Ascertaining Cause of Death in Dhulikhel, Nepal: Medical records and Verbal Autopsy

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Abstract

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Background: Nepal is experiencing a rapid increase in the burden of non-communicable diseases (NCDs). However, cause of death (COD) data in Nepal is scarce and often unreliable. Health policymakers and planners do not have proper data to inform their funding and programmatic decisions.

Objective: We sought to identify the COD distribution and to assess the quality of medical record documentation at Dhulikhel Hospital-Kathmandu University Hospital (DH), a tertiary medical center in suburban Nepal. Additionally, we sought to validate whether the SmartVA application for verbal autopsy could be an effective method for collecting mortality data in Nepal.

Methodology: We conducted key informant interviews with staff at DH to develop an understanding of the hospital's death certification process. Next, we implemented a record review of in-hospital mortality cases. Finally, we used gold standard mortality cases for a pilot study to validate the SmartVA application, which computer certifies verbal autopsies.

Results: We identified 135 in-hospital deaths at DH in 2014. We reviewed the medical records and death certificate of 107 cases (26.7% files were missing), including 8 files from 2013. Of the 107 cases reviewed, 44 (41%) were assigned Level 1 and 36 (34%) as Level 2, indicating sufficient evidence for an accurate diagnosis. Of the 66 adult gold standard cases (Level 1 or 2), 15.2% stemmed from infectious causes; 78.8% were caused by cancer, cirrhosis, CVD, COPD, or injury. Top causes of pediatric deaths were preterm delivery (42.9%), pneumonia (14.3%), and birth asphyxia (14.3%). Verbal autopsies were conducted with 48 gold standard cases. We found overall agreement (Kappa) of .46 for adult VAs. A Kappa based on broader ICD-10 categories was .65. Disease specific measures of accuracy varied widely, with sensitivities ranging from 0% (e.g. lung

cancer) to 100% (e.g. falls). Cause-Specific Mortality Fraction Accuracy was calculated to be .58.

Discussion: NCDs pose a major threat to suburban Nepalese populations. Ongoing, countrywide mortality data collection will be crucial for evidence-based priority setting. In the hospital, records keeping and documentation was not seen as a major priority. Many files were missing or contained insufficient information for classifying COD. Though not perfect for all causes, we found the SmartVA application to be useful for providing general COD data, specifically in settings where death certification is unavailable.

Recommendations: DH has good potential to become an important source of mortality data for Nepal. Because many deaths occur at home in Nepal, verbal autopsy should be implemented in the Dhulikhel Heart Study and scaled up throughout the country as a supplemental method of tracking mortality where death certification is currently unavailable.

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List of Tables, Figures, and Boxes

Acronyms

DH	Dhulikhel Hospital-Kathmandu University Hospital
COPD	Chronic Obstructive Pulmonary Disease
CSMF	Cause Specific Mortality Fraction
COD	Cause of Death
CVD	Cardiovascular Disease
DHS	Dhulikhel Heart Study
ICD	International Classification of Diseases
ICU	Intensive Care Unit
IHD	Ischemic Heart Disease
IHME	Institute for Health Metrics and Evaluation
IRB	Institutional Review Board
NCD	Non-communicable disease
NICU	Neonatal Intensive Care Unit
ODK	Open Data Kit
PHMRC	Population Health Metrics Research Consortium
VA	Verbal Autopsy
WHO	World Health Organization

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I. Introduction

a. Background and Literature Review

Nepal is experiencing a health transition familiar to many developing countries in recent years, that is, an increase in the rate of chronic, non-communicable diseases (NCDs) (1–10). According to data from the Institute for Health Metrics and Evaluation (IHME), only one out of the top five contributors to the burden of disease in 1990 was a non-communicable condition (COPD). As of 2010, three of the top five were non-communicable (ischemic heart disease, COPD, and stroke) (9). The percentage of deaths related to NCDs (excluding injuries) in Nepal varies, with estimates ranging from 49.2% (9) to 60%, up from 30.3% in 1990 (9). One hospital-based study in Nepal showed that 36.5% of admitted patients suffered from NCDs (5), and the Annual Report by the Nepal Ministry of Health and Population found that 82% of outpatient cases in 2010/2011 were non-communicable (4).

Much of the rising burden of NCDs is due to the effects that globalization and urbanization are having on the health behaviors of many people in Nepal (1). In terms of risk factors for NCDs, eight of the top ten risk factors for mortality in Nepal are primarily associated with NCDs, including dietary risks, household air pollution, high blood pressure, smoking, high fasting plasma glucose, alcohol use, and physical activity (9). The smoking rate among females in Nepal is the highest in South Asia. As of 2011, 37% of males and 25% of females smoke tobacco (11) in Nepal.

Although initial epidemiological studies have given us estimates of the changing mortality burden, data from Nepal are scarce and often unreliable, especially in rural areas with few health services (1,5,12–15). Nepal has an established vital registration system; however, it fails to capture most deaths and cannot be used to provide accurate cause of death (COD) estimates (15–17). In recent World Health Organization reports, Nepal has made available the number of deaths each year, but offered no information on the causes (18). The limited cause of death data available typically comes from hospital death records, the weak vital registration system, or small cross-sectional studies, none of which provide a comprehensive or accurate epidemiological picture (5,19,20). Additionally, the data is often an extrapolation of COD distribution patterns from other countries, such as India and the Philippines (12). Even hospital data on cause of death is not always reported accurately – in fact, substantial misdiagnoses are common (21).

Without a well-functioning vital registration system or other population-wide epidemiological studies on mortality, decision-makers lack accurate and up-to-date data to inform health policy and

programming. Unfortunately, it is a common problem that countries facing the most severe health burdens often have the least vital registration data available (22). Currently, Nepal does not have the capacity to implement large-scale comprehensive surveillance systems throughout the country. Therefore, feasible and realistic alternatives are required for gathering mortality data in Nepal. One such alternative that has proven successful gather accurate cause-specific mortality statistics is the Verbal Autopsy (VA) method (23–25). Verbal autopsy helps determine probable cause of death in cases where there are no medical records or documented death certification. It is performed by interviewing a close caregiver of the deceased regarding the signs and symptoms that preceded the decedent's death. Verbal autopsy has had limited use in Nepal, but mostly to generate mortality data on a single cause, such as neonatal mortality (26–30), birth asphyxia (31), under-five mortality (32), and maternal mortality (33,34), and only one of these was a country-wide survey.

Although verbal autopsy is often used to generate mortality data in settings where deaths occur outside of a health facility, it has significant limitations (35). First, VA is not suited for recognizing all causes of death. Causes of death with less specific or overlapping symptoms are difficult to identify through a verbal interview. Secondly, it does not allow for more than one cause of death, so in cases where there are overlapping underlying causes, some causes will be missed. Additionally, verbal autopsy, if poorly conducted, can lead to misleading results. Because of the limitations of verbal autopsy, it is not a perfect method for gathering population-wide mortality data, but it can be useful where vital registration is limited or in countries with ill-defined cause of death data (36).

