Methodological trends in studies based on verbal autopsies before and after published guidelines

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Objective To report on the uptake of guidelines published in the early 1990s with specific recommendations about the design of future studies based on verbal autopsy conducted for mortality surveillance.

Methods We conducted a systematic literature search of all verbal autopsy studies published before January 2006 and extracted from the studies a standard set of data. We then compared studies designed before and after the recommendations were issued in terms of seven key methodological indicators.

Findings We found 102 studies conducted in 39 countries; 60 were designed before and 42 after the guidelines were issued. The methods used in these 102 studies varied considerably. While some encouraging trends were noted, there is no evidence that the design recommendations have been systematically implemented. Specifically, there was no clear increase in the proportion of studies with a combined questionnaire (63% before recommendations versus 74% after; $P = 0.3$), a trained interviewer (70% versus 70%; $P = 1.0$), a suitable respondent (98% versus 100%; $P = 1.0$), an optimal recall period (84% versus 97%; $P = 0.2$), predefined algorithms (28% versus 38%; $P = 0.4$), an option for assigning multiple causes of death (30% versus 38%; $P = 0.3$), or a follow-up validation study (83% versus 72%; $P = 0.7$).

Conclusion Expert recommendations for optimal design of verbal autopsy studies have been incompletely implemented to date. Better uptake of design recommendations through enhanced collaboration between research teams is likely to produce better mortality statistics from an increasing number of verbal autopsy studies.

Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Information about the causes of death in a population is essential for monitoring health and planning appropriate health services.[1] While most higher-income countries have in place robust processes for documenting deaths and their causes, many developing countries lack such systems due to organizational and economic constraints and other factors.[2]

Verbal autopsy-based cause of death recording systems are widely used in countries where vital registration and death certification systems are weak and most people die at home without medical certification of the cause of death.[3] A verbal autopsy is a method used to determine the cause of death from data collected about the symptoms and signs of illness and the events preceding death.[4,5] This method is based on the hypothesis that the symptoms and signs surrounding most causes of death can be recognized, recollected and reported by a person present during the period prior to death.[6,7] For the information provided by verbal autopsies to be maximally reliable, certain design characteristics need to be incorporated into studies based on verbal autopsy methods. To ensure that the data collected is of high quality, the data collection tool should have structured and unstructured questions, interviewers should be specially trained, interviewees should have remained close to the deceased during illness, and between death and data collection only a short time interval should have elapsed. Similarly, for cause of death to be accurately assigned, algorithms for translating the data into causes of death must be clearly defined and the possibility of assign-

ing multiple causes of death (i.e. immediate, underlying and contributory) must be present. Finally, subsequent validation studies should be carried out.

To optimize the use of these methods, in the early 1990s WHO convened a series of expert meetings that led to the publication of several reports[4,5,7,8] in which key design features for studies based on verbal autopsy methods were recommended. Three of the four reports – one of them the outcome of a workshop sponsored jointly by WHO and the United Nations Children's Fund – were published in international journals, and the fourth was published by WHO. However, the extent to which the guidelines were systematically disseminated to relevant parties and their effect on study design are unclear. Thus, the objective of this study was to determine whether the expert recommendations published from 1992 to 1994 influenced the way researchers conduct verbal autopsy studies.

Methods

Search strategy

From June 2005 to May 2006, we conducted computerized searches of PubMed and WHO[9] databases using as key phrases "verbal autopsy", "mortality surveillance", "mortality statistics", "post mortem interview" and "cause of death". References quoted in original publications and in the websites of the International Network of Field Sites with Continuous Demographic Evaluation of Populations and their Health

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(INDEPTH Network)[10] and the Adult Morbidity and Mortality Project[11] were manually searched for additional information.

Study inclusion and exclusion criteria

To be included in this review, studies had to fulfil certain criteria. They had to: (i) have been published before 2006 in a peer reviewed journal or as a report accessible through a web search; (ii) describe the verbal autopsy method used, and (iii) be written in English or French. A study reporting data in more than one paper was included only once, and data from the paper which described the methods in the greatest detail were used.

