Cerebrovascular disease (CVD), according to WHO, is the leading cause of death in Bulgaria; it reached 284.3 per 100,000 population in 1993. However, differences exist within the country with urban areas having rates between 154 and 242 per 100,000 population, while rural areas have rates of 251–667 per 100,000 population. These differences persist even after age standardization.

Epidemiological studies reveal a long-standing upward trend in CVD mortality over the last 25 years. The validity of CVD mortality statistics is of primary importance because this upward trend could be explained by inaccuracies of the statistical data and so investigation of the validity of CVD mortality statistics is of primary importance.

Many studies have dealt with the validity of mortality statistics. Several have investigated the accuracy of diagnostic information obtained from hospital records. Most studies have used hospital inpatient populations and compared clinical diagnosis with autopsy findings. Other investigations have analysed official mortality statistics or data for certain diagnostic groups, e.g., cancer, heart disease, respiratory disease and CVD.

The aim of this study was to develop and test instruments for assessing the validity of CVD mortality statistics in Bulgaria.

**MATERIALS AND METHODS**

There were three phases to the investigation, each performed according to a specific protocol. The aim of the first phase (Phase A) was to develop and validate an adequate instrument for assessing reliably the presence/absence of CVD in deceased patients.

For every death a structured questionnaire was completed before the autopsy results were received and a decision made on: (1) presence/absence of CVD and (2) underlying cause of death (Figure 1). The questionnaire included data on age, sex, previous and concomitant
FIGURE 1 Research scheme for verification of the questionnaire on CVD in deceased
certain diseases, type of onset and course of the main disease, definite symptoms and signs, and the place and time of death. Most of the questions required a simple yes/no answer. The questionnaire was validated in 325 inpatients aged ≥20 years. Of these, 247 (76%) had CVD, and the remainder had brain tumours, brain trauma, heart disease, including myocardial infarction, and respiratory and other somatic diseases. All underwent autopsy. The mean age of the study group was 65.8 years (58.8% men, 41.2% women).

A file was prepared for every death. It contained (1) the questionnaire, (2) a copy of the case history and the autopsy protocol, (3) brief comment on the reason for accepting the presence/absence of CVD for the particular case, (4) a copy of the death certificate and (5) neurological and nosological expert assessment. For the latter another instrument was constructed which was designed to assess the accuracy of the diagnosis, and the arrangement and completeness of the death certificate checking the coding of the underlying cause of death.

The aim of the second phase (Phase B) of the study was to assess the applicability of the questionnaire in making a valid decision on the presence/absence of CVD in those brought in dead when used by medical personnel other than neurologists (physicians or medical assistants), who usually certify deaths outside hospitals.

This phase was necessary because the questionnaire was initially validated using only autopsy-verified inpatients. However, the same questionnaire was also intended to define the presence/absence of CVD in those who died outside hospital, which is usually the case in Bulgaria: over 50% of CVD patients died at home.

In phase B, for those dying outside hospital, another “twin” copy of each questionnaire completed in phase A was used. These copies contained only information which is feasible to collect for deaths occurring outside hospital. In all 1072 ‘twin’ copies were prepared. According to the research protocol the copies were given to participants in the study team. Using the information provided each team member had to make decisions on: (1) the presence/absence of CVD and (2) the underlying cause of death.

In each phase of the investigation different samples were taken: (1) Phase A—a selective (biased) sample of those dying in hospital; (2) Phase B—a hypothetical sample of those dying outside hospital and (3) Phase C—a random sample from the death certificates in three Regional Centres.

Information in three regions in the country—Blagoevgrad, Burgass and Dobrich. The sample comprised 119 death certificates selected from all those who died aged ≥20 years with CVD or another diagnosis.

According to the protocol (Figure 3) a copy was prepared for each death certificate in the sample. The local neurologists in the three regions were asked to complete a questionnaire for each of the death certificates in the sample from their region using the following sources of information: the medical records (if available from hospital or outpatient clinics and/or data from the certifiers and/or data from the attending physician and/or data from the regional physician/ regional medical assistant and/or data from the relatives of the deceased. Using the questionnaire the local neurologists were asked to make two decisions: (1) the presence/absence of CVD and (2) the underlying cause of death. Thus each file in this phase consisted of: (1) the questionnaire and (2) a copy of the original death certificate. Again, each file was given to the Central Expert Board for (3) expert neurological and nosological assessment.

In comparison with the two previous phases, where the verification of CVD was provided by autopsy findings, the validity of CVD on the death certificate in this phase was provided by a double assessment—one by the local neurologist and the other by the neurologist from the Central Expert Board.

