Abstract (183 words)

Background: Despite intensive efforts over the past decade to improve the quality of data collection for maternal mortality, methodological challenges remain. **Purpose:** To draw upon the knowledge generated through current and past methodologies for the measurement of maternal mortality, and address the need for improved data collection methods in a resource-limited setting, including the need for cause-specific maternal mortality data. **Methods:** A pilot study to test the feasibility of a community-based, mixed methods approach for civil vital registration with maternal cause of death attribution by mid-level providers was conducted in Tigray, Ethiopia from August 2010-August 2011. Community-based workers (TBAs, CBRHAs and HEWS) were mobilitzised to identify, verify and register respectively all deaths and births in the project area. Local priests played a significant role in the reporting and monitoring of the registry. Nurses and nurse-midwives were trained to administer verbal autopsy for all deaths of females age 12-49, and assign primary cause of death using WHO International Disease Classification standards. **Results:** a community-based approach to data collection for maternal mortality, maximizing existing local health care infrastructure and human capacity is a feasible intervention.

Globally 350,000-500,000 women die each year from complications during pregnancy and childbirth (1). Despite intensive efforts over the past decade to improve the quality of data collection for maternal mortality, methodological challenges remain. In the least developed countries, vital registration systems are incomplete or nonexistent, census data collection ocurrs infrequently, and research-intensive data collection such as population-level household surveys are costly and sporadic. The overall lack of reliable data on maternal mortality at district or regional level hinders prevention efforts, advocacy, prioritization, and budget allocation. (2, 3).

This paper will provide a review of existing methods for the measurment of maternal mortality, propose a new approach to community-based measurement, and present results of a pilot project testing the feasibility of this new approach for measurement.

Background

The WHO has recognized the importance of reliable data, advising that countries prioritize the development of comprehensive VR programs.(4) Such systems, however, have historically succeeded in settings in which the majority of births occur in health facilities that are equipped to capture this information. In settings in which the majority of births and deaths occur at home, such VR systems can miss the majority of vital events, including the large majority of maternal deaths.(5, 6) Because of vast differences in the ability to capture data, there is enormous variability in the coverage and reliability of VR systems around the world.(4) There is a significant need for stronger, more reliable VR systems in order to recognize and respond to trends in births and deaths in sub-Saharan Africa.(7) Thus, the development of VR systems should be prioritized in order to better understand demographic and health-related trends and to measure progress toward health-related goals.

Existing approaches to capture vital events, such as sentinel surveillance (SS) and population-based surveys, are prohibitively expensive and time-consuming. Such efforts are often, therefore, infrequent, short-lived, and unable to produce reliable longitudinal data (8). To better measure vital events in resource-poor settings, it will prove essential to cultivate and build upon existing systems, and to involve local community members and low and mid-level health providers in data collection. Such systems will require investments in sustainable infrastructure that can lead to the accurate capture of vital events occurring outside of health facilities, and will thus need to be administered at least in part by people who are not necessarily physicians or trained health providers, as well as community members and volunteers, to ensure the collection of reliable VR data in resource-poor settings.(9, 10)

Historical approaches to maternal mortality measurement. A variety of population-based approaches have historically been employed to measure maternal mortality. One such approach is the sisterhood method, which relies on a technique of questioning women about whether any of their adult sisters died during pregnancy or

childbirth.(11) Other population-based surveys, such as the Demographic and Health Surveys (DHS), and national censuses, have also been used to ascertain information about births and deaths within families, and are sometimes equipped to capture maternal deaths. Despite the important data that have been generated through these methodologies, concerns remain. SS systems often collect data from relatively small geographic areas, thus generating data that are not generalizable to the broader population. In addition, SS systems can be costly, and it thus may not be feasible to rely on these systems to produce high-quality data indefinitely.(6) In addition, census data have, proven unreliable in the estimation of maternal mortality ratios.(12) The development of Reproductive Age Mortality Studies (RAMOS) represented a major step forward in employing a mixed-methods approach to measuring maternal mortality,(6, 13) and has served as a valuable guide in further developing such approaches. RAMOS studies rely on VR to ascertain deaths of women of reproductive age and employs verbal autopsy to assign cause of death (COD). The utility of RAMOS, however, is contingent upon the reliability of available data from VR and other sources(14); in settings in which these data are not available, RAMOS alone has not been a feasible method for acquiring complete maternal mortality data, particularly for events occurring outside facilities.(15)