The Institute for Health Metrics and Evaluation has recently developed SmartVA, an application that implements computer certification of verbal autopsies using the Tariff Method (37,38). Through verbal autopsy interviews collected on the Open Data Kit collection system, the tool electronically processes data and produces a cause of death estimate at both individual and population levels for 34 adult causes, 21 child causes, and 6 neonatal causes [Appendix A]. This SmartVA application was just made freely available to the public in late 2013. Conducting verbal autopsy electronically removes the need for physician certification, thus saving significant time and resources. The SmartVA application has been shown to be equally or more effective at accurately identifying cause of death compared to paper-based physician-certified methods and other computer-certified methods (38,39)

Dhulikhel Hospital-Kathmandu University Hospital (DH) in Dhulikhel, Nepal is a private, tertiary, not for profit institution that is currently seeking to expand community-based data to measure the

impact and trends of cardiovascular disease (CVD). The hospital is conducting The Dhulikhel Heart Study (DHS) (40), a longitudinal cohort study designed to provide comprehensive data to evaluate CVD prevalence, incidence, risk factors, and related mortality. The study is considering using the SmartVA application for ascertaining cause of death among its participants who die outside of the health system. For identifying COD among hospital-based deaths, it is currently unknown if the DH hospital data on cause of death is reliable. Identifying the reliability of death certification at DH, defining weaknesses in the process of death certification, and assessing the SmartVA system for validity and practicality will allow Dhulikhel to improve their contributions to mortality data in Nepal.

b. Aims and Objectives

To address the great need for better mortality data in Nepal, we designed a study to conduct a pilot validation of the SmartVA application using medical records and data from Dhulikhel Hospital-Kathmandu University Hospital. Aims and objectives of the study are described below.

Aim 1: To evaluate the reliability of current mortality reporting and death certification at DH. Objectives are described below.

1) To identify challenges and areas of potential improvement to the process of death certification at DH.
2) To assess how many of the medical records at the hospital were comprehensive and included enough evidence in order to obtain a definitive diagnosis.
3) To determine the cause of death distribution at DH by identifying the main causes of death among gold standard mortality cases from 2014.

Aim 2: To validate whether the SmartVA application for verbal autopsy could be an effective method for collecting mortality data in Nepal. Objectives are described below.

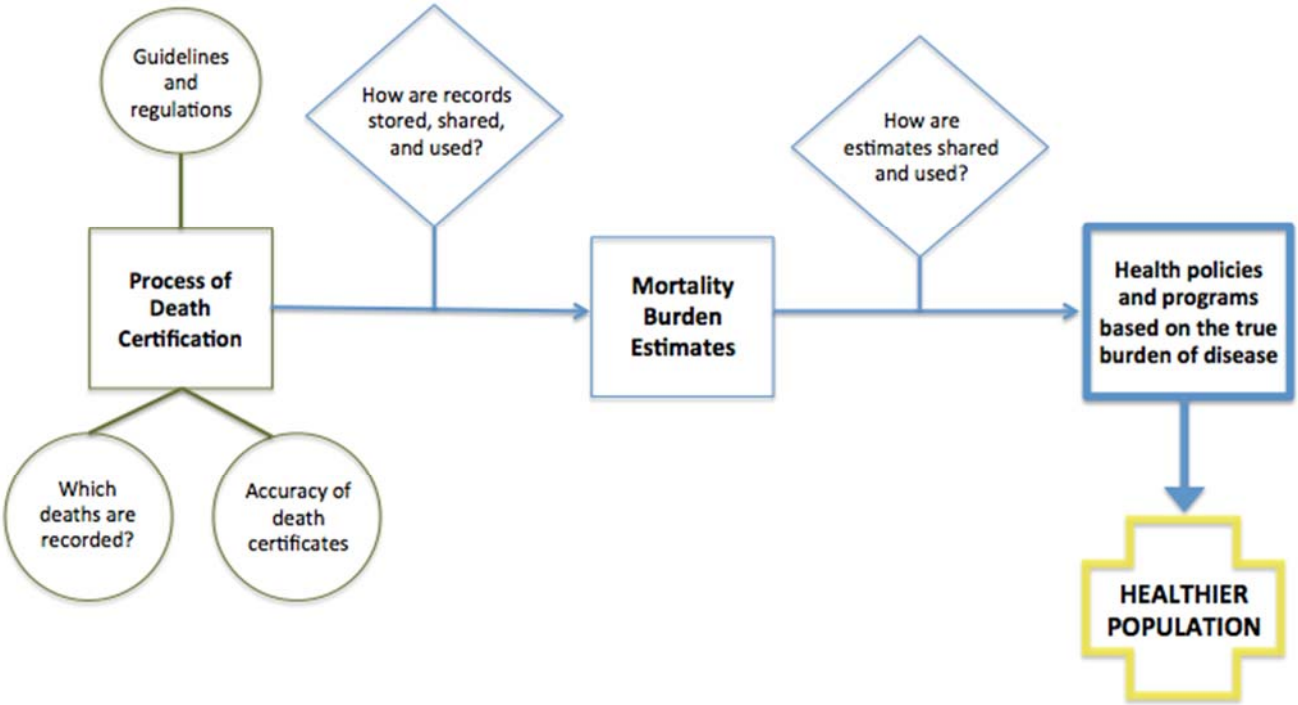
1) In order to evaluate the VA tool's precision, we aimed to determine how frequently the cause of death obtained from gold standard medical records matched the cause of death determined using the SmartVA tool.
2) To understand the operational characteristics of the tool, we aimed to look at any barriers, challenges, and/or benefits experienced by the interviewer during the administration of the verbal autopsy.

c. Conceptual model

One outcome of having accurate estimates of the mortality burden is the ability to design effective health policies and programs that address the relevant health problems in a society. More effective health programming should eventually lead to better patient outcomes and a healthier population. A variety of causes may lead to the misrepresentation of a country's mortality burden. Firstly, these errors may stem from insufficient political regulations regarding vital registration leading municipalities to give a low priority to recording deaths. Secondly, unequal distribution of vital registration is a major potential source of misrepresentation. For example, if rural areas with limited health services are not reporting deaths as frequently as urban areas, the cause of death distribution will not be truly representative. Another major source of misrepresentation stems from ill-defined cause of death estimates. If physicians are not accurately assigning causes of death, reported estimates will consequently be incorrect. After municipalities collect mortality records, improper storage, sharing, or use may occur, resulting in underreporting or inaccurate reporting of mortality.

This conceptual model, displayed in Figure 1, laid the foundation for our study. It presents the components of the process of death certification and the impacts they have on eventual health policies and programs. With the goal of improving mortality burden estimates in Nepal, we decided to focus on the process of death certification and pinpoint areas of possible improvement.

Figure 1: Conceptual Model of Death Certification Impacts on Health Policies and Programs



II. Methods

There were four phases to our study. In the first phase, we conducted a qualitative investigation of the process of death certification at Dhulikhel Hospital. The second phase determined the quality of cause of death ascertainment in medical records at the hospital and to establish the cause of death distribution from 2014. The next phase was to conduct a validation study of the SmartVA tool. Because physical autopsies are unavailable in Nepal due to cultural and practical reasons, we selected our gold standard cases through a medical record review. After conducting the verbal autopsy interviews, we analyzed the interview data to see how frequently the cause of death obtained from gold standard medical records matched the cause of death determined using the SmartVA tool. In the final stage, we assessed the usability of the tool, noting implementation challenges experienced during interviews.

a. Study setting and sample

This study was conducted under the supervision and coordination of the Dhulikhel Heart Study, which is a longitudinal cohort study focusing on cardiovascular disease and its risk factors in a sub-urban community of Nepal. The DHS is based out of Dhulikhel Hospital-Kathmandu University Hospital (Dhulikhel, Nepal), a private, tertiary, not for profit institution that serves a catchment area of 1.9 million people. The target population for our study included residents of Dhulikhel and the surrounding catchment region. All participants were 18 years of age or older. Three separate groups of participants were recruited:

1. Key Informants

   Key informants were staff of Dhulikhel Hospital and had a working knowledge of the hospital's process of death certification. The administrative director of the hospital was interviewed first, and further participants were selected from each department in the hospital that had mortality cases in 2014. Participants were selected based on their involvement with critical patients, certifying causes of death, and/or writing death certificates at the hospital. This group was comprised mostly of Nurses-in-Charge, Medical Officers, and Consultants.

