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Results of the validation of a newly designed va instrument for neonates

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Abstract: It was a validation of a simplified, user friendly Newly designed Verbal Autopsy Instrument in Neonates. Reliability varied from 99.74% to 98.48%. The overall diagnostic accuracy was 91.47. The overall agreement of the New tool with the WHO VA tool was 0.576 with P value of .000.

Key Words: *Verbal Autopsy, Neonates, New tool, Reliability, Repeatability, Reproducibility, Accuracy, Agreement*

Cause specific mortality is a vital indicator for assessing demographic change and for planning public health interventions[1]. Many developing countries and even some developed countries still lack up-to-date data on the causes of death especially neonatal deaths, because of various factors[2]. In this scenario, verbal autopsy (VA) proves to be one of the reliable methods to compile the _community or Population diagnoses' of major causes of diseases[3]. Verbal autopsy is an approach to ascertain probable cause of death by interviewing relatives and caretakers of the deceased[4]. The current study was aimed to develop and assess a new verbal autopsy instrument for Neonates which would be simple, reliable, accurate, time efficient and user friendly.

The study tool is a newly designed Verbal Autopsy instrument for ascertaining the CoDs of neonates. The Instrument formatted in a single paper, double-sided layout with eight sections and 39 questions. The questionnaire has closed ended narrative and open-ended narrative. Administering WHO VA tool consumes approximately 35 minutes, whereas the new VA tool interview lasts for 15 minutes only.

It was a retrospective cohort randomized study conducted in the Metropolitan City of Chennai and the surrounding field areas. It attracted clinical information from the members of the family, otherwise known as the respondents who had a neonatal deathduring the immediate past one year. The required sample size calculated for 95% sensitivity was 74.

The Data was collected from the Institute of Child Health and Hospital for Children, Chennai. Residential addresses and the contact details of all the deceased collected during the survey and was subjected to the Inclusion Exclusion Criteria. Inclusion criteria included i) Families of all neonatal deaths that occurred during the immediate past one year ii) Families of the deceased reside within 100km of the facility/ reside within 100km of the tertiary health care setting in Chennai. Exclusion Criteria included i) Still births ii) Untraceable Informants (Mother not available); ii) Untraceable address (migrated from residence, those who recorded wrong address); iii) those who are unwilling to participate in studied) Rare deaths v) Undiagnosed deaths. Untraceable addressees and Untraceable Informants are actually performance characteristics of the data. Informants unwilling for Interview are the study characteristics and it helps in assessing the quality of evidence of your study.

From among the chosen 445 subjects for study, 258 subjects were selected after applying inclusion / exclusion criteria and willingness to participate in the study. Then month wise classification of subjects and then equi-distribution of each unit into two, randomly allocating one to each tool. The identities of both the social workers and physicians were blinded for avoiding nepotism or favouritism. For the sake of transparency, reliability and objectivity. 50% of the sample was allotted to Social worker A and the other 50% to social worker B, under the 2 categories of equally distributed units. The social workers were clearly instructed not to look at the death certificate. The entire subject was methodically coded by two independent Physicians. Then the CoD was compared separately against the gold standard hospital diagnosis. Out of 258, only 86 gave consent for second interview and interviews done after one week. Out of 86, in 20 subjects new VA instrument applied for reliability studies and in 66 different instrument applied for agreement studies.

Data maintenance: All the forms were checked for the completeness, consistency and errors while filling the forms. Quality checks were also conducted in 10% of questionnaire by the Investigator independently and compared with social workers for agreement. All the data stored electronically on the researcher‘s personal laptop, which was password protected, not available for public review or scrutiny. The data will be double checked by the guide and will be used for research purpose only. Relevant data will be exported from MS excel file to SPSS. Statistical Analytical methods like SPSS, OpenEpi software were used for data analysis.

Repeatability of the New Instrument

S.No	Question	R1		R2		R3		R4		R5		R6		R7		R8		R9		R10	
		I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2
1	Q 1a																				
2	Q 1b																				
3	Q 1c																				
4	Q 1d																				
5	Q 1e																				
6	Q 1f																				
7	Q 1g																				
8	Q 1h																				
9	Q 1i																				
10	Q 1j																				
11	**Q 2**																				
12	Q 3a																				
13	Q 3b																				
14	Q 3c																				
15	Q 3d																				
16	Q 3e																				
17	Q 3f																				
18	Q 3g																				
19	Q 3h																				

20	Q 4a																			
21	Q 4b																			
22	Q 4c																			
23	Q 4d																			
24	Q 5a																			
25	Q 5b																			
26	Q 5c																			
27	Q 5d																			
28	Q 5e																			
29	Q 6a																			
30	Q 6b																			
31	Q 6c																			
32	Q 6d																			
33	Q 6e																			
34	Q 6f																			
35	Q 6g																			
36	Q 6h																			
37	Q 6i																			
38	Q 7a																			
39	Q 7b																			

Describing the Repeatability Tabular Column: Q is Question, R is Respondent of the Diseased, I1 is First Interview, I2 is Second Interview, Yellow Horizontal Row is the Question on Respondents thoughts on the Death of the Diseased, and Black Box indicates that the second interview response was different from the first