Data extraction

Standard information was extracted from all eligible studies by one reviewer for English-language studies (RJ) and another for French-language studies (A-PK). The information included the following: country in which the data were collected; age group studied; number of deaths observed; approach used to classify deaths; questionnaire format; interviewers' education and gender; type of respondent from whom information was obtained; recall period; granting of consent; type and nature of adjudication process; number of causes of death assignable per case; and presence or absence of a validation study. Unless otherwise indicated, all studies were assumed to have been designed three years prior to publication.

Outcomes

For this study, outcomes were based on seven key recommendations extracted from the published guidelines (Table 1), as follows: (i) a *combined questionnaire* including both a series of structured questions and an open narrative section, (ii) a *trained interviewer* educated in verbal autopsy methods and interviewing skills, (iii) a *suitable respondent* who tended to the deceased during illness (usually a family member or caretaker), (iv) a *recall period of less than 5 years* between the dates of death and data collection, (v) *predefined criteria or algorithms* to guide the assignment of causes of death, (vi) ability to assign *multiple causes of death*, such as immediate, underlying, and contributory, and (vii) the performance of a *validation study* to ascertain the reliability of the causes of death assigned. Immediate, underlying and contributory causes are illustrated by the example of a death from stroke (underlying cause) resulting from a secondary pneumonia (immediate cause) in a patient with a history of hypertension (contributory cause).

Analysis

For the primary analyses, studies were divided into those designed before and after 31 December 1994. The proportion of studies in each of these two groups that contained each recommended methodological feature was compared. Sensitivity analyses were performed using the dates when the guidelines were laid down – 31 December 1992 and 31 December 1996 – with no effect on the study conclusions for any measure. Studies for which the particular indicator measured was not reported were excluded from the relevant analysis. Means were compared with Pearson's χ^2 test, and all analyses were performed with SPSS version 12.0 (SPSS Inc., Chicago, IL, United States of America). Fisher's exact test was used for expected counts less than 5.

Results

The search identified 102 studies conducted in 39 developing countries (Appendix A, available at: http://www.thegeorgeinstitute.org/iih/index.cfm?7E6B9894-AED4-1907-C50B-BBFFB82559F8#methodological-trends-in-studies-using-verbal-autopsies). The first study was conducted in Bangladesh in 1968[12] and the last in the Democratic Republic of the Congo in 2003–2004.[13] The 99 studies that reported data comprised a total of 139 258 deaths. The number of deaths in each study ranged from 15 to 80 000, with a mean of 1407 and a median of 271. Sixty studies were designed before and 42 studies after the end of 1994. Half of all the studies were of deaths in infants and children, about one-fourth were of maternal deaths and about one-fourth were about deaths in adulthood or at any age.

Methodology indices

The methodology indices used were reported in 80% of the studies or more, except in the case of the recall period and the performance of a validation study, which were reported in only 58.8% and 27% of the studies, respectively (Table 2). Of the studies that provided methodology data, two-thirds or more followed each of the four main guideline recommendations regarding data collection. Almost all studies used a suitable respondent and had a recall period of less than 5 years. There was, however, no strong evidence that these or other recommended data collection indices were used more often after 1994 ($P > 0.22$).

Recommended methods for assigning the cause of death were applied much less frequently than recommended data collection methods. Predefined algorithms for assigning the cause of death or the ability to assign multiple causes of death were found in only about one-third of the verbal

Table 1. **Key aspects of methodology extracted from recommendations for verbal autopsy study design published in the early 1990s**

	Year of publication			
	1992[7]	1994[5]	1994 (workshop in 1992)[8]	1994[4]
Data collection				
Combined questionnaire	X	X	X	
Trained interviewer	X	X		X
Suitable respondent	X	X		X
Recall period < 5 years		X		
Cause of death assignment				
Predefined criteria or algorithms		X	X	X
Multiple causes of death assignable	X	X	X	X
Other				
Validation study	X	X	X	

Table 2. Features of data collection and cause of death assignment process in studies designed before and after 31 December 1994 (i.e. before and after guidelines for verbal autopsy study design)

	No. of studies with data available	Before guidelines		After guidelines		P-value[a]
		n/N	%	n/N	%	
Data collection						
Combined questionnaire	83	31/49	63.3	25/34	73.5	0.3
Trained interviewer	100	42/60	70.0	28/40	70.0	1.00
Suitable respondent	83	41/42	97.6	41/41	100.0	1.00
Recall period < 5 years	61	26/31	83.9	29/30	96.7	0.2
Cause of death assignment						
Predefined criteria or algorithms	90	15/53	28.3	14/37	37.8	0.4
Multiple causes of death assignable	94	16/54	29.6	15/40	37.5	0.33
Other						
Validation study	36	15/18	83.3	13/18	72.2	0.7

n, number of studies with characteristic known to be present; N, number of studies with characteristic known to be or not be present.

