California Pregnancy-Associated Mortality Review: Mixed Methods Approach for Improved Case Identification, Cause of Death Analyses and Translation of Findings

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Abstract After several decades of declining rates, maternal mortality climbed in California from a three-year moving average of 9.4 deaths per 100,000 live births in 1999-2001 to a high of 14.0 deaths per 100,000 live births in 2006–2008 (p < 0.001). The Maternal, Child and Adolescent Health Division of the California Department of Public Health developed a mixed method approach to identify and investigate maternal deaths to inform prevention strategies. This paper describes the methodology of the California Pregnancy-Associated Mortality Review (CA-PAMR) and its advantages for improved surveillance, cause of death analysis, and translation of findings. From 2002 to 2004, 1,598,792 live births occurred in California and 555 women died while pregnant or within one year of pregnancy. A screening algorithm identified cases for review that were likely to be pregnancy-related. Medical records were then abstracted and reviewed by a multidisciplinary committee to determine cause of death, contributing factors, and opportunities for quality

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California Maternal Quality Care Collaborative, Stanford University, Medical School Office Building, 1265 Welch Road, MS 5415, Stanford, CA 94305, USA e-mail: CMorton@stanford.edu improvement. Mixed methods were used to analyze, synthesize and translate Committee recommendations for improved care. Of 211 cases selected for review, 145 deaths were determined to be pregnancy-related. CA-PAMR methods corrected misclassification of cases and more accurately identified the leading causes of death. Cardiovascular disease emerged as the leading cause of pregnancy-related deaths (20 %), and African-American women were disproportionately represented among cardiovascular deaths. Overall, the chance to prevent the fatal outcome appeared good or strong in 40 % of cases reviewed. The CA-PAMR methodology resulted in additional case finding, improved accuracy of the causes of pregnancy-related deaths, and evidence to guide development of prevention and quality improvement efforts.

Keywords Pregnancy-related deaths · Maternal mortality · Mortality review · Surveillance systems · Vital statistics · Quality improvement

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Background

Maternal mortality is an important indicator of population health and the quality of health care in a society. For each maternal death, many more women experience pregnancyrelated morbidity of varying severity [1-3]. Maternal deaths and morbidities are significant in terms of families' psychological impact, years of lost productivity and the costs of publicly financed maternity care services [4]. After several decades of decline, maternal mortality rates began to climb in California and the United States (U.S.) in the early 2000s [5, 6]. This increase prompted the Centers for Disease Control and Prevention (CDC) to issue guidance for the investigation of pregnancy-related deaths [4], defined as deaths directly related to the physiologic changes of pregnancy, or from causes aggravated by the pregnancy or its management within one year of termination of the pregnancy.

In California, where one in eight U.S. births occurs, the maternal mortality rate rose from a moving three-year average of 9.4 deaths per 100,000 live births in 1999–2001 to 14.0 deaths per 100,000 live births in 2006–2008, with a recent drop to 11.6 in 2008–2010. African-American women are three times more likely than women of other racial groups to die from pregnancy-related causes, with 33.8 deaths per 100,000 live births, compared to rates of 10.7 for White, non-Hispanic women, 10.4 for Hispanic women and 9.6 for Asian/Pacific Islander women, using three-year aggregated data from 2008 to 2010.

Possible reasons for the rise in maternal mortality include: (1) improved case identification [7], (2) increased maternal age or prevalence of underlying chronic health conditions in women of reproductive age, (3) increased inequities based on social determinants of health, and (4) issues related to quality of maternity care. These potential explanations are not mutually exclusive; it is likely that some proportion of deaths can be attributed to one or more reasons.

The Maternal, Child and Adolescent Health (MCAH) Division of the California Department of Public Health (CDPH) initiated the California Pregnancy-Associated Mortality Review (CA-PAMR) in order to investigate the rise in maternal mortality and associated racial/ethnic disparities, and to guide policy and programmatic interventions. This paper describes in detail the methodology developed for CA-PAMR, and its advantages for improved case identification, cause of death analysis, and translation to prevention strategies, based on review of three years of maternal deaths.

Methodology

With the goals of reducing maternal morbidity and mortality through both public health and maternity care actions, CA-PAMR was implemented using four key components recommended by the CDC [4]: (1) enhanced surveillance of maternal deaths using available public health data; (2) medical record review to produce a synopsis of events culminating in the death of each woman; (3) case review by a multidisciplinary group of maternal health experts to determine causation and preventability, and; (4) translation of findings into quality improvement initiatives to improve maternity care and overall maternal health.

