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Improving surveillance for the hidden half of fetal-infant mortality: A pilot study of the expansion of the Pregnancy Risk Assessment Monitoring System (PRAMS) to include stillbirth

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Abstract

Purpose: In the US, stillbirths (fetal deaths ≥ 20 weeks' gestation) are now more common than infant deaths. Nationally-available data are limited, and little is known about women's experiences around the time of a loss. The Pregnancy Risk Assessment Monitoring System (PRAMS), a state-based survey of women with a recent live birth, could be expanded to include women who experienced a stillbirth. We aimed to determine whether women with a recent stillbirth would be amenable to a PRAMS-like survey.

Methods: Eligible women were Georgia residents aged ≥ 18 years with a reported stillbirth from 12/1/12–2/28/13, identified through fetal death certificates. Women received a handwritten sympathy card, followed by a mailed questionnaire about their health and experiences around the time of the loss. Non-responders received two additional mailings and up to three phone calls.

Results: During the study period, 149 eligible women had a reported stillbirth. Forty-nine (33%) women responded. Excluding women with invalid contact information (n=26) yields an adjusted response rate of 40%. Response differed by race/ethnicity, but not by fetal, delivery, or other maternal characteristics.

Conclusions: Women appear willing to respond to a survey regarding a recent stillbirth. Further studies of the inclusion of stillbirths in PRAMS are warranted.

Keywords

Stillbirth; fetal death; spontaneous abortion; pregnancy; surveys and questionnaires; data collection

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INTRODUCTION

Stillbirths are now more common than infant deaths in the United States, with approximately 23,000 families experiencing a stillbirth each year.¹ These pregnancy losses occur after 20 weeks' gestation, and can devastate and forever change the lives of those who endure them. After experiencing a stillbirth, women with no prior history of depression have a two-fold increase in the risk of depressive symptoms up to at least 3 years after the loss.² Despite a burden that, for the first time, exceeds that of infant mortality (23,595 reported stillbirths¹ vs. 23,446 reported infant deaths in 2013³) much less attention has been paid to understanding and preventing stillbirth. A major barrier to stillbirth prevention is the quality of available data; the only national source of stillbirth data is in the form of vital records, which suffer from frequent missing and misreported data.⁴⁻¹⁴

When a stillbirth occurs, health care professionals generally have a single opportunity to provide support to grieving families. Some research suggests that women and their families are not adequately supported around the time of the loss.^{15,16} Even if fetal death reporting is brought up to the quality of live birth reporting, complementary efforts will be needed to improve our understanding of the experiences of those who have had a stillbirth, including identifying areas for improving the support they receive around the time of the loss and once they return home.

An existing surveillance program, the Pregnancy Risk Assessment Monitoring System (PRAMS), can be leveraged as a model for surveying women who have recently experienced a stillbirth. PRAMS, an ongoing surveillance project conducted jointly by the Centers for Disease Control and Prevention (CDC) and state health departments since 1987, conducts annual state-based surveillance of women within 2-4 months of a live birth regarding their experiences around the time of the pregnancy.¹⁷ Women are selected for participation in PRAMS through their infants' birth certificates, and are initially contacted by mail, with telephone follow-up for non-responders. Since pregnancy losses that meet reporting requirements should receive a fetal death certificate, similar methodologies could be adapted to conduct surveillance of women who have experienced a stillbirth. Expanding PRAMS to include stillbirth could supplement data available on the fetal death certificate to better understand women's experiences around the time of the loss.

To our knowledge, there have been no cold-contact studies of women with a known pregnancy loss in the United States, and given the sensitive nature of this topic, it is unknown whether such women would be amenable to a PRAMS-like survey shortly after their pregnancy loss. For these reasons, we conducted a pilot study of the expansion of PRAMS methodology to include stillbirths in Georgia to determine: 1) whether women with a recent stillbirth are willing to respond to a mailed survey, 2) what response rate could be achieved, and 3) whether the response rate varies by maternal and delivery characteristics.

MATERIALS AND METHODS

We sought to identify a sample of 250 Georgia residents aged 18 years or older with a recent stillbirth. With approximately 1,000 stillbirths occurring annually in Georgia,¹⁸ we

determined that three months' of data would be required to achieve a sample of this size. Study staff requested Fetal Death Certificate (FDC) data from the Georgia Department of Public Health's vital records office for all pregnancy losses with a reported gestational age of 20 weeks or more that occurred between December 1, 2012 and February 28, 2013. Variables requested included: mother's first and last names, birthdate, race/ethnicity, and mailing address; father's first and last names and birthdate; date and facility of delivery; and the fetus's estimated gestational age, birth weight, sex, and plurality. Since the main method of contacting women was through the mail, we attempted to verify the women's names and addresses through internet searches before initiating contact.