2. Verbal autopsy pilot test group

   Participants in the verbal autopsy pilot group were eligible if they had a family member who passed away in the previous two years, and if they were a caregiver of this person during his or her final illness before dying. This group was recruited through informal methods. We used known contacts of the study research staff, such as hospital staff, friends, neighbors, and

relatives, etc.

3. Verbal autopsy validation group

   Participants in the verbal autopsy validation group were eligible if they had a family member who passed away in the previous year (Jan 2014-Dec 2014), and if they considered themselves a primary caregiver of this person during his or her final illness before dying. If the family member died suddenly or of causes unrelated to illness, the participant should at least have been a member of the same household as the deceased. Participants were identified through hospital registration records of the patients who died. Typically, a family member or other emergency contact was listed in the patient's file.

Additionally, the interviewers of the verbal autopsy questionnaires were recruited as participants to give us feedback on the challenges and barriers to conducting verbal autopsy in Dhulikhel.

The following exclusion criteria were applied to all verbal autopsy participant groups: individuals in institutionalized settings, temporary residents, and mentally challenged individuals. Participants were also excluded if their deceased relative passed away less than two months from the time of interview, out of respect for the mourning period. Key informant participants were excluded if they had worked in Dhulikhel Hospital for less than one year.

b. Data Collection

Our primary study variable consisted of the underlying cause of death of mortality cases at Dhulikhel Hospital in 2014. Cause of death was determined both through medical records and through the SmartVA verbal autopsy analysis software. A variety of other variables were also considered, which are detailed in Box 1.

Mortality data from the hospital records were collected and stored in Microsoft Excel 2011. Qualitative data was recorded and analyzed in Microsoft Word 2011. Verbal autopsy data was collected using tablets running on an Android system and later uploaded and stored in a database using Microsoft Excel 2011.

Box 1: Study variables

Mortality Variables
• Number of deaths at Dhulikhel Hospital (DH) in 2014
• Number of medical records available of 2014 mortality cases
• Number of gold standard mortality cases from 2014*
• Underlying cause of death according to gold standard medical records
• Underlying cause of death according to SmartVA
• Cause specific mortality fractions (CSMF) at DH according to gold standard medical records
• Cause specific mortality fractions (CSMF) at DH according to SmartVA
Demographic variables
• Age (under 14, 15-24, 25-44, 45-64, 65+)
• Sex (male, female)
• Education Level (No education, primary, secondary, post secondary)
Qualitative variables
• Process of death certification at DH
• Documentation and storage of medical files
• Challenges to using verbal autopsy in Dhulikhel

*Gold standard levels were assigned using criteria developed by the Population Health Metrics Research Consortium (PHMRC) in the Gold Standard Verbal Autopsy Validation Study (38).

The four phases of data collection are detailed below.

Phase 1 - Key Informant Interviews

Eleven key informants were recruited for interviews using a qualitative, semi-structured interview guide [Appendix B]. Interviews were conducted in English and voice recorded. The key informant interviews were intended to pinpoint the main challenges in the process of death certification at Dhulikhel Hospital and were also designed to help determine if and/or where verbal autopsy might fit into the current system.

Phase 2 – Determining the Quality of COD Ascertainment

We began by obtaining all mortality files and death certificates of patients who died at DH during 2014. With the assistance of DH forensics physicians, each patient's medical record and death certificate were comprehensively reviewed to estimate the underlying cause of death as accurately as possible. The physicians were trained to use a protocol for diagnosing each cause of death with a set list of definitions for each disease (38). We assigned each case a gold standard level that designated the strength of evidence for each diagnosis. Cause of death information was detailed using the Population Health Metrics Research Consortium's (PHMRC) medical data extraction form (38).

Phase 3 – Validation of SmartVA Against Gold Standard Medical Records

The validation phase began with training two interviewers/research assistants. We translated the verbal autopsy questionnaire (PHMRC Short Instrument) into Nepali with a back-translation to English. The questionnaire was made compatible with the SmartVA tool, which runs electronically on the Open Data Kit (ODK) Collect system on an Android platform. Before the verbal autopsy portion of the interview, a short demographic questionnaire was included regarding the deceased and his/her household.

Prior to beginning of the validation, a series of pilot tests were done with two small groups of participants to perform a face and content validity check and a reliability test. For face validity, we tested the instrument with a medically untrained, local resident to ensure that it was logical and understandable to the average Nepali citizen. We then judged for content validity by having a trained physician evaluate each question to determine whether the questionnaire appeared to be medically valid and understandable. The final phase before the validation interviews began was a reliability test. For this, we conducted the questionnaire with a group of 17 participants. After one week, a different interviewer re-conducted the interviews with the same group of 17 participants. This process gave the interviewers a chance to practice the interview, helped to ensure that our questionnaire was reliable and consistent, and it pointed out areas of improvement before formal validation interviews began.

After pilot testing was complete and necessary changes were made to the questionnaire, recruitment for the validation interviews began. We contacted the caregiver/relative who was linked to the medical records of all gold standard mortality cases (Levels 1 and 2) identified in Phase 2. Interviewers conducted the verbal autopsy questionnaires with all the consenting caregivers/ relatives of the gold standard cases that could be located. We ensured that interviews were only conducted with caregivers/relatives of patients who had died between 2-12 months prior to the time of recruitment.

Phase 4 – Identifying Implementation Challenges of the SmartVA

Following each reliability and validation verbal autopsy interview, the interviewer completed a brief form describing any reactions to or challenges presented by the interview [Appendix C]. This allowed the interviewer to debrief their experience during interviews and express any challenges or concerns that they may have faced. This information will be used to guide the practical implementation of the SmartVA in Nepal and helped us determine the cultural suitability of implementing the instrument in Nepal.

c. *Data Analysis*

Qualitative

All qualitative analysis was performed by the principal investigator only.

For key informant interviews, the following themes were explored: writing the death certificate, assigning cause of death, storing mortality records, physician training on certifying cause of death and writing death certificates, use of ICD codes to classify deaths, and use of verbal autopsy in the hospital and/or community. The interviews were not fully transcribed; however, detailed notes were made during the interview and while reviewing the voice recordings. Open coding was performed using Microsoft Word highlighting the themes listed above. Data was analyzed using both thematic and narrative methods, and themes were sought within and across cases. Findings from this analysis were shared with various interview participants and hospital staff in order to validate the soundness of the results.

Qualitative data from post-interview forms sought to explore: 1) the various challenges experienced during interview, 2) language and comprehension difficulties, 3) alertness and attentiveness of participant, and 4) physical or mental discomfort of the participant. The interviews were transcribed and analyzed using Microsoft Word 2011. Open coding was performed on the responses, and thematic analysis was employed to examine the various themes within the data.

Quantitative

For quality purposes, the study coordinator reviewed the results of each VA interview to ensure consistency, completeness, and correctness. Any questionable content noted was discussed with the interviewer and corrected accordingly. Analysis of VA results was conducted separately for adult and pediatric cases.

