background characteristics, and the antenatal, delivery and postpartum periods. In the event of a live birth, stillbirth, or neonatal death, the interview is done with the mother at around 6 weeks post-partum. In the event of a stillbirth or

neonatal death, a verbal autopsy is also conducted with the mother. In the case of a death of a woman during pregnancy or up to 6 weeks post-partum, the interview and a maternal verbal autopsy are conducted with a close relative or friend. Around 20% of questions of 10-20% of all interviews are cross-checked through a re-interview by the monitoring coordinator. Hard copies of the lists of identifications and of the interviews are sent on a monthly basis to the surveillance manager at the PCP head office in Dhaka. The identifications are entered into an SPSS database dedicated to following-up the birth outcomes. The interview data are entered into a Microsoft Access database. The two datasets can be linked using unique identification numbers. All hard copy questionnaires are archived for future reference. Similar surveillance systems are being used in Nepal, India and Malawi.

3.10 Dealing with loss-to-follow-up

For up to 1 year after the birth identification, the monitoring team will seek to obtain information on birth outcomes, pregnancy-related mortality, maternal mortality and health related behaviors, including for mothers who have temporarily or permanently migrated after birth. After one year, they will be considered lost to follow-up. Interviews are arranged at a time that is convenient for the respondent, and monitors are instructed to only conduct an interview if the respondent feels at ease. On the basis of our previous trial, we expect non-response to be very low.

4. Analysis procedure

4.1 Interim analyses and stopping rules

A meeting of an independent Data Safety Monitoring Board (DSMB) will be convened according to the DAMOCLES charter, after 11/2 years of accumulated surveillance data. The DSMB will be tasked to provide an independent, objective review of the study implementation and accumulated interim data, and to advise on any extension or modification of the trial. In particular, it will review (i) process indicators including women's group coverage and adherence to the implementation plan, (ii) adequacy of the sample size, (iii) comparability of treatment arms, (iv) data quality, and (v) the proposed analysis plan. The intervention allocation will be masked to the board. There are no stopping rules as we do not expect the intervention to have adverse effects at either cluster or participant level.

4.2 Analysis plan

The trial will test the effect of a community mobilization intervention with a high coverage of women's groups. Of the 810 women's groups, 162 are existing groups, which have

been meeting from late 2004 onwards, and 648 are new groups, which held their first meeting in January 2009. The 648 new groups focus on pregnancy, delivery and the newborn period (Cycle 1). The 162 old groups focused on the same until April 2010, after which they started to discuss under-5 and women's health (Cycle 2). The study does not intend to separate out the effects of the old and the new groups, nor of Cycle 1 and Cycle 2. Therefore, any difference in primary and secondary outcomes between intervention and control areas can be due to: (i) increase in coverage of Cycle 1 from 1/1414 to 1/376 (i.e. from 162 to 648 groups), (ii) a 'booster dose' of 162 women's groups with a coverage of 1/1414, (iii) an increase in coverage of women's groups in general (Cycle 1 and 2) from 1/1414 to 1/300. Given that the previous trial had no impact on primary and secondary outcomes and that the focus of Cycle 2 is on the post-neonatal period, we expect any impact on primary and secondary outcomes to be mainly due to increased coverage of Cycle 1. Analysis will be by intention to treat at the individual and cluster level. Participants are assigned to the cluster in which their birth is registered. Participants with missing data on the primary outcome will be excluded from the analyses. The control clusters include three tea garden areas with substantially worse health and socio-economic outcomes compared to the rest of the study area, compromising the comparability of the treatment arms. Analyses will therefore be carried out with and without the tea garden residents. Furthermore, all analyses will be carried out without and with adjustment for potential confounders. Estimates of the intervention effect will be presented with 95% confidence intervals. All analyses will take the clustered design of the study into account. We intend to use SPSS to perform the analyses. As we expect a 6 month time lag for the intervention to take effect, we will use as the trial's primary endpoint the neonatal mortality rate in the last 24 months of the trial.

4.3 Process evaluation

Detailed quantitative and qualitative process evaluation information will be collected throughout the intervention period, to help explain any differences in effect between the old (2005-2007) and the current trial, and formulate alternative hypotheses for the lack of impact of the old trial in comparison with similar trials in India and Nepal. Information will be collected on (1) intervention process, including fidelity to the original intervention protocol, (2) contextual factors that may influence intervention impact, (3) exposure to and participation in the women's group intervention, in particular among pregnant women, and (4) receipt of the intervention by the target population.

Conclusion

Participation in women's groups and community meetings is on a voluntary basis. The participants can choose to leave at any time. Prior to all interviews, the purpose of the data

collection is explained and verbal consent from the interviewee obtained. Interviewees are told that they are free to decline the interview, and can refuse to answer any question. Access to the identifiable individual-level data is limited to surveillance and data entry staff and analysts from the study team.

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