Validation of Verbal Autopsy in Perinatal Deaths – A Prospective Study in Belgaum District, Karnataka, India

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ABSTRACT

Background: The first goal of National Rural Health Mission (NRHM) and the fourth goal of Millennium Development are to reduce under-five mortality rate. In India, data is available for aprox. 3% of the perinatal deaths. The need for good quality data on perinatal deaths is mandatory for public health planning and resources allocation. This has lead to a renewed interest in Verbal autopsy (VA) in poor resource settings. **Objective:** To validate a simplified community-based VA instrument. **Materials and Methods:** A simplified community-based VA instrument was developed. The sample size of 50 was calculated at power – 80%, significance – 5% and sensitivity – 70%. ANMs were trained to assign COD according to the ICD – 10. Following which they administered Verbal Autopsies for every perinatal death occurring in their area. A panel of 3 Physicians was formed who reviewed the VA data and assigned cause of death according to the ICD–10. Kappa Statistics was used to measure the degree of agreement between the ANM and Physician panel assigned COD. **Results:** Out of 50 Perinatal Deaths, the COD assigned by ANM and the COD assigned by the Physician panel were same for 40 of the perinatal deaths, which showed the agreement of 80% [Kappa Statistics = 0.838; P = 0.000 (<0.001)] which indicates statistically significant agreement. There was agreement of 93% for 14 Stillbirths and 75% agreement for 36 Early Neonatal Deaths.

Key words: Verbal autopsy, Perinatal deaths, Developing countries, Community intervention.

INTRODUCTION

Perinatal mortality is a sensitive indicator of health status of a community.[1] Globally, only about a third of all deaths are registered with age, sex, and cause of death, where in the knowledge regarding the cause of death remains scanty for neonatal and perinatal mortality in developing countries.[2] The first goal of National Rural Health Mission (NRHM) and the fourth goal of Millennium

Development are to reduce under-five mortality rate by two-thirds. Estimates around the start of the new millennium showed the Indian under-five mortality rate as 95 per 1000 live births and neonatal mortality (between 0 and 28 days) as 46%. Consequently, two-thirds (48%) of all neonatal deaths occur within in the first 7 days after birth. The perinatal deaths from 28 weeks of gestation up till first 7 days after birth (Perinatal Mortality Rate) in India for the year 2009 is 33/1000 live births.[3] The need for good quality data on perinatal and neonatal mortality, is mandatory for public health planning and resources allocation. This has lead to a renewed interest in Verbal autopsy (VA) in developing countries and poor resource settings.[4] What little is known about causes of death in the world's poorest countries (and those with the highest mortality) comes almost entirely from surveys, and is largely limited to causes of death among children. Even if facility-based routine health information systems could be strengthened to provide better mortality information,

their ability to generate representative statistics is limited in countries, where the vast majority of deaths take place outside the health facilities.[5] Cause-of-death data derived from Verbal Autopsy (VA) are increasingly used for health planning, priority setting, monitoring and evaluation in countries with incomplete or no vital registration systems. . Currently, the VA method is routinely used at over 35 sites, mainly in Africa and Asia.[6] Verbal autopsy has been used in several countries for maternal deaths, but seldom for perinatal cause of death.[1] Verbal autopsy is an indirect method to ascertain the biomedical cause of death from information on symptoms, signs and circumstances preceding death, obtained from the deceased caretakers and can prove to be an essential tool.[3] Sample or sentinel mortality surveillance using standardized "Verbal Autopsy" (VA) procedures represents a viable mid or long-term strategy for improving mortality information. Although VA is a limited tool, the procedure has demonstrated the ability to produce valid estimates of the mortality cause structure in many settings. VA has been applied in numerous countries, among children and adults, and for the purposes of both exploring specific causes of death in research projects and developing an overall description of the mortality structure at the community or population level. The W.H.O and the United Nations Children's Fund have called for the expanded use of the technique to monitor child mortality for at least a decade.[2] Generating data from VA procedures follows a simple, stepwise process. First, deaths are registered using some form of active, community-based reporting system. Second, VA interviews are obtained by trained interviewers who visit the households of the deceased within a specified period after the death. Third, physician certifiers use these completed VA interview forms to assign a specific cause of death, and write death certificates according to protocols based on the *International Statistical Classification of Diseases and Related Health Problems,* 10th revision (ICD-10) report. Lastly, mortality data are tabulated on a periodic basis and fed into routine reporting, planning, and monitoring processes and are used to analyze mortality structures, levels, and trends.[2] In India, there is inadequate information on perinatal and neonatal cause-specific mortality in the rural areas. Physician review, based on a combination of clinical or laboratory data, have constituted the gold standard for most validation studies. Most VA instruments currently in use are excessively long with elaborate coding schemes and hence misclassification frequently occurs. In the present paper, an attempt is made to validate the simplified VA Questionnaire for Perinatal Deaths with the help of ANM's.