Descriptive analysis was conducted on the demographic information collected regarding the VA participants' households. Statistics on the age, sex, and education level of the deceased individuals were enumerated.

The output data from the SmartVA tool was analyzed using measures of sensitivity, specificity, and positive/negative predictive value. These measures were performed using STATA software and were used to evaluate the accuracy of the tool at an individual cause level. These outcomes varied significantly between different causes of death. For accuracy at the population level, Cohen's Kappa was used to provide an overall picture of level of agreement between the SmartVA cause of death estimate and the gold standard cause of death from medical record review. Additionally a Cause Specific Mortality Fraction (CSMF) (41) was calculated to address population-level patterns.

Ethical considerations

Informed consent was received from each participant before beginning data collection. Interviewers were properly trained to be sensitive to the participant's emotional state during the interviews and taught how to handle any adverse events that might occur due to participant distress. Interviewers were also offered regular support, as they too were affected by the sensitive content of the interviews.

Prior to this validation study, the Dhulikhel Heart Study had already received ethical approval to conduct verbal autopsy in Dhulikhel. We submitted a modification to the DHS IRC application through the Kathmandu University School of Medical Sciences Institutional Review Committee to cover all additional procedures we included beyond the initial approval. IRB approval from the University of Washington Human Subjects Division was also received prior to the commencement of the study.

III. Results

a. Key Informant Interview Results

Key informant interviews were conducted with a variety of hospital staff, including in-charge nurses, medical officers, and consultant doctors. Through these interviews, we were able to gain perspective on the process of death certification, especially highlighting themes surrounding cause of death assignment, filling out the death certificate, physician training on death certification, and storage of mortality records. Key information regarding these themes is described below.

Cause of death assignment:

Autopsies are not performed at the hospital, thus the only criteria for establishing cause of death is the physician's knowledge of the patient's illness and any medical history available to the physician. Participants explained that often doctors do not have access to hospital records from previous admissions. In many cases, patients present late to the hospital, not allowing the physicians proper time to conduct a thorough investigation of the illness. In such cases, only the immediate illness is addressed, while co-morbidities often go uninvestigated. However, one participant expressed that deeper, more thorough investigations are often possible, but some doctors only diagnose based on limited evidence and assumptions.

The death certificate:

The medical officer is typically the person responsible for writing the death certificate, though the final cause of death is confirmed with the consultant on duty especially when cases are complicated or the cause of death was in question. One concern noted during interviews was that the death certificate is not designed according to the international standard format, and it does not allow space

to list all contributing and immediate causes in a proper format. It was noted that many medical officers fill out the section for "immediate cause of death" with modes of dying that are improper as an immediate cause, such as "cardiac arrest", "respiratory failure", or "multi-organ failure". The WHO International Classification of Diseases (ICD) coding system is not currently in use at the hospital, though hospital leadership frequently recommends its use.

Physician training on death certification:

Though instruction on ICD codes is provided in Nepal medical colleges, many of the key informants stated that they did not remember learning the classification system. Some participants even mentioned that they did not learn how to write a death certificate in their medical training. Medical officers spend their first 2-3 months at DH in training, where they learn the hospital's system of handling deaths. The forensics department plans to initiate regular trainings every six months on death certification.

b. Medical Record Review and Gold Standard Cause of Death Assignment

A total of 107 adult deaths were identified at Dhulikhel Hospital during 2014, with adult defined as at or above age 15. We were only able to locate the medical records of 77 adult mortality cases. After a thorough investigation, the medical records of 28% (N=30) of the 107 total cases were identified as missing and thus, unable to be used for the medical record review. Because of the high number of cases missing from 2014, we included an additional 8 cases from mid to late 2013, giving us a total number of 85 medical records to review. Basic demographic information of the mortality cases is listed in Table 1. Although we identified a total of 28 pediatric deaths in 2014 and located 22 of their medical records, the majority of the following analysis contains data on adult deaths only.

Figure 2: Recruitment Flowchart for Adult Study Participants

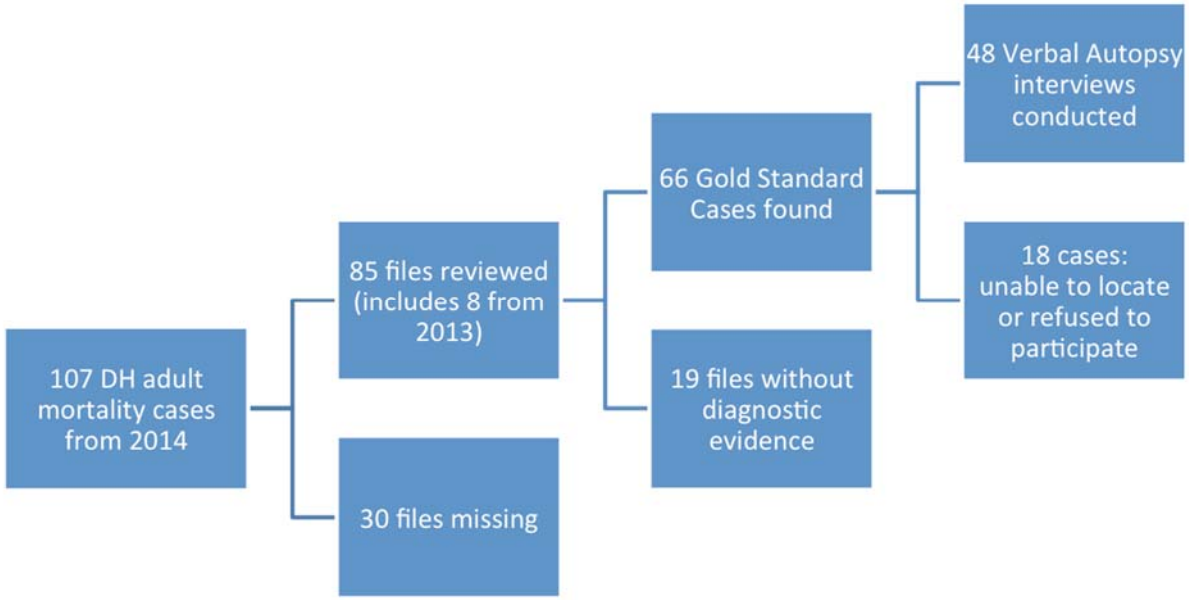


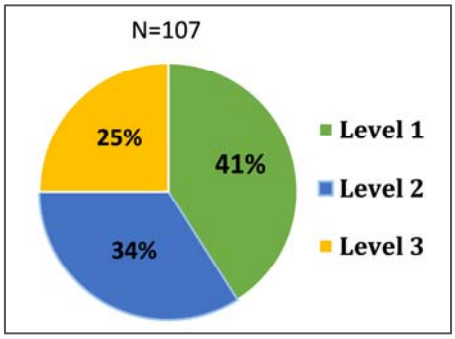
Table 1: Demographic Characteristics of Adult Deaths

Characteristic	%	Number
Sex	(for all files reviewed)	
Male	57.6%	49
Female	42.4%	36
Total		85
Age	(for all files reviewed)	
15-24	1%	1
25-44	20%	17
45-64	28%	24
65+	51%	43
Total		85
Education	(for VA deaths only)	
No education	31%	15
Primary School	46%	22
Secondary School	13%	6
Post Secondary	4%	2
Not listed	6%	3
Total		48

Using PHMRC definitions, 44 cases (adult and child) were considered gold standard, or "Level 1" (highest level of certainty), another 36 cases were considered "Level 2" (A or B) (high level of certainty), and 27 cases were "Level 3" (not enough diagnostic evidence) (displayed in Figure 3). Most of the Level 3 cases failed to meet gold standard criteria due to lack of sufficient diagnostic

procedures performed, or a lack of documentation within the file itself. For example, not including radiology reports or hard copies was noted in 52.6% of the Level 3 cases.