Current approaches to measuring maternal mortality: Focusing on Key Informants. More recent empirical approaches to measuring maternal mortality have demonstrated some success in accurately capturing maternal deaths. Strategies using key informants, who prospectively document all births and deaths in their communities, have been found to be effective in rural, resource-poor settings, and thus represent a promising technique in cases where surveys and traditional SS techniques are infeasible or unsustainable.(16) **Verbal Autopsy.** Verbal autopsy is a widely used, indirect method for determining cause of death (COD), through in-depth interviews, in absence of medical certification. VA involves interviewing appropriate respondents, and assignment of cause of death. (17). Development and refinements of verbal autopsy for maternal death, among other causes, have gained momentum in the last 20 years (18, 19) (20).

Approaches to COD attribution. A variety of approaches exist for the attribution of the most probable cause of death from VA data. However, for any of the approaches, an internationally comparable, classification hierarchy, such as the International Classification of Diseases (ICD)(21), is necessary and allows standardized codes, recoding, and investigation of multiple causes with the flexibility to analyze according the underlying single cause.(8) Approaches to assigning COD from the selected cause list include those that rely on physician-certified verbal autopsy (PCVA), algorithms for computer-certified verbal autopsy (CCVA), and probabilistic determinations.(20) PCVA, the most widely used approach, typically involves review by an expert panel with either joint consensus reconciliation or additional review by a third physician to resolve discrepancies.(22, 23) Although PCVA has been considered a valid approach and produces high rates of concordant assessments, concerns have been raised about PCVA including issues of subjectivity,(20) repeatability, and certain biased coding tendencies(20). Various CCVA methods exist, not subject to the same subjectivity biases, some such methods include the widely used InterVA, and InterVA-M, specifically designed for maternal mortality(24) and Symptom Pattern Method.(25) CCVA, however, most often captures cause-

specific morality fractions (CSMF), which due to selection biases inherent in facility based data, may differ substantially from the distribution of CSMF in the community setting, where the need for VA-based COD attribution is often of greatest. As an example, mortality associated with postpartum hemorrhage is more rapid than mortality associated with obstructed labor. Consequently, women experiencing obstructed labor may have more time to arrive at a facility than women experiencing postpartum hemorrhage, but may be more likely to die in that facility. Deaths from postpartum hemorrhage would thus be expected to be a smaller fraction of maternal deaths in a facility-based dataset than would be expected in a community-based data set.(20, 26)

The need for high-quality maternal mortality data. Despite advances in data collection and cause of death attribution, no single approach to measuring maternal mortality has been demonstrated as universally successful or feasible. Statistical and analytical approaches alone are not sufficient for the development of targeted interventions to reduce mortality, or for measurement of progress toward these targets.(27) It is necessary to employ affordable, sustainable, mixed-methods approaches to maternal mortality measurement in order to generate accurate data about the number of maternal deaths and the most common causes of these deaths.(28)

Through a pilot study conducted in Tigray Ethiopia, we have tested the feasibility of an innovative, approach to obtain timely data on maternal mortality and distribution by cause of death (COD). In addition to testing a system with proven methodologies of data collection, to our knowledge, this study was the first to assess the feasibility of mid-level providers attributing cause of maternal death using VA. The methodology proposed in this paper builds upon these recent findings, expanding the reach of a

community-based, sustainable VR system that accurately identifies and records all maternal deaths.

Maternal Mortality in Ethiopia: In 2008, the adjusted Maternal Mortality Ratio (MMR) for Ethiopia was 470 per 100,000 live-births (WHO, 2010). However, accurate, reliable data on the levels, trends, and differentials in maternal mortality for regional and district levels are sorely needed. Without such data, policies and programs will continue to be implemented without clear evidence to indicate which interventions have the greatest potential for impact.