MATERIAL AND METHODS

Sample Size

The Sample Size of 50 was calculated with 80% power and 5% significance using sensitivity of 70%. The Study was carried out in three Primary Health Center's (PHC's - Vantamuri, Handignur and Kinaye) of K.L.E University, Belgaum.

Study Population

Mothers' residing in communities covered by the 3 PHC's who have a stillbirth or death of a baby within 7 days after birth were included for the study
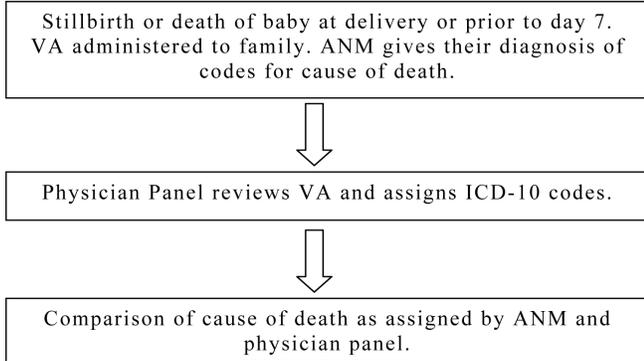
Data Collection Tools

The Auxiliary Nurse Mid-wives (ANMs) of all 3 PHC's who agreed to participate underwent the training in Verbal Autopsy interviewing techniques and assignment of Cause of Death (COD). Three Medical Officers other than 3 PHC's trained in ICD-10 classification formed a physician panel. The simplified VA Questionnaire used included both narrative histories and structured questions.

Study Procedures

a) **Training:** The ANMs who consented underwent the training in VA interviewing techniques and assignment of COD in 2 rounds. The Investigator and a pre identified Physician Panel composed of the three independent physicians (Medical Officers of Hudli, Yamkanmardi and Kadoli PHC's) underwent a training in ICD 10 coding and VA assessment.

b) **Recruitment and Screening Procedures:** The trained investigator was responsible for obtaining consent from ANM's and training them to screen, administer VA and assign cause of death for all perinatal deaths. The ANM's administered the simplified VA instrument to the families up to six months after the death of the neonate. The investigator was also responsible for screening potential families to assess whether they meet the study inclusion criteria.

c) **Verbal Autopsy Administration:** The simplified VA Questionnaire was administered by ANMs to the mother's uptill six months after the death of the neonate. After completing the simplified VA questionnaire, the ANM's assigned COD on a perinatal COD form. Next, the assigned simplified VA Questionnaire was reviewed by physician panel where all the three physicians combinedly assigned one COD on a perinatal COD form. Physicians had access to

the perinatal data collected by birth attendants, available medical records of the neonate and VA information completed by the ANM. The ANM's and Physician panel assigned ICD 10 codes to the 3-character level where possible.

d) Follow up Evaluations and Procedures:

Stillbirth or death of baby at delivery or prior to day 7. VA administered to family. ANM gives their diagnosis of codes for cause of death.

Physician Panel reviews VA and assigns ICD-10 codes.