Figure 3: Gold Standard Level Assignments of Adult and Child Deaths



To ascertain the gold standard cause of death, our team primarily used the patients' medical records rather than the death certificates. At the time of study, Dhulikhel Hospital was using a poorly structured death certificate format that did not follow the WHO international guidelines. Medical Officers would often list all known diagnoses together, with a final immediate cause of death listed separately. The true underlying cause of death was not always clear according to the death certificate alone.

We recorded the cause of death data for the 66 Level 1 and Level 2 adult cases, with the full distribution of causes displayed in Table 2. The cause of death data showed a considerably low percentage of communicable disease, with only 15.2% of deaths stemming from infectious diseases such as pneumonia, diarrhea, or tuberculosis. Non-communicable diseases accounted for the majority of deaths (84.8%), with 78.8% of deaths caused by cancer, cirrhosis, cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD), or injury.

The most common causes of death of the 14 gold standard pediatric cases we identified included preterm delivery (with or without Respiratory Distress Syndrome) (42.9%), pneumonia (14.3%), and birth asphyxia (14.3%). Full pediatric causes of death are listed in Table 3.

a. Verbal Autopsy Testing

The 17 verbal autopsy interviews conducted to estimate reliability prior to the validation interviews showed a variety of inconsistencies between the Round 1 and Round 2 participant responses, ranging from 2-20 inconsistent responses per participant. While some inconsistencies were minor, such as the specific age or date of death, some inconsistencies were of significant consequence (Table 4).

However, as expected, the inconsistencies became less frequent as interviewers gained more experience with the interviews. We found 50% fewer inconsistencies in the second half of reliability interviews compared to the first half. The overall agreement (Kappa) between the cause of death found with Round 1 interviews compared to cause of death found with Round 2 interviews was .59. Kappa based on the broadest ICD-10 category (e.g. circulatory system, digestive system, neoplasms, etc.) increased to .82.

Table 2: Gold Standard Causes of Adult Death

	Age group				
Cause of Death	**15-24**	**25-44**	**45-64**	**65+**	**Total**
Communicable diseases					**10**
Pneumonia	0	1	2	5	**8**
Diarrhea	0	1	0	0	**1**
Tuberculosis	0	0	0	1	**1**
Noncommunicable Diseases					**56**
Circulatory Diseases					
Ischemic Heart Disease					
Acute MI	0	0	0	3	**3**
Congestive Heart Failure	0	0	0	1	**1**
Stroke	0	2	0	4	**6**
Respiratory Diseases					
COPD	0	0	2	8	**10**
Digestive Disorders					
Cirrhosis	0	8	4	1	**13**
Acute calculus cholecystitis	0	0	0	1	**1**
Appendicular perforation	1	0	0	0	**1**
Hernia - Peritonitis	0	0	1	0	**1**
Neoplasms					
Lung Cancer	0	0	0	3	**3**
Stomach Cancer	0	0	1	2	**3**
Colon/Colorectal Cancer	0	1	2	0	**3**
Gallbladder Cancer	0	0	1	0	**1**
Esophageal Cancer	0	0	1	0	**1**
Cholangiocarcinoma	0	0	1	0	**1**
Endocrine/Metabolic Diseases					
Diabetes Mellitus with Renal Failure	0	0	1	1	**2**
Alcohol withdrawal - hyponatremia	0	0	1	0	**1**
External Causes					
Suicide	0	0	1	1	**2**
Falls	0	1	0	2	**3**

Table 3: Causes of Pediatric Deaths

Cause of Death	Total
Neonatal	
Preterm (with or without Respiratory Distress)	**5**
Preterm with Birth Asphyxia	**1**
Birth Asphyxia	**2**
Congenital Malformation	**1**
Meningitis	**1**
Childhood	
Pneumonia	**2**
Cardiovascular Disease	**1**
Bowel Obstruction	**1**

Table 4: Inconsistency Examples from Reliability Testing*

Question	Round 1 Response	Round 2 Response
For how long was X ill before s/he died?	3 months	3 years
Did X use tobacco?	Yes, 5 per day	No
Did X vomit in the week preceding the death?	No	Yes, with blood and black color
Did X have a cough?	Yes, for 2 months	No

*Note that the respondent was the same person for each round, but the interviewer changed.

b. Verbal Autopsy Validation

Out of the 66 gold standard adult cases, we were able to conduct 48 verbal autopsy interviews for validation. Reasons for the 18 cases that for which we were not able to conduct a VA are given in Table 5.

Table 5: Explanations for Gold Standard Cases Not Included in Study

Reason	Number
Could not locate the contact information of relative/caregiver	12
Relative lived too far away	3
Participant refused to participate	2
Other	1

Because of overlapping signs and symptoms for many diseases, verbal autopsy is not able to calculate cause of death with complete accuracy. We found this to be especially true for diagnosing some non-communicable diseases such as COPD, cirrhosis, Ischemic Heart Disease (IHD), and stroke. Examples of the misclassifications include:

- 3/5 misclassifications of cirrhosis were mistaken as "Other Infectious Diseases"
- 3/4 misclassifications of COPD were marked asthma
- 2/2 misclassifications of IHD were mistaken as "Other Cardiovascular Diseases"

For a more complete explanation of misclassification, refer to Table 6.

Table 6: Misclassification Matrix of Adult Deaths

	VA Diagnosis													
Gold Standard Diagnosis	Pneu-monia	COPD	IHD	Stroke	Other CVD	Diabetes	Cirrhosis	Cancer	Asthma	Diarrhea	Other infectious	Falls	Suicide	Others
Pneumonia	**3**									**1**				
COPD		**4**							**3**	**1**				
IHD			**2**		**2**									
Stroke	**1**			**2**										**1**
Other CVD														
Diabetes						**2**								
Cirrhosis	**1**						**4**				**3**			**1**
Cancer	**1**				**1**		**1**	**5**		**1**				**1**
Asthma														
Diarrhea														
Other infectious														
Falls												**3**		
Suicide													**1**	
Others					**2**									**1**

The overall agreement (Kappa) between the adult causes of death found from the VA and the gold standard causes of death determined through record review was .46 when the specific disease (e.g. COPD, lung cancer, falls, stroke, etc.) was used to define cause of death. Kappa based on the broadest ICD-10 category (e.g. circulatory system, digestive system, neoplasms, etc.) was .65.

Although the guidelines are fairly arbitrary, we used the values found in Table 7 for our interpretation of Kappa (42):

Table 7: Kappa Interpretation Guide

Kappa	Strength of Agreement
.00 - .20	Slight
.21 - .40	Fair
.41 - .60	Moderate
.61 - .80	Substantial
.81 - 1.0	Almost Perfect

Using this criteria, our validation results were categorized with a "moderate" strength of agreement. If the broadest ICD-10 categories are used to define cause of death, we find a "substantial" strength of agreement.

In addition to Kappa, we also calculated sensitivity, specificity, and positive/negative predictive values to compare the VA results with the gold standard. These values varied widely, with sensitivities ranging from 0% (e.g. lung cancer) to 100% (e.g. falls). Table 8 provides a summary of these measures of accuracy for the most commonly found causes of death. Due to the small number of cases for some diseases, measures of accuracy were not individually calculated for all causes. Cause-Specific Mortality Fraction Accuracy (CSMF Accuracy) (43) was calculated to be .58, and the Chance-Corrected Concordance (CCC) was .52.

