Author's response to reviews

Title: Whether to report diabetes as the underlying cause-of-death? a survey of internists of different sub-specialties

Authors:

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Version: 2 Date: 17 June 2010

Author's response to reviews: see over
Dear Editor:

Thank you very much for your mail of January 19, 2010. Sorry for such a long delay in replying because of some personal family affairs. We have revised the manuscript according to reviewers’ comments. Please see the following replies indicating the changes we made point by point.

Best regards

Tsung-Hsueh Lu

Editor: We would also suggest including an English version of the questionnaire or case studies as a supplementary file to provide more information to readers (assuming more information was provided than is presented in Table 2).

REPLY: The information of the hypothetical case scenarios in the questionnaires was exact the same as those presented in Table 2. We did not provide detail clinical information for each case scenario because this study did not aim to assess physicians’ competent in providing ‘correct’ underlying cause of death. We aimed in this study to examine physicians’ opinions on relative role of diabetes as the underlying cause of death (UCD) in different situations. We have added Figure 1 to reveal the spectrum of level of probability for which diabetes being selected as the UCD.

Reviewer’s report
Title:
Version: 1 Date: 11 January 2010
Reviewer: Chalapati Rao
Reviewer’s report:
The authors have carefully analysed their data and have derived meaningful conclusions regarding the intent and preference for certification of diabetes as the underlying cause of death by different groups of medical specialists. I offer the following suggestions:
Minor essential revisions.
1. The survey response rates were only about 25%. The authors should state the range of response rates (and range in number of respondents) from the other three studies, to
give the readers an indication of how much higher were the response rates from this study.

**REPLY:** We have provided the response rates of previous three studies.

**CHANGES TO TEXT: page 10 the last paragraph now reads:**

One of the limitations of this study was that the response rate 26% (549/2076) in this study was relatively low compared with previous studies, which ranged from 56% (168/300) to 91% (274/300) in a European study [3], 86% (124/145) among general practitioners in a Taiwan study [4] and 12% (590/4800) among residents in an US study [5].

2. The authors should include in the discussion some specific recommendations to standardise certification practices between different specialists for deaths among diabetic patients, in terms of ensuring that diabetes is listed somewhere on the certificate, either in Part I or Part II.

**REPLY:** Following the suggestion of the reviewer, we have provided one recommendation to standardise certification practices.

**CHANGES TO TEXT: page 12 the last paragraph now reads:**

In terms of the high percentage of reporting diabetes as the UCD by Taiwanese physicians, especially when the diabetic patients coexisted with AMI and cerebrovascular diseases, we suggest the following recommendation. As the cause-of-death section of death certificate is designed according to preventive medicine, the certifying physicians could evaluate how well the prevention has been done. If diabetes were well control (e.g., HbA1c lower than 7%), we suggest that certifiers could enter diabetes in Part II of the death certificate. On the contrary, if the patient did not control blood sugar level well and it is highly possible that diabetes was the perpetrator of cardiovascular diseases, then the certifiers could enter diabetes in Part I of the death certificate.

Discretionary revisions.

1. They could possibly add a statement to justify their conclusions despite the low response rates, in that the findings closely matched their original hypothesis about the hierarchy in the percentages of case scenarios for which diabetes is reported as the underlying cause.

**REPLY:** We added this point in the conclusion paragraph.

**CHANGES TO TEXT: page 13 the first sentence in the last paragraph now reads:**

Conclusions
Despite the low response rates, the findings of this study concord with the original hypothesis about the hierarchy in the percentages of case scenarios for which diabetes is reported as the UCD, i.e., from ‘direct’ diabetic complications to ‘indirect’ macro-vascular complications to ‘opportunistic’ infection and then ‘independent’ competing causes of death. This study further suggests that internists of different sub-specialties have different opinions on the reporting of diabetes as the UCD, especially when the diabetic patient has a coexisting cardiovascular disease. Because of these certifier preferences, underlying cause statistics are not entirely reliable. Therefore, in addition to standardizing certification practices, the authors could also advocate more research using multiple causes of death, which include analyses that use information from Part II of the death certificate.

2. Also, this study indicates that due to these certifier preferences, underlying cause statistics are not entirely reliable. Therefore, in addition to standardizing certification practices, the authors could also advocate more research using multiple causes of death, which include analyses that use information from Part II of the death certificate.