Comparison of cause of death as assigned by ANM and physician panel.

Data Collection
The data was collected from Jan 2008 to Feb 2009 by using simplified validated shortened VA Questionnaire and training the ANM's to assign the COD as per ICD-10 rules and then comparison of the COD was made between the ANM and Physician assigned COD.

Quality Assurance
Interviewer re-training and supportive supervision formed the mainstay of quality assurance for VA processes.

Data Analysis
Using the kappa statistics, a comparison of the ICD-10 coded COD by the panel of physicians and ANM's was made.

Ethical Aspects
Approval was obtained from the K.L.E University's Ethical Committee, Belgaum. Formal informed written consent in local language was sought from all the ANM's, Physician panel and women who were participating in the study. Confidentiality was maintained by labeling all case forms with ID only and no personal identifiers.

RESULTS

Data on 50 perinatal deaths (14 stillbirths and 36 early neonatal deaths) investigated by the verbal autopsy method is tested for validation of the instrument and is discussed in the present paper. The COD assigned by ANM and COD assigned by Physician panel for 50 perinatal deaths were cross tabulated and by using frequency distribution,

the analysis was carried out to check the percentage of agreement between the ANM and Physician panel assigned COD.

Stillbirths
Among a total of 14 stillbirths, the COD P02 was equally assigned by the ANM's and the Physician panel for 8 (16%) of the stillbirths, P07 was equally assigned for 2 (4%) stillbirths, P15, P20 and P21 were equally assigned for each of 3 (6%) stillbirths. Thus, making an agreement of 93% between the ANM assigned and Physician assigned COD for stillbirths at Kappa Statistics (0.9), p [0.00 (<0.001)]. This indicated significant agreement between the COD assigned by ANM and the COD assigned by the Physician panel for the stillbirths. There was disagreement for only one (2%) stillbirth, where in the COD assigned by ANM was P61 and COD assigned by physician panel, was P15 showing overall disagreement of 7% for stillbirths.

Early Neonatal Deaths
Among a total of 36 Early Neonatal Deaths, the COD P02 was assigned similar by both ANM's and Physician panel for 2 (4%) early neonatal deaths, P07 was assigned equally for 9 (18%) of the deaths, P21 was assigned same for 4 (8%) deaths, P22 was assigned equally for 5 (10%) deaths, P23, P29, P59 were assigned separately and equally for each of 3 (6%) early neonatal deaths respectively. P80 was assigned equally for 2 (4%) deaths, P90 and P91 were assigned separately and equally for each of 2 (4%) early neonatal deaths by the ANM and the Physician panel. Thus, making an agreement of 75% between the ANM assigned and Physician assigned COD for early neonatal deaths at Kappa Statistics (0.807), [p=0.000 (<0.001)]. This indicated significant agreement between the COD assigned by ANM and the COD assigned by the Physician panel for the early neonatal deaths. **The disagreement was observed as the COD P07 was** assigned for 2 (4%) of the early neonatal deaths by the ANM, where as both

Table 1: Agreement between ANM and Physician panel assigned Cause of Death (COD) for Stillbirths. (--- Agreement)

COD BY PHYSICIAN PANEL	COD BY ANM						
	P02	P07	P15	P20	P21	P61	TOTAL
P02	8√						8
P07		2√					2
P15			1√			1	2
P20				1√			1
P21					1√		1
TOTAL	8	2	1	1	1	1	14

Early Neonatal Deaths.

of the deaths were assigned as P02 by the physician panel, P21 was assigned for 1 (2%) deaths by ANM compared to P02 by the physician panel, P21 was also assigned for another 2 (4%) deaths by the ANM compared to P07 by the physician panel, P22, P23, P39 each were assigned separately for 3 (6%) of the deaths by ANM compared to P24 for each of the 3 deaths by the physician panel, P76 was assigned for another (2%) death by the ANM compared to P78 by the physician panel. This indicated the over all disagreement of 25% between the COD assigned by the ANM and the physician panel.