Methods

Population

Tigray, the northernmost region of the country has a population of over 4 million people with 81% living in rural areas, and 96% identified as Orthodox Christian.(29) Under the four facility tiers of the Ethiopian national health care system (referral hospital, zonal/district hospital, health center, and health post) the Tigray Health Bureau maintains 1 referral hospital, 12 zonal/district hospitals, 38 health centers, and 600 health posts.(30, 31) As of 2010, the Tigray Health Bureau employed 84 midwives, and 1258 Health Extension Workers (a cadre of female health workers who have been trained to provide basic curative and preventive health services in

rural communities).(32, 33). The pilot project was implemented in rural Tigray, communities of Ataklti, Amba, Bega, involving 3 health posts and 1 health center with a total catchment area of approximately 22,000 people.

Project Components



Note: Because the pilot project is a feasibility project, the audit committee is a component of the project that will be implemented when scale-up is complete in order to determine whether mid-level providers can attribute COD with the same accuracy as physicians.

Community-Based Sentinel Surveillance:

All priests, TBAs and CBRHAs will be responsible for locating and reporting all births and deaths in their designated areas. The community-based providers were given explicit training on how to educate and motivate families to report births and deaths in their homes. They also assist mid-level providers in locating key informants for VA and for the verification of births and stillbirths. The data collection tools used at this level are simple log books with identification of the vital events in a way that is easy for household location.

Vital Registration at the Health Post Level:

To ensure that all vital events are captured, community based health providers were trained to report all births and deaths to the local health post (one in each village) where vital registries are kept up-to-date. Once per month, each of the three health posts compiles a list of all births, stillbirths and deaths of females (aged 12 to 49) for verbal autopsy and verification by mid-level providers. The vital events were registered in Government provided logbooks and distributed to health posts.

Vital Registration & Verbal Autopsy:

For all deaths of females aged 12-49 that occur in the community, one trained mid-level provider is assigned to conduct verbal autopsy interviews. The mid-level provider privately interviews 2 different adults related to the deceased (the closest living male relative and the closest living female relative). These interviews occur after

the traditional 14-day mourning period, and after informed consent are obtained. Upon completion of the VA interviews, the mid-level provider carefully reviews the answers given by both respondents and determine: a) if the death was a maternal death b) if the cause of death was any combination of the five main obstetric causes or "other" and c) the circumstances and contributing factors to death. If the two interviews yield conflicting stories, the mid-level provider arranges an interview with a third key informant. Verification of births and stillbirths were conducted using a specifically created questionnaire.

Although not the target of the study pilot, facility level data continues to be collected. Mid-level providers continue to register all deaths and births that occur in the facility. All records of maternal deaths in facilities undergo maternal death audit and are additionally registered in the vital registration logs.

Training

Community-based health workers (TBAs or CBRHAs) and local priests received 5 days of intensive training in study protocol, and targeted training in Sentinel Surveillance (SS) methodology. As a part of the training process for SS, small teams of priests and community-based health care workers ('community teams') from the same communities created community maps of their catchment area and assign groups of households to each member of the team for SS. The members of the team established a location and time for weekly meetings to collect all data on births and deaths in the community. One member of the team was nominated to notify the health post, on a weekly basis, of all vital events in the catchment area.

Health Extension Workers (HEWs) received 5 days of intensive training to provide comprehensive background information, detailed training in study protocol, and targeted training in Sentinel Surveillance (SS) methodology, and data collection and management for civil vital registration. They received information from the community teams working in SS and would register (in government published vital registration log books) all births and deaths in the catchment of their health post.