REPLY: We added this point in the conclusion paragraph.

CHANGES TO TEXT: page 13 the last two sentences in the last paragraph now read:

Conclusions

Despite the low response rates, the findings of this study concord with the original hypothesis about the hierarchy in the percentages of case scenarios for which diabetes is reported as the UCD, i.e., from ‘direct’ diabetic complications to ‘indirect’ macro-vascular complications to ‘opportunistic’ infection and then ‘independent’ competing causes of death. This study further suggests that internists of different sub-specialties have different opinions on the reporting of diabetes as the UCD, especially when the diabetic patient has a coexisting cardiovascular disease. Because of these certifier preferences, underlying cause statistics are not entirely reliable. Therefore, in addition to standardizing certification practices, the authors could also advocate more research using multiple causes of death, which include analyses that use information from Part II of the death certificate.

Version: 1 Date: 22 December 2009
Reviewer: Eric Jougla
Reviewer's report:
Comments to the Authors
Tsung-Hsueh Lu et al. analyse the discrepancies between internists of different specialties
in the medical certification of the causes of death for diabetic patients. The study is based on the certification of seven case histories by a total of 549 physicians. The objective of the research is important because the tendency to report or not diabetes as the underlying cause (UC) of death may have a strong impact on the official national figures on mortality by diabetes. The study is original because few researches have been published in this field.

Major compulsory revisions
1. The sentence (p4) beginning by "One of the limitations..." and ending with "...certifying physician" is not sufficiently clear. For a better understanding, the authors should state more clearly:
   - the different steps in the process of the production of causes of death (1. certification 2. coding according to the ICD rules),
   - that the study deal only with the certification process,
   - that, to avoid certification errors, the certification is not "open", but restricted to different coherent certification models.

These detailed explanations should be added or reformulated in the Methods section.

REPLY: We have deleted the two sentences (the third and fourth sentences in the first paragraph in page 4) “One of the limitations...certifying physician” which are not very relevant to the main points of this study and making readers confusing.

We also added one paragraph in the Methods section to explain the scope of this study which incorporated many important points provided by the reviewer.

CHANGES TO TEXT: page 5 the first paragraph now reads:

Scope of this study
The process of production of the UCD for official mortality tabulation consist two steps: 1) certification by physicians and 2) coding according to the ICD rules. This study dealt only with the certification process. Previous studies using diabetes-related case scenarios to examine physicians’ certification behavior asked the physicians to complete the cause-of-death section on the dummy death certificate for each case scenario [3–5]. We did not use dummy death certificate in this study because many physicians reported incorrect causal sequences [4,15], which could not provide useful information in judging relative role of diabetes in contributing to death. We thus listed all possible correct layouts of each scenario and let the physician choosing the most suitable layout. Furthermore, we did not provide detail clinical information like previous studies did [3–5] we thus could not provide a reference UCD in each scenario.
2. The low response rate (26%) should be analysed more precisely and discussed. The authors should provide this response rate by specialties (data to introduce in the last line of table 1?). They must also discuss the possible impact of this low rate on the results and give the reasons (refusal to participate, difficulties to certify...).

REPLY: We have provided response rates by specialties in the text. We don’t think it is necessary to provide response rate in the table 1. According to the suggestion of reviewer 1 we listed the response rates of previous similar studies. We also added some words on the possible effects of low response rate in the discussion section.

CHANGES TO TEXT: page 5 the last paragraph now reads: With the help of the Diabetes Association, the Society of Cardiology and the Society of Nephrology in Taiwan, questionnaires were mailed to members with sub-specialty qualifications, and three waves of reminders were sent to those who did not return the questionnaire. A total of 549 physicians returned the questionnaire, representing a response rate of 26% (549/2076). The response rate varied with sub-specialty, and was 34% (116/340) for endocrinologists, 19% (190/1000) for cardiologists, and 33% (243/736) for nephrologists.

CHANGES TO TEXT: page 10 the last paragraph now reads: One of the limitations of this study was that the response rate 26% (549/2076) in this study was not very satisfactory compared with previous studies, which ranged from 56% (168/300) to 91% (274/300) in a European study [3], 86% (124/145) among general practitioners in a Taiwan study [4] and 12% (590/4800) among residents in an US study [5]. However, we don’t think there was possible reason to assume that characteristics of non-respondent in particular specialist differed greatly from other specialists (i.e., misclassification bias) and will bias our conclusions.