Perinatal Deaths

Among a total of 50 perinatal deaths, the COD assigned by ANM and the COD assigned by the Physician panel were same for 40 of the perinatal deaths, which showed the agreement of 80% at Kappa Statistics (0.838), [p=0.000 (<0.001)]. This indicated a significant agreement between the COD assigned by ANM and the COD assigned by the Physician panel for the perinatal deaths. The disagreement between the ANM and Physician panel assigned COD was seen as 3 (6%) perinatal deaths assigned P02 by the Physician panel were assigned as P07, P07 and P21 respectively by the ANM, 2 (4%) perinatal deaths assigned P07 by Physician panel were assigned as P21 for each of 2 deaths by the ANM, 1 (2%) perinatal death assigned P15 by Physician panel was assigned as P61 by ANM, 3 (6%) perinatal deaths assigned P24 by Physician panel were assigned as P22, P23, and P31 respectively by ANM, 1 (2%) perinatal death assigned P78 by Physician panel was assigned as P76 by ANM. This indicated the over all disagreement of 20% between the COD assigned by the ANM and the physician panel.

DISCUSSION

Verbal autopsy is a process or method which consists of retrospective interviews with the next of kin. It is an alternative to autopsies, when cadavers are not available for examination, or when laboratory services for confirmation of cause of death are not accessible or feasible. Experience has shown that verbal autopsies work well for causes of death that have distinctive and noticeable features, not commonly found in other causes of death.[7]

In the present study, data was collected for 50 perinatal deaths. According to several other studies the sample size of 50 perinatal deaths is considered as adequate for validation studies. The study conducted by Kulkarni R.

et al in Maharashtra considered the sample size of 83 perinatal deaths to investigate the cause of death using verbal autopsy.[3]

The study showed that trained ANM's could identify the causes of perinatal deaths by verbal autopsy method (agreement of 80% between ANM and Physician panel assigned cause of death). If the ANM's are adequately trained in their local language, verbal autopsy method is feasible and also helpful to study the causes of death, especially the deaths occurring at home. Several studies suggest that well-trained people can obtain accurate information when the culturally and linguistically appropriate questionnaires are used.[8, 9]

In the present study, the structured closed ended questionnaire is used with inclusion of filter questions. The questionnaire was modified into short VA tool which took nearly half an hour of the respondent's time. The shortened VA questionnaire when used appropriately could yield the cause of death derivation accurately. A WHO consultation report mentions that in the close-ended section filter questions must be included, which are general questions that are followed by more detailed and specific questions if positively answered.[10]

The present study was conducted in a rural community setting. The Verbal Autopsy methods can be effectively used in the rural setting for the perinatal deaths occurring at home and also in recognition of cause of death and also for improving the Vital Registration System Data. Most of the studies show that the previously conducted Verbal Autopsy studies are hospital based. However, in the recent years the same standard procedures for verbal autopsy are being introduced in the rural areas, and diagnoses from these standard procedures are compared with the diagnoses from the routine registration system to measure the reliability of cause of death.[11]

The consented interviewers (ANM) underwent the training in the verbal autopsy methods and identifying the cause of death. The ANM's were well trained for the interviewing techniques so it was not difficult for them to screen and interview the mothers/ close family members where the perinatal deaths had occurred. Only difference observed was the younger ANM's were very well adapted to the interviewing techniques when compared to the older ANM's and they also helped the older ANM's in interviewing where ever it was not feasible. This is the first study having considered the ANM's as the interviewers for validation study in a community based setting, unlike

other studies in different developed and developing countries where experience with verbal autopsy indicates that interviewers require a relatively high level of education. University medical students have often proved inexpensive and capable. Other health care workers might also be a good source of interviewers. Medical doctors are rarely used for verbal autopsy (although they were used in the 2000 Gulu EHF epidemic), since they are a scarce and valuable resource in developing countries, and other educated personnel are capable of being trained to do the interviews.[4] A simulated ANN (Artificial Neural Networks) was trained for classifying cause of death on a subset of verbal autopsy data.[12]