[a] P-value for difference in proportion of studies with each characteristic before and after guidelines for verbal autopsy study design.

autopsy studies. Once again, there was no evidence of a post-1994 increase in the proportion of studies in which the recommended ways of assigning the cause of death had been used ($P > 0.33$). Validation studies had been conducted in about three-fourths of the studies that reported their presence or absence, but only about one-fourth of all studies provided data about this aspect of study design. No statistical difference was found in the proportion of studies carried out before and after the end of 1994 for which a validation study was conducted ($P = 0.69$).

Discussion

This review provides a comprehensive update on the verbal autopsy studies performed in the world up to the time of this review and of the methods applied in them. It highlights the variability of the methods used and the negligible influence exerted by a series of methodological guidelines and reports developed in the early 1990s.[4,5,7]

The efforts undertaken in the early 1990s to standardize the design and conduct of verbal autopsy studies lead one to assume that suboptimal methods were felt to have important consequences. Similarly, the content of the recommendations issued at the time suggests that certain methodological features were felt to ensure a yield of maximally reproducible, valid and comparable information from subsequent verbal autopsy studies. Unfortunately, these features, which were identified and specified more than a decade

ago, have scarcely been implemented, perhaps because researchers have not known about them, have lacked access to the journals that published them or have been unable to afford to apply them in full. It is also possible that the absence of evidence in support of many of the recommendations lessened their value in the eyes of researchers designing new studies. The explanation is beyond the scope of this study but would be a good topic for future research, since some of the possibilities listed above can be addressed quite easily.

It is difficult to know for certain what effect, if any, not following the guidelines had on study findings. Nearly all guideline recommendations appear to have been based on consensus expert opinion rather than on scientific evidence, and it is impossible to know if they do in fact represent best practice. However, despite the lack of evidence, the rationale behind most of the recommendations is plain. For example, the ability to assign multiple causes of death rather than a single cause leads to better opportunities to explore existing problems, such as national biases in cause of death assignment, and allows a more informed evaluation of study results. Likewise, a data collection strategy that combines structured and open data collection techniques is likely to lead to better data collection than one restricted to either technique alone.

In the present study, the evaluation of verbal autopsy study techniques was restricted to a few key design features that were identified as important in

most of the recommendations and that could be easily and objectively extracted from most of the study reports identified. Aspects of study design besides those reported here may have been of equal or greater importance to study integrity. Of the methodological indices studied, several showed positive trends. However, there is no evidence to indicate that such trends are not the result of chance. While the analyses were limited in their ability to detect progress towards the incorporation of some recommended design features that were already being used fairly widely (mainly data collection indices), the study was well placed to detect the potential effects of the guidelines on less widely used features pertaining to cause of death assignment and validation. In particular, little movement was noted towards the use of pre-specified algorithms to aid the allocation of cause of death or the assignment of multiple causes of death, two methodological features that would probably greatly enhance the quality of information derived from verbal autopsy projects. Furthermore, despite specific recommendations in the guidelines, very few studies have attempted to validate their findings, and those that have reported doing so have used very different methods. Validation studies that compare the causes of death derived from the verbal autopsy against gold standard reference diagnoses are particularly necessary.

This review was limited by an absence of data from several studies, which reduced statistical power and

introduced the risk of bias. Given the long time elapsed since many of the reports were published, contacting their authors directly was considered impossible and further bias could have been introduced by the likelihood that it was easier to contact the authors of more recent reports. Although efforts were made to identify all verbal autopsy studies conducted, some may have been missed due to publication in a language other than English or French or in technical reports not widely available. However, it is unlikely that the missing data would have led to a different conclusion regarding the uneven and rather poor quality of many verbal autopsy studies.