The survey instrument was developed in consultation with CDC's PRAMS team, advocates for families who have experienced a stillbirth, hospital bereavement coordinators, and women who recently experienced a stillbirth, with the goal of collecting relevant information while remaining respectful of the sensitive nature of this topic. We included modified questions from the PRAMS survey, as well as stillbirth-specific questions to supplement what is available on the fetal death certificate. Existing PRAMS questions were modified to ensure appropriateness for the target audience (e.g. PRAMS: "*Just before you got pregnant with your new baby, how much did you weigh?*") Modification: "*Just before you got pregnant, how much did you weigh?*"). Stillbirth-specific questions included information about the timing of the death relative to the onset of labor, options offered to the mother or family for memorializing her baby, support received from the hospital staff, questions related to autopsy and the cause(s) of death, and a brief evaluation of the survey itself. A copy of the survey instrument is provided in the Appendix.

We followed the current PRAMS protocol for locating women with a recent live birth, with appropriate modifications for women with a known pregnancy loss (Table 1).¹⁷ Due to budgetary constraints, we were unable to offer incentives for participation; however, we employed other strategies to encourage response.¹⁹ For visual appeal, all mailings were sent in purple envelopes with coordinating postage stamps. Women were first mailed a handwritten sympathy card (the equivalent of the PRAMS pre-letter) that acknowledged the loss and explained that a survey about their health and experiences during their pregnancy would arrive in the mail within a week. Three days later, women were mailed a questionnaire packet which contained a cover letter describing the goals of the study, the questionnaire booklet, a 3-year calendar to aid recall, a list of support resources, and a self-addressed stamped envelope to be used to return the survey. Women who experienced multiple gestation losses were sent two questionnaire booklets in the event that some of their responses differed for each of their babies. Women who did not return a survey within 20 days were sent a "tickler" letter highlighting the importance of their responses and asking them to take the time to complete the survey. Women who did not respond within 20 days of the tickler were sent a second questionnaire packet. The contents of this packet were the same as the first, except the cover letter put greater emphasis on the importance of each mother's response. For those who had yet to respond, telephone follow-up began 21-41 days after the second questionnaire packet. Women who were reached by phone were given the option of completing the survey over the phone with a trained interviewer. A maximum of three phone call attempts were made.

Since stillbirth rates vary by maternal age, race/ethnicity, and marital status,¹ we stratified the results by these variables to determine whether the women who responded had a similar distribution of these variables compared to those who did not. Since this was a pilot study, we did not know whether response rates would differ depending on the length of gestation, or the time since the loss. For this reason, results were also stratified by the gestational age of the fetus and the month of the loss. The values for all of these variables were obtained through the vital records office.

This research was approved by the institutional review boards at Emory University and the Georgia Department of Public Health.

RESULTS

Our initial sample of fetal death certificates included 152 women aged 18 years or older who experienced a stillbirth in Georgia between December 1, 2012 and February 28, 2013. This sample of fetal death certificates differed from our target sample size due to missing values for gestational age and birth weight on many fetal death certificates. Over the course of the study period, three women were found to be ineligible: two women experienced infant deaths erroneously reported as stillbirths, and one woman was deceased at the time of contact. We received responses from 49 of the 149 eligible women, for a crude response rate of 33%. Of these, 42 (86%) responded by mail, and 7 (14%) responded by telephone. Twenty-five (51%) of the responses were received after the mailing of the first questionnaire packet, an additional 8 (16%) responses were received after the tickler, and 9 responses (18%) were received after the second questionnaire packet.

Compared to non-responders, responders were more likely to be non-Hispanic White and married (Table 2). There were no statistically significant differences between responders and nonresponders by maternal age, gestational age of the fetus, or month of delivery.

Twenty-six (17%) of the 149 eligible women never received our study materials—all mail sent to these women was returned undelivered, *and* their telephone number was either missing or invalid on the fetal death certificate. Women who were not reached were more likely to be unmarried than women who received our materials; there were no differences by maternal age, race/ethnicity, gestational age, or the month of delivery (data not shown). Excluding these women who did not have the opportunity to respond to our survey yields an adjusted response rate of 40%. After this adjustment, the only factor remaining statistically significantly different between responders and non-responders was maternal race/ethnicity (Table 3). Seven of the 123 (6%) women that we reached refused participation.