Nurses and Nurse Midwives received 7 days training comprising detailed training in study protocol, in-depth interview technique, VA interview technique with an emphasis on maternal death, and interview technique for sensitive subjects. They engaged in role playing activities using the actual VA survey instrument (which had been field tested in the Tigrinya language, further adapted to cultural and language norms based on suggestions received in the pilot trainings), and familiarized themselves with skip patterns for both open and closed-ended question formats. In addition, they received 4 days of intensive training in COD attribution from VA using WHO recommendation of "classification of single causes of death and any of the combinations of the single causes" (Campbell and Ronsmans, 1994). The minimum list of single causes includes: (i) induced abortion and sepsis; (ii) induced abortion and hemorrhage; (iii) ectopic pregnancy; (iv) spontaneous abortion; (v) antepartum hemorrhage; (vi) postpartum hemorrhage; (vii) sepsis; (viii) eclampsia; and (ix) prolonged labor. We use the International Classification of Diseases (ICD-10) definition of an indirect obstetric death as deaths "*resulting from previous existing disease that developed during pregnancy and which was not due to direct obstetric causes, but was aggravated by physiologic effects of pregnancy.*"(21, 34, 35) However, separate

categories were created for the classification for diseases of local importance, which represent relatively large proportions of maternal deaths, such as hepatitis, malaria, TB, anemia, heart disease, AIDS, tetanus, and injuries (intentional and unintentional).

In order to raise community awareness about the project study, and to encourage active participation from community members, meetings with communities were held on a monthly basis for the first 3 months of the study, and again at the end of the study period. All levels of the research team, from medical staff to TBAs and priests involved in data triangulation, as well as other community-based groups were invited to participate. Broad-based participation was considered necessary not only for the acceptance and uptake of the project by community members, but for the validation of study data by members of the community as well.

Results:

Project Implementation

All of the personnel engaged in the various project components (SS, VR, and VA) worked collaboratively well following the procedures of the study protocol. Monitoring program data shows that the expected meetings for data triangulation were held, as well as the births and deaths verification and VA administration. Mid-level providers were effectively trained to administer VA questionnaire and attribute cause of death. A total of 24 female deaths aged 12-49 were reported. A total of 48 verbal autopsies were conducted. Of those, 4 were correctly identified as maternal deaths. The VA questionnaires were reviewed by an obstetrician/gynecologist and the causes of maternal deaths attributed by the nurse-midwives were in complete accordance with the physician.

Community acceptance of the project and its dialogues. These dialogues were successful in illuminating the factors that could have played a role in maternal deaths in general—without assigning blame or identifying the deceased person or the key informants by name.

Data collected

During the 12 months of the project 856 births and 164 deaths were reported (Table 1). A total of 24 deaths of women of reproductive age, were recorded, 4 of them were classified as maternal deaths, and assigned the cause of "post partum hemorrhage". Data collected provides and estimated crude birth rate of 39.7 births/1000 population; an annual all cause mortality rate of 7.6 deaths/1000 population; an annual reproductive age mortality rate of 2.8/1000; and a maternal mortality ratio of 467/100,000 live births. These data were compared to the 2007 Ethiopian National Census data for the Tigray region which reports an annual crude birth rate of 30.9/1000; an annual all cause mortality rate of 9/1000; and an annual mortality rate for women of reproductive age of 6.3/1000. The most recent maternal mortality ratio for Ethiopia (2008), estimated by the WHO is 450/100,000 live births (Table 1)

Pilot Study Data August 1, 2010-August 1, 2011		2007 Ethiopian Census (Tigray Region)
Crude Data		
	2153	
Total population in pilot area	8	
Total women of reproductive age	8701	
Total births	856	
Total female deaths 12-49	24	
Number of maternal deaths	4	
Total deaths in the project area	164	
Demographic Indicators		
	00.7	20.0
Crude Birth Rate*	39.7	30.9
Crude death rate (males and females)*	7.6	9
Reproductive age mortality rate§	2.8	6.3
Maternal mortality ratio [‡]	467	450

Table 1: Study Data compared to Census Data

* Indicates rate per 1000 population § Indicates rate per 1000 women of reproductive age ‡ Ratio of maternal deaths per 100,000 live births

Discussion

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The methodology we have tested for the collection of vital data with COD for maternal deaths fills a mucharticulated need (7, 14, 36, 37) for improved methods of data collection for maternal mortality. Drawing upon existing human resources and health infrastructure, our methodology establishes an ongoing, communitybased, vital registration system for measurement of vital events (and maternal mortality with COD data) into the local health system. Through the implementation of a community-based data-collection system built within the existing health infrastructure, our approach thus avoids the shortcomings of other measurement techniques, which can be episodic, resource intensive, and often yield only cross sectional or cohort-specific data.