In the context of changing patterns of death in many lower-income countries that rely on verbal autopsy systems for mortality surveillance,[14,15] high quality, standardized techniques are becoming increasingly important.[16] Better uptake of key design recommendations would undoubtedly increase the reproducibility of verbal autopsy studies and the validity and comparability of their results, as well as enhance decision-making processes surrounding health care in lower-income settings. However, how uptake might be further enhanced is not immediately clear, since the recommendations already appear in leading medical journals and/or as downloadable technical reports.[17,18] The establishment of an international network of researchers involved in conducting verbal autopsy projects may facilitate the design of future studies, although it would clearly be impossible to see to it that they were all performed within the framework of such a group. More systematic interaction between international collaborations, such as the INDEPTH Network,[10] the Adult Morbidity and Mortality Project,[11] India's Sample Registration System's prospective study[19] and the Sample Vital Registration with Verbal Autopsy[14] initiative, might be one practical way of enhancing the way verbal autopsy studies are conducted. A recent publication by WHO, representing one more effort to set international standards for verbal autopsy methods, is a positive step forward but unlikely to suffice in and of itself.[20] ■

Competing interests: None declared.

Résumé

Tendances méthodologiques des études reposant sur des autopsies verbales avant et après la publication de directives

Objectif Dresser un rapport sur l'assimilation des directives publiées au début des années 90 et contenant notamment des recommandations spécifiques sur la conception des futures études de surveillance de la mortalité reposant sur l'autopsie verbale.

Méthodes Nous avons réalisé une revue systématique de l'ensemble des études par autopsie verbale publiées avant janvier 2006 et extrait de ces études un jeu de données standard. Nous avons ensuite comparé les études conçues avant et après la publication des directives en utilisant sept indicateurs méthodologiques clés.

Résultats Nous avons recensé 102 études menées dans 39 pays ; 60 d'entre elles avaient été conçues avant et 42 après la publication des directives. Les méthodes utilisées dans ces 102 études étaient très variables. Si certaines tendances encourageantes ont été notées, il n'a pas été relevé de preuve d'une application systématique des recommandations en matière de conception. Plus spécifiquement, il n'a pas été constaté d'augmentation claire

de la proportion d'études utilisant un questionnaire combiné (63 % avant la publication des directives contre 74 % après, p = 0,3), un enquêteur formé (70 % contre 70 %, p = 1,0), des sujets appropriés (98 % contre 100 %, p = 1,0), une période de rappel optimale (84 % contre 97 %, p = 0,2), des algorithmes prédéfinis (28 % contre 38 %, p = 0,4), une option pour l'affectation des causes multiples de décès (30 % contre 38 %, p = 0,3) ou une étude de validation dans le cadre du suivi (83 % contre 72 %, p = 0,7).

Conclusion Les directives des experts concernant la meilleure façon de concevoir les études par autopsie verbale sont à ce jour appliquées de manière incomplète. Une meilleure assimilation de ces recommandations en matière de conception grâce à un renforcement de la collaboration entre les équipes de recherche devrait permettre de produire des statistiques de mortalité de plus grande qualité à partir d'un nombre grandissant d'études par autopsie verbale.

Resumen

Tendencias metodológicas de los estudios basados en autopsias verbales antes y después de la publicación de directrices al respecto

Objetivo Informar sobre el seguimiento de las directrices publicadas a comienzos de los años noventa con recomendaciones específicas para el diseño de los futuros estudios de vigilancia de la mortalidad basados en autopsias verbales.

Métodos Llevamos a cabo una búsqueda sistemática de la bibliografía para localizar todos los estudios basados en autopsias verbales publicados antes de enero de 2006 y extraer de ellos un conjunto estándar de datos. Para comparar los estudios diseñados antes y después de que se formularan las recomendaciones se emplearon siete indicadores metodológicos clave.

Resultados Hallamos 102 estudios realizados en 39 países; 60 se habían diseñado antes de que se publicaran las directrices,

y 42 después de su publicación. Se observaron diferencias considerables en los métodos utilizados por esos 102 estudios. Aunque se detectaron algunas tendencias alentadoras, no hay indicios de que se hayan aplicado sistemáticamente las recomendaciones en materia de diseño. Más concretamente, no aumentó claramente la proporción de estudios con un cuestionario combinado (63% antes de las recomendaciones frente a 74% después de las mismas; p = 0,3), un encuestador adiestrado (70% frente a 70%; p = 1,0), un encuestado idóneo (98% frente a 100%; p = 1,0), un periodo de rememoración óptimo (84% frente a 97%; p = 0,2), algoritmos predefinidos (28% frente a 38%; p = 0,4), una opción para asignar varias causas de defunción (30%

frente a 38%; *p* = 0,3), o un estudio de validación de seguimiento (83% frente a 72%; *p* = 0,7).