Of the death certificates in the sample, CVD was entered on 111 (93.28%). The mean age of the diseased was 71.81 years; 47.9% of them were males and 52.1% females. Of the total number of deaths, 82.61% of the death certificates were completed for those who died at home, and 17.39% for hospital deaths. Half of the death certificates were completed by attending physicians, 34.8% by physicians from the Emergency Medical Aid Service, and 15.2% by medical assistants.

In each phase of the investigation different samples were taken: (1) Phase A—a selective (biased) sample of those dying in hospital; (2) Phase B—a hypothetical sample of those dying outside hospital and (3) Phase C—a random sample from the death certificates in three Regional Centres.

Statistical analysis of the information from each of the three phases (Figures 1–3) followed the same pattern.

1. Evaluation of the sensitivity and specificity of the developed questionnaire for making a reliable decision on the presence/absence of CVD for those dying in hospital, those dying outside hospital and assessing the validity of CVD mortality statistics.23

2. Evaluation of the validity of the mortality statistics: for establishing the presence/absence of CVD; distinguishing the underlying cause of death and entering it in the correct place on the death certificate; completion...
and arrangement of the death certificate and outlining and coding the underlying cause of death.

RESULTS
Because of different sampling methods, the data obtained from the three study groups have been analysed separately.

Sensitivity and Specificity of the Questionnaire
Phase A. A decision on the presence/absence of CVD was made for 303 (93.23%) of the deceased. For the remaining 6.77% it was stressed that no firm decision could be made (Table 1).

Sensitivity was 0.971 and specificity 0.936; the Index of Jouden was 0.908. The positive predictive value was 0.983 and the negative predictive value was 0.894.

Phase B. A decision on the presence/absence of CVD was made for 989 (92.26%) out of the total of 1072 ‘twin’-copies. For the remaining 7.74% the participants have reported that no firm decision on the presence/absence of CVD was possible (Table 2).
Sensitivity reached 0.941 and specificity was 0.758. The positive predictive value of the questionnaire at this level of application was 0.932 and the negative predictive value was 0.787. The Index of Jouden was 0.700.

Phase C. Out of all 119 death certificates in this sample, the local neurologist assigned 11 (9.1%) to the group in which no firm decision on CVD presence/absence could be made (Table 3). The Central Expert Board assigned only 4 (3.36%) under this heading. Sensitivity was 0.947 and specificity 1.00. The Index of Jouden was 0.970.

After making a decision on presence/absence of CVD in certain deceased, the personnel, who had certified the death, had to complete a death certificate for each case.
The analysis of the validity of the CVD mortality statistics and especially the evaluation of the causes for certain inaccuracies went through the following stages:

(i) Registration of CVD on the death certificate;  
(ii) CVD entered as the underlying cause of death and  
(iii) ICD code number of the underlying cause of death.

**Validity of the Mortality Statistics**  
**Phase A.** A slight reduction in the proportion of true positives was established when CVD was entered on the death certificate (96.77%) (Table 4), entered as the underlying cause of death in the correct place (95.36%) (Table 5) and finally coded according to the ICD (91.75%) (Table 6). On the contrary, the false positives show a corresponding increase—from 3.23% to 8.25%. False negatives, however, increased rapidly from one stage to another—from 5.04% (Table 4) at the initial stage to 13.79% (Table 5) and finally to 38.98% (Table 6).

If supposing that the 325 certificates totalled 100%, then the population of those indicating CVD as the
The underlying cause of death will be 63.58% (189 true positives + 17 false positives). However, when adding the false negatives (46) to the true positives (189), then the true proportion of CVD as the underlying cause of death will reach 72.53%, i.e. an underestimation of CVD by 8.95% according to mortality statistics will be obtained.

Hypothetical sample of patients who died outside hospital. A slight reduction in the percentage of true positives was noted when progressing from the stage of CVD registration on the death certificate to it being specified as the underlying cause of death (Table 7, Table 8). Again, the reverse is valid for false positives. Emphasis should be placed on the slight decrease in the rate of false negatives.

Taking into account the direction of the mode from this study group, owing to the hypothetical nature, the assumption is that 9.57% of the positives and 25.16% of negative cases will be wrongly coded.

Phase C. The proportion of true positives did not change significantly (Tables 9–11). Simultaneously a rapid increase in the percentage of false negatives was established: from 0% at the stage of CVD registration on the death certificate to it being specified as the underlying cause of death (Table 7, Table 8). Again, the reverse is valid for false positives. Emphasis should be placed on the slight decrease in the rate of false negatives.