Reproducibility of the New Instrument

S. No	Question	R11		R12		R13		R14		R15		R16		R17		R18		R19		R20	
		I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2	I1	I2
1	Q 1a																				
2	Q 1b																				
3	Q 1c																				
4	Q 1d																				
5	Q 1e																				
6	Q 1f																				
7	Q 1g																				
8	Q 1h																				
9	Q 1i																				
10	Q 1j																				
11	**Q 2**																				
12	Q 3a																				
13	Q 3b																				
14	Q 3c																				

15	Q 3d																				
16	Q 3e																				
17	Q 3f																				
18	Q 3g																				
19	Q 3h																				
20	Q 4a																				
21	Q 4b																				
22	Q 4c																				
23	Q 4d																				
24	Q 5a																				
25	Q 5b																				
26	Q 5c																				
27	Q 5d																				
28	Q 5e														■						
29	Q 6a																				
30	Q 6b																				
31	Q 6c																				
32	Q 6d																				
33	Q 6e																				
34	Q 6f																				
35	Q 6g																				
36	Q 6h																				
37	Q 6i																				
38	Q 7a																				
39	Q 7b				■																

Describing the Reproducibility Tabular Column: Q is Question, R is Respondent of the Diseased, I1 is First Interview, I2 is Second Interview, Yellow Horizontal Row is the Question on Respondents thoughts on the Death of the Diseased, and Black Box indicates that the second interview response was different from the first one.

Reliability of the VA Instrument: The term *reliability* refers to the consistency of a measure. A reliable scale should provide the same results at each point of measurement. This is referred to as a test re-test approach in estimating reliability[5]. The test re-test approach is also commonly used to evaluate the reliability of questionnaires -- especially when the construct being measured is assumed to be stable over time. Thus, the reliability is very much dependent on the quality of measurement of an assessment tool in producing stable and consistent results[6].

The foremost criterion for the reliability of the tool is its efficacy in *repeatability*[7]. The Intra-observer reliability is ascertained by administering the new tool to a selected small sample after a week by the same social worker on the same case after getting their special consent. This is the first simple source of validation. Out of 39 questionnaires, only one Question No 2 is mainly open end questionnaire, it‘s about Respondents thoughts on the cause of death of the diseased. Rest 38 are mainly closed end questionnaires. In the study test done in 10 subjects and the overall agreement between the first interview and the second interview was

99.48%. With all questionnaires and 99.74 with closed end questionnaire. The next important source of checking the reliability of the tool is its effectiveness in *reproducibility*. The involvement of two independent health workers and two independent physicians using the same VA tool helps in attaining the inter observer reliability. In the study test done in 10 subjects and the overall agreement between the first interview and the second interview was 98.97%. With all questionnaires and 99.48 with closed end questionnaire.

Accuracy of the VA instrument: The overall sensitivity, PPV and Diagnostic accuracy of the new tool found to be 91.47%, 100% and 91.47% respectively in contrast to the WHO tool with 94.57%, 100%, and 94.57%. The diagnostic accuracy for determining Congenital malformations, Preterm and Low birth weight is 96.12 for both tools. The diagnostic accuracy for Pneumonia and Birth Asphyxia in New VA tool is 96.12 slightly lower than WHO VA tool 98.45. Again in determining sepsis the WHO tool performed better with 99.22 than New VA tool with 96.12. little lower than WHO tool.

ACCURACY OF THE INSTRUMENT (MAIN STUDY)

Cause of Neonatal deaths as determined through Hospital diagnosis versus New VA tool-Main study

Diagnostic Criteria	ICD code	Hospital Deaths	New tool Deaths	Matched	Unmatched
Sepsis	**P369**	**34**	**35**	**32**	**3**
C.Malformations	**Q**	**25**	**24**	**22**	**2**
Pneumonia	**P239**	**18**	**18**	**16**	**2**
Prematurity	**P073**	**17**	**17**	**16**	**1**
Birth Asphyxia	**P021-P2**	**18**	**18**	**16**	**2**
Low birth weight	**P071**	**17**	**17**	**16**	**1**
Total		**129**	**129**	**118**	**11**

ICD Code: International Classification of Diseases, Matched: means number of cases correctly diagnosed by New tool, Unmatched: number of cases wrongly diagnosed by New Tool

Validation of New VA tool with Hospital records based on various Diagnostic test measures-Main studies

Diagnostic c Criteria	ICD code	Sensitivity with 95%CI	Specificity with 95%CI	PPV with 95%CI	NPV with 95%CI	DA with 95%CI
Sepsis	**P369**	**94.12 (80.91, 98.37)**	**96.84 (91.12, 98.93)**	**91.43 (77.62, 97.04)**	**97.87 (92.57, 99.41)**	**96.12 (91.25, 98.33)**
C.Malformations	**Q**	**88 (70.04, 95.83)**	**98.08 (93.26, 99.47)**	**91.67 (74.15, 97.68)**	**97.14 (91.93, 99.02)**	**96.12 (91.25, 98.33)**
Pneumonia	**P239**	**88.89 (67.2, 96.9)**	**98.2 (93.67, 99.5)**	**88.89 (67.2, 96.9)**	**98.2 (93.67, 99.5)**	**96.9 (92.3, 98.79)**