CA-PAMR is a collaborative effort by MCAH with volunteer committee members and contracted partners, the Public Health Institute (PHI) and the California Maternal Quality Care Collaborative (CMQCC). The review is conducted on behalf of the CDPH under legislative authority of California Health and Safety Codes §§100325, 100330, and 100335. All CA-PAMR data acquisition, protocols, data abstraction forms and contact letters were approved by the Committee for the Protection of Human Subjects of the State of California Health and Human Services Agency, as well as the institutional review boards of partner organizations.

Enhanced Case Finding Using Public Health Data

Like many states, case ascertainment in CA-PAMR begins with the identification of maternal deaths through a validated [8, 9] linkage of birth, fetal death and maternal death certificates to identify a cohort of women who died while pregnant or within a year post-pregnancy referred to as "pregnancy-associated deaths." In California, the linkage file is merged with hospital discharge data and additional public health records are obtained for each case including copies of death certificates, coroner and medical examiner reports, autopsy, and toxicology reports. Collectively, these data sources comprise California's enhanced surveillance of maternal deaths, which provide a much richer snapshot of the circumstances leading to a woman's demise than death certificates alone. CA-PAMR began with review of 2002 deaths in order to assess changes in the coding of pregnancy-related deaths introduced in 2003 and will continue through the period of the steepest rise in maternal mortality rates.

Case Selection Algorithm

California's childbearing population is large; therefore the number of pregnancy-associated deaths is also large, with 170–200 per annual cohort. Accordingly, CA-PAMR developed a case selection algorithm to identify the like-liest yield of pregnancy-related cases among each cohort. The cohort is first divided based on the International Classification of Disease, version 10 (ICD-10) codes into obstetric maternal deaths ("O" codes) and non-obstetric

maternal deaths ("non-O" codes). All O-code cases are further divided into "early" (during pregnancy or <42 days postpartum) and "late" (43-365 days postpartum) deaths. All early O-code deaths are included for review with the exception of deaths from ectopic pregnancy or abortion-related complications, since fetal death certificates are unavailable for deaths occurring before 20 weeks gestation. All late O-code deaths are screened for exclusion by reviewing information in the linkage file, abstracted death certificates and coroner reports, the hospital discharge summary, or if necessary, full medical records. If screening does not find any language suggestive of pregnancy or a death related to pregnancy, these cases are excluded from review. Second, among the non-O-code deaths, all motor vehicle accidents, homicides and suicides are excluded from review, as data from the pilot phase of CA-PAMR revealed that a medical record review, absent mental health or law enforcement records, was insufficient to determine pregnancy-relatedness in many cases. The remaining non-O-code deaths are screened for inclusion using the same process described above, and any deaths that might be pregnancy-related are included for case review by the CA-PAMR Committee.

Medical Record Review

Once cases are selected for review, copies of all available medical records (prenatal records, hospitalization records, outpatient and emergency department visits, medical transport documentation) are obtained. Trained abstractors enter information onto standardized abstraction forms which were pre-tested and adapted from forms developed by the CDC and Florida's Department of Health maternal mortality review [4, 10]. Chronological, standardized narratives (i.e., case summary) of each woman's experience from pregnancy to death are de-identified and transcribed. The detailed case summary includes pertinent medical history, examination findings, diagnostic results and documentation of key events including vital signs, medication, nursing, obstetric, anesthesia and resuscitation care.

Case Review by a Multidisciplinary Committee

CA-PAMR Committee members are appointed by the MCAH Director. The clinical specialties represented on the Committee include obstetrics, maternal fetal medicine, anesthesiology, neonatology, midwifery, labor and delivery nursing, emergency medicine, and cardiology. Committee members sign a confidentiality agreement, conflict of interest disclosure, and recusal policy for cases about which they may have prior or independent knowledge. All members serve in a volunteer capacity with reimbursement for travel expenses only. Committee members may opt to participate in sub-analyses or in the development or dissemination of quality improvement tools and strategies.

Approximately 20 committee members participate in quarterly daylong case review meetings and review approximately 15 cases per meeting. Cases are assigned to three primary reviewers according to their expertise and to ensure representation of nursing or midwifery and physician specialties for each case. The primary reviewers present their findings for full Committee discussion that ends with consensus determinations as to:

- (a) whether the death was pregnancy-related; and if so,
- (b) the causes of death using diagnostic categories similar to other maternal mortality reviews;
- (c) risk factors and risk levels at prenatal care and delivery;
- (d) factors that contributed to the death;
- (e) chance to alter outcome (preventability), and;
- (f) opportunities for quality improvement.