Conclusión Las recomendaciones formuladas por los expertos para optimizar el diseño de los estudios basados en autopsias verbales se han aplicado solo parcialmente hasta la fecha. Un

mayor cumplimiento de ese tipo de recomendaciones gracias a una colaboración más idónea entre los equipos de investigación permitiría probablemente obtener mejores estadísticas de mortalidad a partir del creciente número de estudios basados en autopsias verbales.

ملخص

الاتجاهات المنهجية في الدراسات المرتكزة على الصفة التشريحية اللفظية قبل وبعد الدلائل الإرشادية المنشورة

الهدف: إعداد تقرير عن الانتفاع بالدلائل الإرشادية المنشورة في مطلع التسعينيات مع توصيات خاصة حول تصميم دراسات مستقبلية مستندة على الصفة التشريحية اللفظية التي تنفذ من أجل ترصُّد الوفيات.

الطريقة: أجرى الباحثون بحثاً منهجياً في النشريات عن جميع الدراسات المنشورة قبل كانون الثاني/يناير 2006، حول الصفحة التشريحية، والمستخلصة من دراسات ذات مجموعة معيارية من المعطيات، ثم قارنوا بعد ذلك الدراسات المصممة قبل إصدار التوصيات بالدراسات المصممة بعدها من حيث المؤشرات المنهجية الأساسية السبعة.

الموجودات: وجد الباحثون 102 دراسة نفذت في 39 بلداً، صمم 60 منها قبل إصدار الدلائل الإرشادية و42 منها بعد إصدارها. وتتفاوت الطرق التي استخدمت فيها الدراسات الـ 102 تفاوتاً ملحوظاً. ورغم ملاحظة بعض الاتجاهات المشجعة لم يكن هناك من بيِّنات على أن تصميم التوصيات قد نفذ بشكل منهجي. وبصورة محددة، لم يكن هناك ازدياد واضح في نسبة الدراسات ذات الاستبيانات المشتركة (فقد كانت 63% قبل صدور التوصيات وأصبحت 74% بعد صدورها، بقوة احتمال P = 0.3)، ولا في نسبة الأشخاص المدربين القائمين بإجراء المقابلات (فقد كانت 70% قبل

صدور التوصيات وأصبحت 70% بعد صدورها، بقوة احتمال P = 1.0)، ولا في نسبة المستجيبين المناسبين (فقد كانت 98% قبل صدور التوصيات وأصبحت 100% بعدها، بقوة احتمال P = 1.0)، ولا في الفترة الأفضل للإبلاغ (فقد كانت 84% قبل صدور التوصيات وأصبحت 97% بعدها بقوة احتمال P = 0.2). ولا في الخوارزميات المعرَّفة مسبقاً (فقد كانت 28% قبل صدور التوصيات وأصبحت 38% بعدها، بقوة احتمال P = 0.4)، ولا في إتاحة الاختيار لتعيين الأسباب المتعددة للوفيات (فقد كانت 30% قبل صدور التوصيات وأصبحت 38% بعد صدورها، بقوة احتمال P = 0.3)، ولا في إجراء دراسة متابعة لتوثيق المصدوقية (فقد كانت قبل صدور التوصيات 83% وأصبحت بعد صدورها 72%، بقوة احتمال P = 0.7).

الاستنتاج: لم يتم حتى اليوم تنفيذ توصيات الخبراء حول التصميم الأفضل للدراسات حول الصفة التشريحية اللفظية على الوجه الأكمل، ويغلب أن يؤدي الانتفاع بشكل أفضل من التوصيات الموضوعة، من خلال تعاون معزز بين فرق البحوث، إلى إنتاج إحصائيات أفضل لمعدلات الوفيات، مستمدة من عدد أكبر من الدراسات حول الصفة التشريحية اللفظية.

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