3. Who have decided of the list of correct layouts for each scenarios (cause of death specialists, physicians.. ?) and why the authors did not choose, for each case history, a reference certification (gold standard). This would have provided interesting elements for a more precise analysis of the results.

REPLY: The list of correct layouts for each scenario was all possible layouts with reasonable causal sequences between reported diseases. We do not think we can choose a reference certification because we did not provide detail clinical information in each scenario and this is not the intent of this study.

CHANGES TO TEXT: page 5 the first paragraph now reads: Scope of this study
The process of production of the UCD for official mortality tabulation consists of two steps: 1) certification by physicians and 2) coding according to the ICD rules. This study dealt only with the certification process. Previous studies using diabetes-related case scenarios to examine physicians' certification behavior asked the physicians to complete the cause-of-death section on the dummy death certificate for each case scenario [3–5]. We did not use dummy death certificates in this study because many physicians reported incorrect causal sequences [4,15], which could not provide useful information in judging the relative role of diabetes in contributing to death. We thus listed all possible correct layouts of each scenario and let the physician choose the most suitable layout. Furthermore, we did not provide detailed clinical information like previous studies did [3–5]; we thus could not provide a reference UCD for each scenario.

4. Results: the authors say that the age distribution did not differ between specialists (but in Table 1, cardiologists aged more than 60 years represent 14% of the total (versus 4 and 3% for the other specialties).

**REPLY:** We revised the manuscript and indicated that responding cardiologists were much older than other specialties.

**CHANGES TO TEXT:** Page 8, the second sentence in the first paragraph now reads:

The characteristics of the responding physicians are shown in Table 1. The age distribution of cardiologists was a little bit different from the other two specialists, which composed more aged respondents. A higher percentage of nephrologists practiced in clinics (most of these clinics were dialysis centers). Only half of the responding physicians had issued a death certificate within the past half-year.

5. Figure 1 presents the main results of the study. It should be replaced by a table giving the different exact numbers and percentages.

**REPLY:** We have presented the main results by a table (Table 2), which shows exact numbers and percentages of each response by specialists.

6. The authors should go further in the discussion of various points:

- the general problem of the status of diabetes (risk factor or disease?),

**REPLY:** In explaining why physicians in Taiwan were more likely to report diabetes as the UCD we have added one paragraph in Discussion section to indicate the status of diabetes management in Taiwan.

**CHANGES TO TEXT:** Page 11, the third paragraph now reads:

One of the possible reasons why Taiwanese physicians reported higher percentage in
selecting diabetes as the UCD was that the status of diabetes management in Taiwan was suboptimal. According to a cohort study of 2446 patients (from 25 diabetic centers) with more than 12 months of diabetes management found that 59% of participants had HbA1c >7.4% [16]. Another nationwide surveys to evaluate the status of diabetes control in 7541 diabetes subjects among 114 accredited Diabetes Health Promotion Centers in Taiwan in 2006 indicated that only 32.4% of subjects whose HbA1c levels was less than 7% [17]. The authors of above mentioned two studies all concluded that the majority of Taiwanese patients had unsatisfactory glycaemic control which may lead to diabetes complications.

- justification of the choice made to propose certification layouts instead of filling a death certificate from scratch,

**REPLY:** We have added one paragraph in Methods section to justify the choice made to propose certification layouts instead of filling a death certificate.

**CHENGES TO TEXT: page 5 the first paragraph now reads:**

**Scope of this study**

The process of production of the UCD for official mortality tabulation consist two steps: 1) certification by physicians and 2) coding according to the ICD rules. This study dealt only with the certification process. Previous studies using diabetes-related case scenarios to examine physicians’ certification behavior asked the physicians to complete the cause-of-death section on the dummy death certificate for each case scenario [3–5]. We did not use dummy death certificate in this study because many physicians reported incorrect causal sequences [4,15], which could not provide useful information in judging relative role of diabetes in contributing to death. We thus listed all possible correct layouts of each scenario and let the physician choosing the most suitable layout. Furthermore, we did not provide detail clinical information like previous studies did [3–5] we thus could not provide a reference UCD in each scenario.