Pregnancy-related deaths from cardiovascular disease are classified into 'cardiomyopathy' and 'other cardiovascular' deaths by the Committee. Committee cardiologists further refine the causes of death into the types of cardiomyopathy and cardiovascular disease.

Committee determinations are captured on a structured form. Contributing factors are grouped into patient, health care provider or health care facility/system related categories. Individual factors within each contributing factor category were developed based on a saturation of themes identified during reviews performed in the pilot period. Opportunities for improvement in the quality of care are solicited from the Committee with the following question: "What alternative approaches to recognition, diagnosis, treatment or follow-up, if implemented, may have led to better patient care and/or a better outcome?" The quality improvement opportunities (QIOs) are distilled and reflected back to the group for final consensus and weighting. The preventability of each woman's death is determined based upon the degree of probability (none to strong) to alter the fatal outcome, both overall and through improved preconception health. Cases with a good or strong chance to alter outcome help set priorities for prevention and quality improvement efforts.

Data Management and Analysis

Data generated from the Committee's determinations are merged with quantitative data from the linkage file and medical records, and then analyzed using SPSS software, Version 20.0. Checks for inter-rater reliability among medical record abstractors are performed and 10 % of cases are re-entered to check for data entry error. Unadjusted odds ratios (ORs) and 95 % confidence intervals (CI) are calculated using the Risk Estimate statistic for bivariate analysis. The OIOs for each case are collected as open-ended text data and then categorized and tagged using emergent inductive themes based on the grounded theory approach of Strauss and Corbin [11]. The analysis of OIOs was initially informed by existing qualitative research on maternal morbidity and mortality [12, 13], and was adapted to correspond to methodology developed by CA-PAMR to specifically translate findings to activities that reduce future maternal morbidity and mortality. As such, the QIOs are organized into the same three domains as the contributing factors: patient, health care provider, and health care facility (or system), and the QIOs are often nested and tagged with greater specificity within the individual contributing factors. Figure 1 shows examples of the variety and granularity of quality improvement opportunities that correspond to a contributing factor, and illustrates how the CA-PAMR methodology can move from an associated risk factor to a deterministic or more 'causal' finding which can be translated to a potential preventive action. For example, one contributing factor (inadequate response to or management of a preeclampsia case) is linked to a specific quality improvement opportunity (a need for improved monitoring of and response to changes in blood pressure and vital signs). Qualitative analyses of QIOs are performed within each major cause of death category using Dedoose, version 4.2.75, which permits mixed methods analysis, visualization of text-based data, and integration of quantitative data [14].

Findings

Pregnancy-Relatedness and Misclassification of O Codes

From 2002 through 2004, California experienced 1,598,792 live births and 555 women died while pregnant or within 1 year of pregnancy, comprising the pregnancyassociated death cohort. From this cohort, 139 cases were originally coded as obstetric maternal deaths (O-codes) and 416 were coded as non-obstetric maternal deaths (non-Ocodes) (Fig. 2). Of 139 O-code cases, eight were excluded from review, one based on lack of records and seven based on the absence of any information indicating the death was related to pregnancy, and for those seven, each death could be attributed to other not-pregnancy related causes, such as cancer or a motor vehicle crash. The CA-PAMR Committee reviewed the remaining 131 cases and 109 were determined to be pregnancy-related. Of the 416 non-Ocode cases, 94 cases of traumatic death were excluded and the remaining 322 cases were screened for inclusion, yielding 80 cases for review. The Committee determined that 36 of the 80 non-O-code cases were pregnancy-related.

In summary, the Committee reviewed 211 cases and designated 145 as pregnancy-related, resulting in a net increase of six cases beyond those reported by death certificates alone during 2002–2004. Thirty-six deaths were reclassified as pregnancy-related, the majority of which (75 %) occurred in the early postpartum period with 39 % (n = 14) of the deaths among African-American women. Most of the additional case ascertainment of pregnancy-related deaths (n = 24) occurred among deaths coded as not pregnancy-related "Diseases of the Circulatory System" ("I" codes) on the death certificate and, post-review, half of these were determined to be pregnancy-related cardiovascular deaths.