While over 40% of urban Ethiopian women deliver in a health facility, only 2.4% of rural women do the same.(38) In a country where of the vast majority of the population lives in rural areas,(29) facility based data on maternal deaths is likely to differ systematically from data collected at the community level. The necessity of

relying upon facility-based data to generate and validate computer algorithms for CCVA, and the inherent disadvantages of such an approach in a predominantly rural population, led us to chose PCVA as the 'gold standard' against which to compare mid-level provider COD attribution. Relying on doctors to review VA results is prohibitively expensive in low-resource settings,(23, 25) and an inefficient use of a scarce human resources as it diverts them from their clinical duties.(23) Our proposal draws on the theory of task shifting,(39, 40) and applies it to a new domain by shifting the task of COD assignment from physicians to mid-level providers (nurses and midwives). To date, this approach has not been implemented outside of the initial study. Our study design trains mid-level providers to conduct the VA semi-structured interviews and to assign COD. This process will then be implemented in the field, allowing for comparison with physician review. While both lay interviewers and mid-level providers have conducted VA interviews successfully,(17) using mid-level providers as interviewers allows for the use of more sophisticated medical classification of COD. Moreover, by interviewing at least two respondents, our methodology improves the likelihood of obtaining reliable information of the events leading to death.

We are confident that the results from the study reflect the vital events that have occurred in the communities where the study was conducted. All key mortality and CBR estimates are whiting the ranges of what we had expected for this rural population. It is important to note that the reproductive age mortality rate is slightly lower than what was captured by the 2007 census, two factors could contribute to this phenomena: first, numerous health interventions targeted at women and mothers have been implemented by the Tigray Health Bureau in the past 3 years, which may have had an impact on the mortality rate of women of reproductive age, and second the legalization of abortion may have contributed to the reduction in deaths of women of reproductive age; deaths that were captured by the census but not labeled as maternal deaths. Tigray is in the forefront of implementing comprehensive abortion care services and these rural areas have benefited from such services.

The identification of all births and deaths in their communities by non salaried non health care providers might pose a challenge in the scale up of the proposed approach. However, this can be mitigated by the continuous engagement of the communities in the potential solutions for improvements of maternal mortality interventions, as seen in the pilot project.

Conclusion

This research has the potential to make a significant impact on the study of vital events and on methodologies to measure maternal mortality at the community level with more accuracy and reliability. Establishing a community-based VR system has the potential to serve as a model for the efficient collection of accurate, timely data on vital events in low resource settings. Training mid-level providers to establish cause and circumstances surrounding maternal deaths (including abortion-related deaths) has the potential to generate accurate COD data for maternal deaths. Such data have been called for at the global level by experts across the field, and have great potential to inform MCH policy and funding prioritization.

In addition to a redoubled global commitment to reducing maternal mortality, data collection systems for measuring maternal mortality must be re-envisioned in order to track progress accurately and efficiently. Especially in resource-poor settings, reliable morbidity and mortality data are difficult to come by, but are key to developing evidence-based policies in health. Data generated by some of the measurement systems currently in use (specifically Vital Registry, Sentinel Surveillance, and Verbal Autopsy) on their own can provide reliable estimates of the levels and differentials of important indicators such as maternal morbidity and mortality, but often put an extraordinary burden on already feeble systems. The system that has been set into action through the pilot project in Ethiopia aims to build a new, sustainable methodology for the ongoing measurement of maternal mortality that has the potential to serve as a blueprint for local and national governments to implement a low-cost, practical method of measuring vital events, as well as community-based solutions to improve maternal health.

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