Item non-response was very low for most questions (range: $n = 0-3$, 0-6%); exceptions include gestational age at first prenatal care visit ($n = 7$, 14%) and questions related to the autopsy (range: $n = 5-9$, 10-18%). Forty-six (94%) respondents answered at least one question from the portion of the questionnaire which sought to evaluate the survey itself. The mean time reported to complete the survey was 65 minutes, with a median completion time of 21 minutes. Most women indicated that the questions were very ($n = 37$; 77%) or somewhat ($n = 6$; 13%) easy to understand. Women were asked whether there were any

questions that were difficult for them to answer. Of the 42 women who responded to this question, 8 (19%) indicated that there was at least one question that was difficult for them to answer. These questions included those pertaining to the support they received in the hospital and those regarding the investigation into the causes of death, because they triggered an emotional reaction.

Twenty-five (51%) of the responders provided written feedback about the survey itself, as well as additional thoughts about their experiences and/or the health of mothers and babies in Georgia. Many of these women provided additional details regarding the circumstances surrounding their loss. Forty percent of these women expressed gratitude that research was being conducted to learn more about stillbirth, and four specifically mentioned that they sincerely appreciated the handwritten sympathy card. One woman who responded by telephone indicated that she was grateful to have had someone to talk to, and that it was helpful to her in sorting out her emotions regarding the loss.

DISCUSSION

This study sampled women who experienced a stillbirth via fetal death certificates in an effort to learn about their health and experiences around the time of the loss. Results from this pilot study suggest that expanding PRAMS to include women with stillbirths is feasible. Very few women who were approached refused participation, and among those who responded, a number expressed gratitude that research was underway to better understand stillbirth in the United States.

Excluding women with invalid addresses and phone numbers, we obtained an adjusted response rate of 40%. This adjusted response rate differed only by maternal race and ethnicity. Although PRAMS does not exclude women who were unreached when calculating response rates, this was an important consideration for this study which aimed at assessing the acceptability of a PRAMS-like survey among women with a recent stillbirth. It is important to know what the response rate was among women who received our study materials. The adjusted response rate of 40% is very promising for the future of the expansion of PRAMS to include stillbirths, especially since new PRAMS sites achieve similar response rates during their first year, while offering incentives (Denise D'Angelo, oral communication, July 2014). Due to budgetary constraints, we were unable to offer incentives for participation. Future studies of women who recently experienced a stillbirth should consider offering appropriate incentives for participation, such as charms or tokens to honor and memorialize the baby.

Our findings that non-Hispanic Black women were less likely to respond than non-Hispanic White women parallel those of Georgia PRAMS, where, in 2012, the response rate was 72% for non-Hispanic White women, and 59% for non-Hispanic Black women.²⁰ Despite the similarities between our findings and those of Georgia PRAMS, the lower response rate among non-Hispanic Black women who experienced a stillbirth is of concern because these women have a 2-fold increase in the risk of stillbirth compared to non-Hispanic White women.¹ Differential response rates by maternal race and ethnicity will only introduce bias if those who do not respond are fundamentally different from those who do. Since we lack

additional information about the women who did not respond, it is unknown whether the distribution of their risk factors for stillbirth differ from those who responded. For this reason, efforts to improve response rates among non-Hispanic Black women who experienced a stillbirth are warranted. Studies aimed at improving PRAMS response rates among African American women in Wisconsin and Ohio found that changes in the incentives did positively impact response rates for this group.^{21,22} Future studies of the expansion of PRAMS to include stillbirth should offer appropriate incentives, and determine whether response rates continue to differ by maternal race and ethnicity.

A limitation of this study is that, despite reaching out to women relatively soon after the stillbirth, the contact information recorded on the fetal death certificate was no longer valid 3-6 months after delivery for 17% of the sample. This suggests that these women are very mobile and that it might be worthwhile to narrow this window, such that women are contacted no later than 4 months post-delivery. We did not observe any differences in response rates by the month of loss, which suggests that the response rate would not suffer by sampling women closer to the time of the loss. Future studies of the expansion of PRAMS to include women who experienced a stillbirth should consider using additional data sources in order to obtain the most up-to-date contact information for women in the sample. This may include a paid service, such as LexisNexis, or linkage with Medicaid or other health department databases, such as WIC.

Our study has two additional limitations. Although maternal education has previously been associated with PRAMS response rates,¹⁷ we were unable to assess this association in our data because maternal education was missing on the fetal death certificate for over one-quarter of the eligible sample. Additionally, the generalizability of the study results may be limited since we only included women who experienced a stillbirth during a 3-month period in Georgia. Study findings may not be applicable to women living in other states due to differences in maternal characteristics and/or vital records data quality. For this reason, studies of the expansion of PRAMS to include stillbirth in other states are warranted.