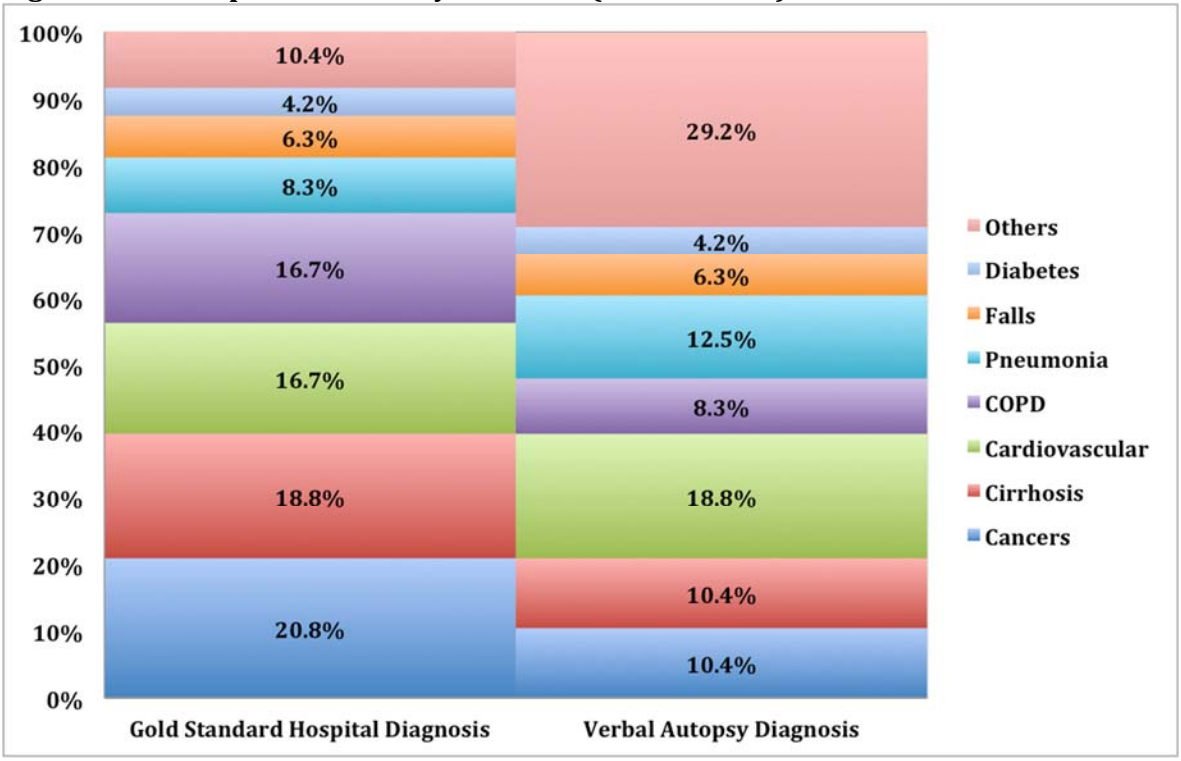
Finally, we calculated the population cause-specific mortality fractions (CSMF) based on both the gold standard list of causes and the VA-derived causes of death (see Figure 4).

Table 8: Validation Characteristics of the Most Frequently Found Causes of Adult Death

Cause of Death	N	Sensitivity	Specificity	PPV	NPV
Cancers*					
all cancers	10	10%	89.5%	20%	79.1%
Digestive Diseases					
Cirrhosis	9	44.4%	97.4%	80%	88.4%
Respiratory Diseases					
COPD	8	50%	100%	100%	90.9%
Pneumonia	4	75%	93.2%	50%	97.6%
Circulatory Diseases					
Ischemic Heart Disease	4	50%	100%	100%	95.7%
Stroke	4	50%	100%	100%	95.7%
Accidents and Injuries					
Falls	3	100%	100%	100%	100%

* Accuracies for an exact cancer match are provided in the table; however, if we broaden the category to "any cancer", accuracy improves with a sensitivity of 50%. For example, under this definition, a gold standard diagnosis of colorectal cancer and a VA diagnosis of cervical cancer would be considered a match.

Figure 4: Cause Specific Mortality Fractions (Adult Deaths)



Verbal autopsies were also conducted with the gold standard pediatric cases. Out of the 8 pediatric interviews conducted, 3 (37.5%) of the VA-derived causes of death matched its respective gold standard cause of death.

c. Post Interview Analysis – Implementation Challenges

Interviewers completed a post-interview report after each reliability and validation interview. By far, the greatest challenge during interviews was participant discomfort and distress. Having to recall the details of the death of a family member was a difficult task for all the participants, but we noted considerable discomfort in at least 15 of the participants. Interviewers reported events such as "the participant was being emotional, and I had to stop the questionnaire for awhile". Other comments included, "the participant got emotional and started crying" and "he was complaining about the quantity of questions and was not willing to tell anything regarding his wife's death". Interviews of a neonatal death were particularly challenging (emotionally) for the participant.

At least six other comments included instances of external disruptions to the interview. These included events such as the participant having to attend to a crying child, participants being in a rush to finish the interview, participants receiving phone calls mid-interview, and one participant who tried to listen to headphones during the interview.

There were a variety of other challenges detailed by the interviewers. One interviewer noted on multiple occasions, the respondent acted rudely or impolitely and did not want to answer the interview questions. On multiple occasions it was noted that the participants were very long-winded in their responses. She noted that the participant "took a long time for the interview, answering many more details that were not requested." Another respondent was "not directly answering the questions – answering other things when asked about one thing." On the other hand, another comment noted the participant "seemed bored" and just gave short, one-word responses to questions.

Another theme noted in the interviewers' reports was the participants' desire to receive more information regarding the death of their relative. Often, the participants left the hospital following their relative's death without a clear picture of what caused the death. Some falsely assumed that the verbal autopsy interview would help bring clarity to their situation. On multiple occasions, participants were skeptical about the interview, and did not fully comprehend what the purpose of the interview was. Two separate participants mentioned that they were expecting more details about the study before agreeing to an interview date.

A common logistical challenge noted by the interviewers was the difficulty of finding the participant's home as the directions given were not always clear or correct, and addresses are rarely exact. Though challenges existed, there were many positive reports as well and many welcoming, helpful participants who were happy to be interviewed and hospitable towards the interviewers.

IV. Discussion

Of the mortality files we reviewed at Dhulikhel Hospital, 75% were considered to have a high level of diagnostic evidence according to our gold standard criteria. The cause of death distribution of these cases showed a surprisingly high number of deaths resulting from non-communicable disease, mostly attributed to circulatory diseases, respiratory diseases, digestive disorders, or cancer. Nearly all of the infectious diseases stemmed from pneumonia.

Results from the verbal autopsy showed a wide variation in the SmartVA's accuracy in identifying individual causes of death, with some causes identified with 100% sensitivity and others as low as 0%. On a population-wide level, results showed Cause-Specific Mortality Fraction Accuracy to be .58. Though SmartVA was not able to perfectly ascertain all causes of death, most of the misclassifications still fell within the gold standard cause's broader ICD disease category.