The CA-PAMR enhanced surveillance methodology also revealed that misclassification occurred in the reverse: 22 deaths were reclassified from pregnancy-related to notpregnancy-related, most (59 %) occurred in the late postpartum phase and only two were among African-American women. The majority (68 %) of these misclassified deaths were reported on the death certificate with nonspecific O codes such as O95-O99 and, post-review, the deaths were more accurately attributed to cancer (n = 3), cardiovascular disease (n = 5), cerebral vascular accidents (n = 4), drug abuse complications (n = 3), infection (n = 1), or other medical conditions (n = 6) that were not related to or aggravated by pregnancy.

Causes of Death

Prior to CA-PAMR, the leading causes of pregnancyrelated deaths based on death certificate O codes during the study period (N = 139) were preeclampsia/eclampsia (16 %), obstetric hemorrhage (15 %), amniotic fluid embolism (11 %), sepsis/infection (6 %), and 5) pulmonary embolism (6 %). In addition, a large proportion of deaths (43 %) were assigned nonspecific obstetric codes. After CA-PAMR review (N = 145), the five leading causes of pregnancy-related deaths were determined to be: cardiovascular disease (20 %), preeclampsia/eclampsia (17 %), obstetric hemorrhage (11 %), amniotic fluid embolism (10%), and pulmonary embolism (8%). Table 1 describes causes of death before and after review for the 145 cases determined to be pregnancy-related, as well as the cause-specific pregnancy-related mortality rates. Misclassification was most pronounced in the 29 deaths attributed to cardiovascular disease by CA-PAMR, with 13 (45 %) reclassified as pregnancy-related. Based on CA-PAMR findings, cardiovascular disease had the highest mortality rate of 1.8 per 100,000 live births, followed by preeclampsia/eclampsia with a rate of 1.6 per 100,000 live births.

CA-PAMR also provided greater insight into racial/ethnic disparities. African-American women accounted for over a

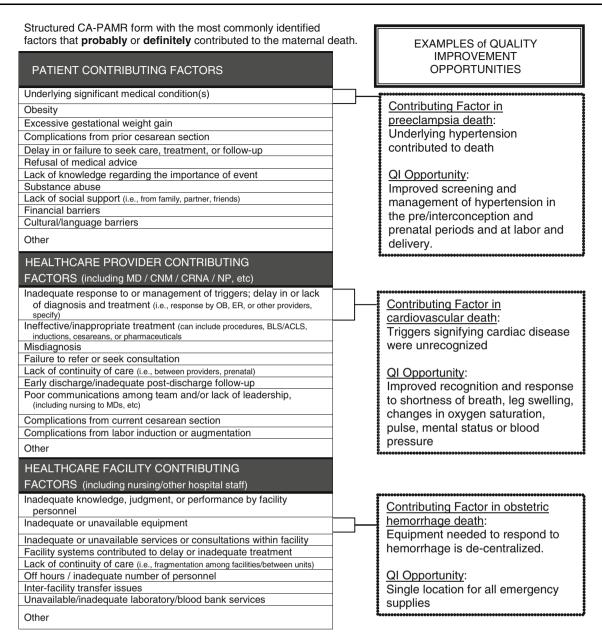


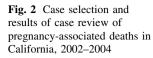
Fig. 1 Contributing factors and relationship to quality improvement opportunities identified for maternal deaths, California 2002-2004

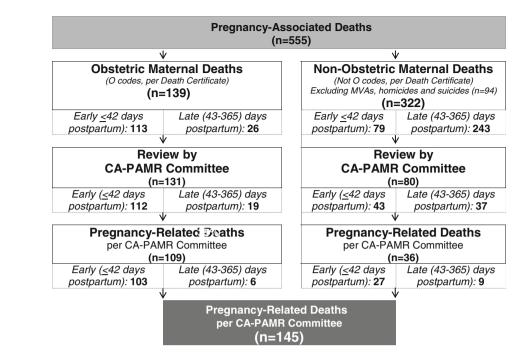
third of the 29 deaths from cardiovascular disease. The risk of death for African-American women from any cardiovascular disease was three and a half times that of non-Hispanic White women (OR 3.5, CI 1.09, 11.54) and four times higher for death from cardiomyopathy (OR 4.1,1.00, 16.99).

Contributing Factors, Quality Improvement Opportunities and Chance to Alter Outcome

Of the 145 pregnancy-related deaths, nearly all had more than one contributing factor identified and most had numerous quality improvement opportunities. To date, the QIO analysis for preeclampsia cases identified several themes related to health care providers; specifically, the need for more timely response to clinical triggers as a means to reduce delays in diagnosis and/or treatment that contributed to the deaths. A similar effort is underway for the cardiovascular cases, where preliminary themes suggest more opportunities related to patient factors, such as underlying health status.