Prematurity	**P073**	**94.12 (73.02, 98.95)**	**99.11 (95.12, 99.84)**	**94.12 (73.02, 98.95)**	**99.11 (95.12, 99.84)**	**98.45 (94.52, 99.57)**
Birth Asphyxia	**P021-P2**	**88.89 (67.2, 96.9)**	**98.2 (93.67, 99.5)**	**88.89 (67.2, 96.9)**	**98.2 (93.67, 99.5)**	**96.9 (92.3, 98.79)**
Low birth weigh	**P071**	**94.12 (73.02, 98.95)**	**99.11 (95.12, 99.84)**	**94.12 (73.02, 98.95)**	**99.11 (95.12, 99.84)**	**98.45 (94.52, 99.57)**
Over all		**91.47 (85.38, 95.17)**		**100 (96.85, 100)**		**91.47 (85.38, 95.17)**

ICD Code: Internal Classification of Diseases, CI: Confidence Interval, PPV: Positive Predictive Value, NPV: Negative Predictive Value

Cause of Neonatal deaths as determined through Hospital diagnosis versus WHO VA tool-Main study

Diagnostic Criteria	ICD code	Hospital Deaths	New tool Deaths	Matched	Unmatched
Sepsis	**P369**	**32**	**33**	**32**	**1**
C.Malformations	**Q**	**27**	**26**	**24**	**2**
Pneumonia	**P239**	**20**	**20**	**19**	**1**
Prematurity	**P073**	**20**	**20**	**19**	**1**
Birth Asphyxia	**P021-P2**	**15**	**15**	**14**	**1**
Low birth weight	**P071**	**15**	**15**	**14**	**1**
Total		**129**	**129**	**122**	**7**

ICD Code: International Classification of Diseases, Matched: means number of cases correctly diagnosed by New tool, Unmatched: number of cases wrongly diagnosed by New Tool

Validation of WHO VA tool with Hospital records based on various Diagnostic test measures-Main studies

Diagnostic Criteria	ICD code	Sensitivity with 95%CI	Specificity with 95%CI	PPV with 95%CI	NPV with 95%CI	DA with 95%CI
Sepsis	**P369**	**100 (89.28, 100)**	**98.97 (94.39, 99.82)**	**96.97 (84.68, 99.46)**	**100 (96.15, 100)**	**99.22 (95.74, 99.86)**
C.Malformations	**Q**	**88.89 (71.94, 96.15)**	**98.04 (93.13, 99.46)**	**92.31 (75.86, 97.86)**	**97.09 (91.78, 99)**	**96.12 (91.25, 98.33)**
Pneumonia	**P239**	**95 (76.39, 99.11)**	**99.08 (94.99, 99.84)**	**95 (76.39, 99.11)**	**99.08 (94.99, 99.84)**	**98.45 (94.52, 99.57)**

Prematurity	**P073**	**95 (76.39, 99.11)**	**99.08 (94.99, 99.84)**	**95 (76.39, 99.11)**	**99.08 (94.99, 99.84)**	**98.45 (94.52, 99.57)**
Birth Asphyxia	**P021-P2**	**93.33 (70.18, 98.81)**	**99.12 (95.2, 99.84)**	**93.33 (70.18, 98.81)**	**99.12 (95.2, 99.84)**	**98.45 (94.52, 99.57)**
Low birth weigh	**P071**	**93.33 (70.18, 98.81)**	**99.12 (95.2, 99.84)**	**93.33 (70.18, 98.81)**	**99.12 (95.2, 99.84)**	**98.45 (94.52, 99.57)**

ICD Code: Internal Classification of Diseases, CI: Confidence Interval, PPV: Positive Predictive Value, NPV: Negative Predictive Value

Agreement of the New VA tool with the WHO tool: Out of 66 subjects the new tool picked up 58 subjects correctly and the WHO tool picked up 61 cases correctly. Out of the 66 cases, 57 cases both tools picked up correctly and 4 cases both tools went wrong. The overall kappa agreement is 0.576 with Value of .000.

NT * WHO Cross tabulation

Count				
		WHO		
		1	2	Total
NT	1	57	1	58
	2	4	4	8
Total		61	5	66

Symmetric Measures

	Value	Asymp. Std. Error	Approx. T[b]	P-value
Measure of Agreement Kappa	.576	.169	4.837	.000
N of Valid Cases	66			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Time Efficiency & Effectiveness: In the current study the WHO VA interview on an average took 36 minutes for complete interview, whereas the newly developed VA interview ~~took 14.8 minutes.~~

Comparative Characteristics of New VA Instrument and WHO VA Instrument

Characteristics	New VA Instrument	WHO VA Instrument
Number of Sections	8	10
Number of Questions	39	145
Number of Pages	2	9
Typical Interview Duration	15	36
Overall Sensitivity	91.47	94.57
Overall Specificity	100	100
Overall Diagnostic Accuracy	91.47	94.57

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