Our team identified a total number of 135 in-hospital deaths during 2014; however, this number does

not include the many cases that left the hospital against medical advice and died at home. In Nepal, many choose either to not go to a hospital or not to remain in the hospital after it becomes clear that the condition is terminal; they prefer to die in the comfort of their homes. Because the vital registration is so limited in Nepal, home deaths typically go undocumented and their cause of death is never registered. In a country like Nepal that has a high number of home deaths coupled with a weak vital registration system, verbal autopsy can be a valuable method for collecting mortality data, especially for home deaths in the community. Verbal Autopsy has rarely been used in Nepal, and there are major potential benefits to scaling up its implementation. To our knowledge, our study was the first attempt in Nepal to validate a verbal autopsy tool that assesses all-cause mortality, and one of the first attempts worldwide to validate the SmartVA tool using the shortened version of the PHMRC questionnaire.

The Cause-Specific Mortality Fraction Accuracy that we calculated is in agreement with the results of the original PHMRC validation study using the Tariff Method (39). With a median CSMF Accuracy of .745, the PHMRC study result was higher than our result of .58, but not considerably different. Because our sample originated from only one study site and did not include cases representing all SmartVA causes of death, we did not expect our results to match entirely. The SmartVA is a new tool, and initial results from its application in the field are proving to be fairly consistent.

The COD distribution found through medical record review mostly agrees with the few existing studies and reports that provide COD data from Nepal. Our findings that COPD, CVD, cirrhosis (caused by alcoholic liver disease), and certain cancers are some of the biggest causes of adult deaths are in line with the IHME 2010 burden of disease report. Our data is also compatible with the general trends of life expectancy in Nepal. It is clear that the average life expectancy has risen over the past couple decades in Nepal, from 58 for males and 59 for females in 1990 to 69 for males and 72 for females in 2012 (44). This increase in life expectancy is largely due to decreases in neonatal disorders and other infectious diseases, such as diarrheal diseases. Thus, people are generally living longer lives and more affected by non-communicable diseases that become common with older age.

The literature is also consistent with our findings of a high burden of lower respiratory infections, specifically pneumonia. According to IHME data, lower respiratory infections was the leading cause of death in 1990, and this did not change in the 2010 findings (45). Although our findings did not put lower respiratory infections as the leading cause of death at Dhulikhel Hospital, pneumonia was still identified as a major burden.

Overall, our study found a lower burden of communicable diseases than that found in other studies

(IHME, WHO). We did not see a high number of infectious diseases such as diarrheal diseases, tuberculosis, or HIV/AIDS, all which rank in the top ten causes of death according to IHME 2010 data (9). Though the true cause of these inconsistencies is unknown, it is likely due to a hospital bias, given that patients who die in a suburban hospital are not necessarily similar to populations who die at home or in rural areas. Because patients who die in a hospital are not necessarily representative of all Nepal, generalizability is affected. Previous studies have shown variations in urban versus rural causes of morbidity and mortality, with infectious and nutritional diseases being more prevalent in rural areas.

Through this study, we found that with small improvements to records storage and the thoroughness of documentation, the medical records at Dhulikhel Hospital can provide an excellent source of data for future studies. The first concern we observed was the substantial percentage of mortality cases with missing medical records. Key informant interviews showed that a systematic process of submitting and storing medical files exists; however, storage space for medical records was lacking. Second, in our process to identify gold standard cases, we were impacted by missing or incomplete documentation. For example, many files had missing reports, especially x-ray or other imaging tests. In one case of a 3-month-old baby whose cause of death was registered as meningitis, the doctor had ordered a lumbar puncture, but no test results were included in the rest of the file. Without these results, it was impossible to confirm a gold standard diagnosis of meningitis. Other times, patient progress was not fully documented, such as missing notes on vital signs throughout the patient's admission. A high volume of research takes place at Dhulikhel Hospital, thus small improvements in these target areas could result in major increases to the quality of study data.

Dhulikhel Hospital is gradually recognizing the importance of a standardized certification process, and administration is responding by initiating more frequent trainings on coding and writing death certificates. Hospital administration is also strongly encouraging use of ICD codes, though its implementation has not yet seen progress, and further training of doctors is required. Although its use is minimal, the hospital utilizes an electronic medical records system, which automatically can assign ICD codes. Thus, scaling up the use of electronic recording could also enable a more widespread use of ICD coding for death certification. During the study's implementation, the hospital made plans to move to the international WHO standard death certificate, which will allow for great improvements to the mortality data that is reported.

There are a few Nepali cultural factors that are important to mention that may have impacted our

implementation of the verbal autopsies. First, is the Bikram Sambat calendar that is used in Nepal. The Nepali calendar does not follow the same dates as the Gregorian calendar. Thus, converting dates, such as birth and death dates, was often complicated. Additionally, the overall concept of time in Nepal is different from the linear concept of time typical in Western cultures. Responses to time related questions, such as "For how long was X ill before s/he died?" were not always clear. Another cultural factor present was the emphasis placed on protecting the reputation of the deceased. This was evident in a few scenarios. First, the interviewers themselves were hesitant to ask some questions, particularly a question regarding HIV/AIDS. The respondents were often hesitant to honestly answer some questions, particularly related to health behaviors such as tobacco use. It was noted that participants discussing the death of a suicide case often did not cooperate well with the questions.

The last cultural factor we noted was how frequently the participant's understanding of their relative's cause of death did not match the true cause of death. For the question asking "Did a health care worker tell you the cause of death," responses were often very different from the cause actually listed on the death certificate or found through record review. Whether this discrepancy stems from misinformation given by the health care worker or from the patient party's own misunderstanding of the information is unclear. In general, Nepali doctors spend less time communicating with patients and their families than is often observed in a western, patient-centered health model, and this might possibly explain why patient parties are leaving without a full understanding of how their relative died. This may also relate to the finding that some participants hoped that the verbal autopsy would provide them with further details regarding the death of their relative.

Most participants found it distressing to discuss the death of their relative; however, we found that nearly all were eventually able to discuss details about the death and open up to the interviewer. In fact, some participants were very willing to talk about the death. For some, it was perhaps a rare opportunity to be asked about their relative and they were waiting for a chance to open up and share about the situation. In this sense, the VA interview may have been helpful in the healing process of grieving family members.

Based on the results of this study, we recommend use of verbal autopsy in Nepal with the PHMRC survey and SmartVA analysis software; although, we recommend with caution. Because of our small sample size, the study did not provide rigorous evidence of the validity of the tool; however, the study was only intended to offer a general impression of the accuracy and feasibility of the tool. The small sample size also limited our ability to perform proper statistical analysis to estimate a chance-

corrected CSMF. Due to its numerous shortcomings, verbal autopsy should be used with caution, especially with certain causes of death that are more difficult to capture because of overlapping symptoms. In this study, specific types of cancer were difficult to capture with VA as well as some chronic diseases such as ischemic heart disease, stroke, COPD, and diseases of the liver. Further research is necessary to find ways of differentiating the symptoms of these important diseases, especially between different types of cancers.

The reliability testing demonstrated multiple explanations for obtaining misclassifications in our study. On the interviewer side, errors can stem from poor delivery of the question, lack of thoroughness in explaining questions that were unclear to the participant, trying to rush the interview, or even skipping questions for various reasons. On the participant side, explanations include recall errors and in some cases, cultural factors involving the protection of the deceased's reputation. Recall bias may be likely for at least three reasons. Firstly, relatives of a patient who died in a hospital are likely exposed to more information regarding the deceased's symptoms and diagnoses than a non-hospital death. Thus, they may be more informed about the cause of death and therefore able to better answer the VA questions. Secondly, even though we limited the time of interview to one year after the death of the patient, participants still may have simply forgot the deceased's exact symptoms. Finally, issues of shock, stress, or guilt related to the death may cloud the recall of information related to the death. The Kappas we calculated for reliability show us that despite some major differences between participant responses from Round A vs. Round B, they did not considerably change the outcome.