Among all CA-PAMR deaths, the chance to alter outcome was judged to be good or strong in 40 % of the cases, meaning that with a different course of action or circumstance (e.g., timing of treatment, better recognition/ response to changing clinical status, etc.) the fatal outcome may have been prevented.





Discussion

The CA-PAMR methodology has some advantages that may inform other state efforts to investigate maternal mortality:

- The activities are the responsibility of a state agency, namely the CDPH, which is advantageous in establishing legal authority, institutional longevity and helping to translate findings into programmatic or regulatory action;
- Linkage of vital statistics data improves case ascertainment [7, 15–17]. Nearly 25 % of pregnancy-related cases were originally classified as not-pregnancyrelated prior to the CA-PAMR case screening and indepth case review process. The criteria for case selection and the review process are particularly effective in identifying additional pregnancy-related deaths from cardiovascular disease among African-American women.
- Our data suggests that maternal mortality rates calculated from death certificate O codes may be underestimated in 2002–2004, especially among African Americans and for cardiovascular disease since this group comprised a large proportion of the newly ascertained pregnancy-related deaths. Further, rates based on deaths identified in PAMRs are unlikely to match official maternal mortality rates because of the misclassification of deaths on the death certificate and potential exclusion of early (<20 weeks gestation) pregnancy-related deaths.

- Comprehensive record review is enabled by linkage to hospital discharge data and leads to improved accuracy regarding the causes of death as compared to causes recorded on death certificates. For example, based on the first three years of data from CA-PAMR, cardiac disease has emerged as the leading cause of pregnancy-related death with a pregnancy mortality rate of 1.8 per 100,000 births. This finding is consistent with the findings from Florida, the U.S., United Kingdom, and Netherlands [10, 15, 16], however, it may not have been recognized in California without introducing the CA-PAMR methodology.
- An in-depth medical record review yields information that is often poorly documented within public health population-based datasets, such as the woman's medical history, comorbidities, or risk factors, and this information is essential for consensus decision-making regarding preventability.
- CA-PAMR identifies cases with a good to strong chance to alter the outcome and qualitative analysis suggests priority areas to target quality improvement strategies in order to prevent future severe morbidity and deaths. Three toolkits addressing the leading and preventable causes of death have been developed (e.g., obstetric hemorrhage) or are currently under development (e.g., preeclampsia and cardiovascular disease) for the maternity care community. Additionally, California public health pre- and inter-conception health and chronic disease programs are incorporating patientrelated messages and resources to improve women's health status before, during and after pregnancy.

	Initial death certificate cause of death and classification ^a		CA-PAMR Committee cause of death	
	Pregnancy- related deaths N (%)	Not pregnancy- related deaths N (%)	Total pregnancy- related deaths N (%)	Cause-specific pregnancy-related mortality rate (per 100,000 live births)
Cardiovascular disease	16 (15)	13 (36)	29 (20)	1.8
Cardiomyopathy	10 (9)	9 (25)	19 (13)	1.2 ^b
Other cardiovascular	6 (6)	4 (11)	10 (7)	0.6 ^b
Preeclampsia/eclampsia	19 (17)	6 (17)	25 (17)	1.6
Obstetric hemorrhage	16 (15)	0	16 (11)	1.0
Amniotic fluid embolism	15 (14)	0	15 (10)	0.9
Deep vein thrombosis/pulmonary embolism	12 (11)	3 (8)	15 (10)	0.9
Sepsis/infection	9 (8)	1 (3)	10 (7)	0.6
Cerebral vascular accident	5 (5)	4 (11)	9 (6)	0.6
Anesthesia complications	3 (3)	1 (3)	4 (3)	_
Acute fatty liver	3 (3)	0	3 (2)	_
Drug abuse complications	0	3 (8)	3 (2)	_
Cancer (diagnosis or treatment delayed by pregnancy)	2 (2)	0	2 (1)	-
Other ^c	9 (8)	5 (13)	14 (10)	_
TOTAL (%)	109 (75)	36 (25)	145	_

Table 1 Causes of pregnancy-related deaths: comparison of death certificate causes to causes of death per CA-PAMR Committee, 2002–2004

Mortality rates are not calculated for causes of death with less than five events