Since the PRAMS inception in 1987, its data have been used to improve the health and lives of mothers and their babies, including successes related to safe sleep, breastfeeding, and integration of intimate partner violence screening into women's health services.²³ An expansion of PRAMS to include stillbirths could have a similar impact on the health and wellbeing of women who experience a stillbirth. These data could be used to identify areas for improvement in the care that women receive around the time of the loss, as well as barriers surrounding autopsy and other evaluations of the cause(s) of death. In combination with data collected by PRAMS for live births, these data may also be used to identify and monitor trends in risk factors for stillbirth. Although US stillbirth rates are higher than more than half of high-income countries,²⁴ the relative number of stillbirths that occur annually is small in comparison to the number of live births sampled by participating PRAMS states. Including these women in the PRAMS operations should be feasible, and would expand the impact of these programs.

Further pilot studies of women with recent stillbirths are warranted, and should consider slight modifications to the protocol used in this study, including contacting women no more

than four months after delivery, obtaining valid contact information through a paid service or via linkage with other health department databases, and offering appropriate incentives for participation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations and Acronyms

CDC	Centers for Disease Control and Prevention
FDC	Fetal death certificate
PRAMS	Pregnancy Risk Assessment Monitoring System

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Table 1.

Comparison of the Follow-up Schedules for the PRAMS Stillbirth Pilot and PRAMS

Type of Contact	PRAMS Stillbirth Pilot	PRAMS Live birth
Pre-letter	—	—
Initial Mailed Questionnaire Packet	3 days	3-7 days ^a
Tickler	20 days	7-10 days
Second Mailed Questionnaire Packet	20 days	7-14 days
Third Mailed Questionnaire Packet	— ^b	7-14 days
Telephone Follow-Up	21-41 days (up to 3 calls ^b)	7-14 days (up to 15 calls)

^aDays correspond to the interval between each contact and the previous contact

^bTo be sensitive to the grieving process, and avoid what might be considered “aggressive follow-up,” we only sent two mailed survey packets, and limited telephone attempts to three.

Table 2.Characteristics of the sample of eligible women, stratified by response status ^{a, b}

Characteristic ^c	Overall Sample (N = 149)	Responded (n = 49)	Did Not Respond (n = 100)	p-value
Maternal Age (years) ^d	27.6 (6.8)	27.9 (7.0)	27.5 (6.8)	0.74
Maternal Race/Ethnicity				< 0.001
Non-Hispanic White	48 (32)	27 (55)	21 (21)	
Non-Hispanic Black	81 (54)	18 (37)	63 (63)	
Hispanic	14 (9)	1 (2)	13 (13)	
Other	5 (3)	2 (4)	3 (3)	
Missing	1 (< 1)	1 (2)	0 (0)	
Mother Married				0.01
Yes	57 (38)	26 (53)	31 (32)	
No	90 (60)	23 (47)	67 (68)	
Missing	2 (1)	0 (0)	2 (2)	
Month of Loss				0.60
December	57 (38)	16 (33)	41 (41)	
January	49 (33)	17 (35)	32 (32)	
February	43 (29)	16 (33)	27 (27)	
Gestational Age (completed weeks) ^d	28.7 (7.1)	29.7 (7.1)	28.2 (7.0)	0.23

^aValues are n(%) unless otherwise specified^bPercentages may not sum to 100 due to rounding^cAs reported on the Fetal Death Certificate^dMean (SD)

Table 3.Characteristics of the sample of eligible women, excluding those we did not reach, stratified by response ^{a,b}

Characteristic ^c	Responded (n = 49)	Did Not Respond (n = 74)	p-value
Maternal Age (years) ^d	27.9 (7.0)	28.0 (6.7)	0.95
Maternal Race/Ethnicity			< 0.001
Non-Hispanic White	27 (55)	17 (23)	
Non-Hispanic Black	18(37)	45 (61)	
Hispanic	1 (2)	10 (14)	
Other	2 (4)	2 (3)	
Missing	1 (2)	0 (0)	
Mother Married			0.08
Yes	26 (53)	27 (36)	
No	23 (47)	46 (62)	
Missing	0 (0)	1 (1)	
Month of Loss			0.76
December	16 (33)	28 (38)	
January	17 (35)	26 (35)	
February	16 (33)	20 (27)	
Gestational Age (completed weeks) ^d	29.7 (7.1)	28.9 (7.2)	0.54

^aValues are n(%) unless otherwise specified^bPercentages may not sum to 100 due to rounding^cAs reported on the Fetal Death Certificate^dMean (SD)