Other explanations for misclassification that we identified throughout the study include divergent definitions of certain causes (sepsis was defined differently at DH than definition found in the PHMRC gold standard definitions) and cases with competing causes of death. For example, one case in our study had the following overlapping causes of death listed on the death certificate: COPD with corpulmunary with valvular heart disease and cirrhosis caused by alcoholic liver disease. In such cases, it is difficult to identify the true underlying cause of death when full medical records available, let alone with verbal autopsy.

We were unable to validate neonatal deaths, as all neonates included in the study were kept isolated in NICU and out of direct contact with the family members. Thus, responses to the verbal autopsy questions were largely inaccurate. This could also have affected the adult VA results, as many adult patients were kept in ICU. However, caregivers had greater access to ICU patients compared to NICU patients. Additionally, caregivers of adult cases had more information regarding the patient's illness prior to hospitalization. For future in-hospital validation of neonatal VA, it would be more

appropriate to conduct the VA with an NICU nurse or health worker immediately after the death of the patient.

Overall, our team was pleased with the automated format of the SmartVA and the Android-based questionnaire. Although the purchase of tablets adds cost to a study, we found that it will ultimately save substantial resources by removing the need for physician-review, which is required in non-data derived verbal autopsies. Verbal autopsy requiring physician-review would not likely be a feasible solution long-term at the hospital or its rural outreach centers.

In our study, VA interviewers had previously received certificates in the medical field; however, we concluded that medical training is not necessarily required for future interviewers. With the relatively simple and straightforward structure of the questionnaire, extensive medical knowledge is not a necessity. With thorough training on the meaning of and response options for each question, interviewers from any background could perform this role.

Ideally, Nepal would have a well-functioning vital registration system that provides comprehensive, up-to-date, and on-going cause of death data. Because this is not yet reality, alternative methods of gathering mortality data are required in the interim. Verbal autopsy may be the best method of tracking mortality in districts where death certification is currently unavailable, as long as the limitations of the results are understood. VA data can help meet the need to provide decision-makers with crucial mortality data for the development of health policies and programming.

V. Recommendations

Initially, we recommend the SmartVA tool to be implemented within the Dhulikhel Heart Study as the primary method of collecting mortality data when medical records and/or death certificates are unavailable. This will allow the study to be able to better understand the burden of disease in Dhulikhel and to justify specific health programming based on evidence. Though SmartVA has not been validated in a rural Nepal, we are confident that it can be used to at least develop a general assessment of the cause of death distribution in rural areas. Thus, Dhulikhel Hospital should consider SmartVA for gathering mortality data throughout the catchment areas of their rural outreach centers. Additionally, SmartVA may be useful as a method of collecting supplementary mortality data in other population-based studies or reports, such as the Nepal Demographic and Health Survey, or in areas with current demographic surveillance sites.

We also noted a few areas of possible improvement to the hospital's process of records documentation and storage. We developed recommendations to address these issues, particularly regarding the thoroughness of documentation in patient files, using internationally recognized standards for coding and reporting deaths, and hiring a Records Manager to oversee the process of records collection and storage. A detailed summary of recommendations for Dhulikhel Hospital is provided in Box 2.

Box 2: Recommendations for Dhulikhel Hospital

Medical Records - Documentation
• Include diagnostic test reports in file • Document key patient history and progress • Use ICD codes to document cause of death • Specify a clear chain of events on death certificate • Use WHO standard death certificate format • Every 6 months, the forensics department will hold trainings on completing the death certificate
Registration and Records Management
• Hire a Records Manager • Collect complete contact information for patient and family • Designate a file storage location • Standardize process of storing and organizing records • Mortality data collection
Verbal Autopsy
• Use Verbal Autopsy for COD ascertainment of all Dhulikhel Heart Study participants who die at home • Use Verbal Autopsy to collect mortality data in communities served by the rural outreach center network

VI. Conclusions

Dhulikhel Hospital-Kathmandu University Hospital has good potential for becoming an excellent source of cause of death data for the country of Nepal. With small improvements to the thoroughness of documentation, an improved format for the DC, and use of ICD codes, the medical records at Dhulikhel Hospital can provide valid data for ongoing cause of death reporting. Additionally, they can potentially provide urgently needed data from throughout Nepal if they are able to implement routine data collection of verbal autopsies within their network of 18 rural outreach clinics.

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VIII. Appendices

Appendix A: PHMRC Cause of Death List

(this list represents the causes of death that SmartVA can potentially identify)

Adult Cause List	Child Cause List	Neonatal Cause List
AIDS	AIDS	Birth asphyxia
Asthma	Bite of Venomous Animal	Congenital malformation
Bite of Venomous Animal	Diarrhea/Dysentery	Meningitis/Sepsis
Breast Cancer	Drowning	Pneumonia
Cervical Cancer	Encephalitis	Preterm Delivery
Cirrhosis	Falls	Stillbirth
Colorectal Cancer	Fires	6 causes
COPD	Hemorrhagic fever	
Diabetes	Malaria	
Diarrhea/Dysentery	Measles	
Drowning	Meningitis	
Epilepsy	Other Cancers	
Esophageal Cancer	Other Cardiovascular Diseases	
Falls	Other Defined Causes of Child Deaths	
Fires	Other Digestive Diseases	
Homicide	Other Infectious Diseases	
Acute Myocardial Infarction	Pneumonia	
Leukemia/Lymphomas	Poisonings	
Lung Cancer	Road Traffic	
Malaria	Sepsis	
Maternal	Violent Death	
Other Cardiovascular Diseases	21 causes	
Other Infectious Diseases		
Other Injuries		
Other Non-communicable Diseases		
Pneumonia		
Poisonings		
Prostate Cancer		
Renal Failure		
Road Traffic		
Stomach Cancer		
Stroke		
Suicide		
TB		
34 causes		

Appendix B: Semi-Structured Interview Guide for Key Informant Interviews

1. What is your formal title here at the hospital?

2. How long have you been at the hospital?

3. Who is responsible for filling out death certificates?

4. When there is a death, how is the cause of death decided, and with what information are these decisions made?

5. Please describe the process between the death of a patient and when a death certificate is filed.

6. How are death records stored? Are computers used during the process?

7. What training and practice do doctors receive in certifying the cause of death?

8. Do hospital staff use the International Classification of Diseases and Related Health Problems (ICD-10) when classifying deaths?

    i. If yes: Where do physicians receive training on ICD-10?
    ii. If no: What classification method is used?

9. Is the information on death certificates used for any specific purposes within the hospital?

10. How could VA be useful? In Dhulikhel? In Outreach Centers? Nepal?

11. Do you have recommendations for who else should be interviewed regarding this process?

Appendix C: Post Interview Form

Interviewer Name: _____

Date of Interview: _____ Participant Code: _____

General reactions regarding the interview: _____

_____

_____

Barriers to conducting the interview or other challenges presented during interview:

_____

_____

_____

Please rank according to the participant's behavior:
(1 = no concerns noted, 5 = major concern noted)

Language difficulties or comprehension challenges:

1 2 3 4 5

Alertness/attentiveness:

1 2 3 4 5

Physical/mental discomfort:

1 2 3 4 5