^a Pregnancy-related deaths are indicated by the following ICD-10 cause of death classification O codes: A34, **O**00-**O**95, **O**96, and **O**98-**O**99. Not-pregnancy-related deaths are indicated by all other non-O codes

^b Risk of death for African-American women from cardiovascular disease, compared to Non-Hispanic Whites, for any cardiovascular disease was three and a half times that for 'Other cardiovascular disease' (OR 3.5, CI 1.09, 11.54) and four times higher for cardiomyopathy deaths (OR 4.1,1.00, 16.99)

^c "Other" causes include 14 cases of pregnancy-related death that are not part of the other listed clinical causes of death. These include: acute necrotizing pancreatitis, airway obstruction from thyroid goiter, complications of bariatric surgery, congenital tracheal stenosis, epileptic seizure, iatrogenic hemothorax secondary to thoracentesis, pneumonia and pneumonitis (2), renal artery aneurysm, ruptured splenic aneurysm, thrombotic events (3) (thrombocytopenic purpura (2) and thrombotic cerebellar infarct), and an unknown cause because lacked sufficient documentation, especially autopsy results

- The Committee membership has been very stable since onset which contributes to validity of findings, cost efficiencies, and high level of commitment to the entire project from data collection through analysis to education and development of quality improvement tools [18].
- Hospital participation has been extremely high; nearly all requests for hospital records were honored, which may be attributed to the authority asserted by the CDPH, but may also be influenced by the fact that the primary goal is to inform tools and strategies for quality improvement which are then shared with hospitals.
- CA-PAMR does not exist in isolation. The project was designed to be integrated with an ongoing quality improvement program of the CMQCC and to inform quality improvement efforts of other organizations. The ongoing translation of findings to action moves beyond the issuance of recommendations and has garnered

public and private investment and partnership to support long-term sustainability of maternal health quality improvement efforts.

Limitations

Case ascertainment is likely to be underestimated for three reasons: (1) We were unable to review all non-O-code deaths due to resource limitations. Additional pregnancyrelated deaths might be identified from in-depth review of more non-O-code deaths, particularly those related to suicide (e.g., from postpartum depression) and homicide. (2) The linkage file includes women only if their death was linked to a live birth or fetal death of 20 weeks gestation or more, and therefore excludes pregnancy-related deaths resulting from ectopic pregnancy or abortion, for which four to eight deaths were reported annually in California during 2002–2004. (3) Occasionally, the lack or inadequacy of autopsy reports hindered confidence in assigning cause of death.

The contributing factors identified are not likely to be exhaustive. Reliance on medical and coroner record review by clinicians introduces a possible bias toward the recognition of factors related to the clinical practice of health professionals, and perhaps less identification of factors involving the health care delivery system or the patient's barriers to health. A retrospective review to assess preventability is limited because one cannot know for certain whether a different outcome would have occurred in the presence of a different set of factors or decision-making processes. However, despite these limits, the Committee was able to identify opportunities in nearly all deaths reviewed that can inform patient safety and quality improvement efforts.

Conclusion

While CA-PAMR continues to review additional years of cases, some conclusions can be made about the methodology based on our experience thus far:

- The methodology of CA-PAMR has resulted in additional case finding, improved accuracy regarding the causes of pregnancy-related deaths, associated racial disparities, and greater insight into cardiovascular disease, specifically cardiomyopathy, as one of the leading causes of pregnancy-related deaths;
- Development of a case selection algorithm may inform other states or nations needing to target a subset of pregnancy-associated deaths;
- Misclassification of pregnancy-relatedness occurs in both directions; therefore, improvements in the national reporting and coding of maternal deaths are needed;
- Medical record review is sufficient for some but not all cases of pregnancy-associated deaths; and some cases, such as homicide and suicide deaths, require additional source data from law enforcement, mental health or surrogate interviews;
- 5. Development of a structured set of contributing factors and associated opportunities for quality improvement is a useful addition to previously described methodologies for maternal mortality reviews. Integrating such data with administrative and medical data improves our epidemiologic understanding of pregnancy-related mortality and our ability to design prevention strategies.
- Mortality reviews are inherently complex undertakings and must be built on foundations of trust and commitment to prevent future morbidity and mortality. CA-PAMR demonstrates the importance and capacity of

long-term partnerships of public health for authority and funding, health care institutions for confidential access to medical records, health care experts for interpretation of findings and rigorous data collection and analysis by public health investigators.

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