In the study, mothers were the respondents for most of the perinatal deaths. Mothers are the best respondents in case of illness or the deaths as they explain each and every event or the activities occurring during the period of the death by which the ANM can arrive at a cause of death. In the study of verbal autopsy for Ebola Virus Haemorrhagic Fever, the respondent was adult caregiver who is likely to know about contacts with infected people to which the deceased might have been exposed before becoming ill and other contacts of the deceased during illness. In deceased child, the mother was the respondent.? (Roels *et al.*, 1999) used a hierarchical approach to selection in order of preference: Individuals residing in the same household (i.e. sharing the same cooking fire) and who knew the deceased well (e.g. the deceased patient's spouse or oldest child), Individuals from a different household who knew the deceased well (e.g. the deceased patient's parents or grandparents), Individuals residing on the same parcel of land as the deceased (e.g. the deceased patient's landlord or closest neighbour).[7]

The recall period was fixed at 6 months in the present study. The recall period will not affect the validity of the tool, as death is such an event that neither the mother nor the family members will forget even after a gap of many months. According to Participants in the London School of Hygiene and Tropical Medicine (LSHTM) workshop, the recall of circumstances of death would be adequate up to 12 months after the event.[13] Garene and Fountain found in rural Senegal, the adequate period of history recall to be 3–9 months after the death has occurred.[14] The study conducted by Kulkarni R. *et al.* in Maharashtra showed that the recall period was fixed at 6 months.[3]

Very few deaths that occur at home were under reported or were reported by the secondary personnel. The reason for under reporting according to this study is the migration.

The study conducted in Syria, showed that a large proportion of deaths occur at home and these deaths may go unreported or they may be diagnosed and reported by lay people. Routine statistics on child mortality should be looked at as an underestimation of the real figures, and they should be validated.[15]

In the present study, out of 50 perinatal deaths, the cause of death assigned by ANM and the cause of death assigned by the Physician panel were similar for 40 of the perinatal deaths, which showed the agreement of 80% [Kappa Statistics=0.838; P=0.000 (<0.001)] which shows statistically significant agreement. The study conducted by Proctor MH *et al.* showed the feasibility of using health workers trained in verbal autopsy methodology to operate in remote rural areas of Africa where in the records of 40 deaths in Cameroon were reviewed by the attending physician, compared with that obtained by health worker who administered a verbal autopsy to the family. In 70% of the cases the physician and HW were in exact agreement.[16] In another study, verbal autopsies and medical records (MR) were collected for 3123 deaths in the perinatal/neonatal period, post-neonatal <5 age groups in Tanzania. Causes of death were assigned by physician panels using the International Classification of Disease, revision 10. Validity was measured by Cause-Specific Mortality Fractions (CSMF). Criteria for evaluating VA performance in generating true proportional mortality were applied. Verbal autopsy produced accurate CSMFs for nine causes in different age groups.[17] The instrument using both open-ended and closed questions identified and resulted in a best agreement (kappa index) of 0.64 for all causes of deaths in India.[14] A study conducted in Bavi District, Vietnam, in 1999, showed that the diagnosis was made by two physicians separately, with good agreement (k~0.84) and then were combined to reach one single underlying cause of death for each case.[9] A study in a rural setting of South Africa, showed that trained fieldworkers elicited signs and symptoms of the terminal illness from a close caregiver, using a comprehensive questionnaire written in the local language. Questionnaires were assessed blind by three clinicians who assigned a probable cause of death using a stepwise consensus process. Validation involved comparison of VA diagnoses with hospital reference diagnoses obtained for those who died in a district hospital; and calculation of sensitivity, specificity and positive predictive value (PPV) for children under 5 years. A total of 127 hospital diagnoses satisfied the criteria for inclusion as reference diagnoses. For communicable diseases, sensitivity of VA diagnoses among children was 69%, specificity 96%, and PPV 90%; Lower values were

found for non-communicable diseases: 75, 91 and 86% among children.[18]

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