- the impact of the results on the need to train certifiers on the understanding of the concept of UC (versus contributing cause),

**REPLY:** After three paragraphs indicating higher percentage of reporting diabetes as the UCD by Taiwanese physicians we added one paragraph to provide practical suggestion for certifiers how to decide whether to report diabetes as the UCD for diabetic patients died from AMI or cerebrovascular disease.

**CHENGES TO TEXT: page 12 the last paragraph now reads:**

In terms of the high percentage of reporting diabetes as the UCD by Taiwanese
physicians, especially when the diabetic patients coexisted with AMI and cerebrovascular diseases, we suggest the following recommendation. As the cause-of-death section of death certificate is designed according to preventive medicine, the certifying physicians could evaluate how well the prevention has been done. If diabetes were well control (e.g., HbA1c lower than 7%), we suggest that certifiers could enter diabetes in Part II of the death certificate. On the contrary, if the patient did not control blood sugar level well and it is highly possible that diabetes was the perpetrator of cardiovascular diseases, then the certifiers could enter diabetes in Part I of the death certificate.

- the usefulness of the results for the mortality data users,
- the potential of multiple cause of death analysis to avoid the problem of the selection of the UC in the case of diabetic patients.

REPLY: We have added these points in the conclusions section.

**CHANGES TO TEXT: page 13 the last paragraph now reads:**

**Conclusions**

Despite the low response rates, the findings of this study concord with the original hypothesis about the hierarchy in the percentages of case scenarios for which diabetes is reported as the UCD, i.e., from ‘direct’ diabetic complications to ‘indirect’ macro-vascular complications to ‘opportunistic’ infection and then ‘independent’ competing causes of death. This study further suggests that internists of different sub-specialties have different opinions on the reporting of diabetes as the UCD, especially when the diabetic patient has a coexisting cardiovascular disease. Because of these certifier preferences, underlying cause statistics are not entirely reliable. Therefore, in addition to standardizing certification practices, the authors could also advocate more research using multiple causes of death, which include analyses that use information from Part II of the death certificate.

Minor essential revisions
* p4 - "case scenarios" in the methods part and "case histories" in the discussion (p11) ?
  **REPLY: We have uniformly used case scenarios in the revised manuscript.**

* p7 - the sentence "To avoid certification errors, two measures were taken" is not clear
  **REPLY: We did not use “two measures” in the revised manuscript and rewrote the sentence. We hope that it will become much clearer.**

**CHANGES TO TEXT: page 6 the first sentence in the last paragraph now reads:**

To avoid the responding physician reporting incorrect causal sequence on dummy
death certificate for each case scenario, we firstly provided an instruction on cause-of-death certification published by the Department of Health of Taiwan was included along with the questionnaire to remind the physicians how to correctly certify cause-of-death statements. We then used a specific choice form for each case scenario, which listed all possible ‘correct’ layouts of cause-of-death statements. Thus, the chosen causal relationship between diseases and the assigned UCD represented the real intent of the certifying physician.

* p11 - "two measures" - recall which measures

**REPLY: We did not use “two measures” in the revised manuscript and hope that it will not confuse the readers.**

**CHANGES TO TEXT: page 10 the second sentence in the second paragraph now reads:**

One strength of this study was that we simplified the case scenarios and standardized the wordings, explicitly asking the certifying physicians whether diabetes “initiated” the death process, which could reduce the diversity in interpreting the same case scenarios. The second strength was the use of choice form which listed all correct layouts of relationships between causes-of-death for each case scenario thus could avoid the reporting of incorrect causal sequences.

* p11 - response rate: replace "not very satisfactory" by "low"

**REPLY: Revised accordingly**

**CHANGES TO TEXT: page 10 the first sentence in the last paragraph now reads:**

One of the limitations of this study was that the response rate 26% (549/2076) in this study was not very satisfactory compared with previous studies, which ranged from 56% (168/300) to 91% (274/300) in a European study [3], 86% (124/145) among general practitioners in a Taiwan study [4] and 12% (590/4800) among residents in an US study [5].

* p 13 - the sentence:"A study by Murray... " is not clear

**REPLY: We have deleted this paragraph in the revised manuscript.**

* p13 - why a reference to the US handbook and not to the WHO International classification of diseases?

**REPLY: We have deleted this paragraph in the revised manuscript. We also changed the reference 2 from the US handbook into WHO ICD-10 Vol. 2.**