Taking into account the direction of the mode from this study group, owing to the hypothetical nature, the assumption is that 9.57% of the positives and 25.16% of negative cases will be wrongly coded.

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**Table 7 Registration of CVD on the death certificates**

<table>
<thead>
<tr>
<th>CVD registered on the death certificates</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD according to the autopsy results of the original cases</td>
<td>Yes 735/92.10%</td>
<td>81/29.78%</td>
<td>816</td>
</tr>
<tr>
<td>No 637/79.90%</td>
<td>191/70.22%</td>
<td>254</td>
<td></td>
</tr>
<tr>
<td>Total 798/100%</td>
<td>272/100%</td>
<td>1070</td>
<td></td>
</tr>
</tbody>
</table>

**Table 8 CVD entered as the underlying cause of death on the death certificates**

<table>
<thead>
<tr>
<th>CVD entered as the underlying cause of death on the death certificates</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD assigned as the underlying cause on the death certificates</td>
<td>Yes 709/90.43%</td>
<td>73/25.61%</td>
<td>782</td>
</tr>
<tr>
<td>No 75/9.57%</td>
<td>212/74.38%</td>
<td>287</td>
<td></td>
</tr>
<tr>
<td>Total 784/100%</td>
<td>285/100%</td>
<td>1069</td>
<td></td>
</tr>
</tbody>
</table>

**Table 9 Registration of CVD on the death certificates**

<table>
<thead>
<tr>
<th>Entering CVD on the death certificates</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD according to the double neurological assessment</td>
<td>Yes 104/96.30%</td>
<td>–</td>
<td>104</td>
</tr>
<tr>
<td>No 4/3.70%</td>
<td>7/100%</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Total 108/100%</td>
<td>7/100%</td>
<td>115*a</td>
<td></td>
</tr>
</tbody>
</table>

*a Neurological assessment impossible for four death certificates.

**Table 10 CVD entered on the death certificates as the underlying cause of death**

<table>
<thead>
<tr>
<th>CVD entered as the underlying cause on the death certificates</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD assigned as the underlying cause of death by the Expert Board</td>
<td>Yes 101/97.11%</td>
<td>4/30.77%</td>
<td>105</td>
</tr>
<tr>
<td>No 3/2.88%</td>
<td>9/69.23%</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Total 104/100%</td>
<td>13/100%</td>
<td>117*a</td>
<td></td>
</tr>
</tbody>
</table>

*a Expert assessment impossible for two death certificates.

**Table 11 Outlining and coding the underlying cause of death**

<table>
<thead>
<tr>
<th>CVD according to the ICD code given by the Expert Board</th>
<th>Yes</th>
<th>No</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVD according to the ICD</td>
<td>Yes 60/96.77%</td>
<td>47/82.46%</td>
<td>107</td>
</tr>
<tr>
<td>No 2/3.23%</td>
<td>10/17.54%</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Total 62/100%</td>
<td>57/100%</td>
<td>119</td>
<td></td>
</tr>
</tbody>
</table>

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estimation of CVD of 37.81%. The quality of death certificate completion in the three phases of the investigation was estimated by the nosologist from the Central Expert Board according to three previous stated definitions; these referred to completeness, systematic and logical arrangement of the respective diagnoses in the correct place on the certificate considered to be direct, underlying and contributory causes of death, in compliance with WHO requirements (Table 12).

DISCUSSION

The indices of sensitivity and specificity of the questionnaire obtained at each level of application show that a reliable decision on the presence/absence of CVD at the time of death is possible. Moreover, sensitivity remains at almost the same level during the three phases of the study. Specificity is considered lower when the questionnaire is applied to those who died outside hospital and when used by non-neurologists, although it is still within reasonable limits.

The proportions of cases defined as ‘uncertain’ have similar values, although there is a slight increase between the study group who died in hospital compared to the sample of death certificates.

In relation to mortality statistics from CVD, the results show that inaccuracies increase from the initial stage of establishment and registration of CVD to the next stage of accepting it as the underlying cause of death and entering it in the correct place on the death certificate. This is predominantly due to the medical personnel responsible for certifying death. It was found that they are either inexperienced or they do not correctly apply the WHO requirements for differentiating the underlying cause of death and for completing death certificates. Moreover, the proportion of death certificates that are, either incomplete and/or unsystematically filled in, is high; this represents a potential source of inaccuracy at the next stage and leads to an incorrect ICD coding. As has already been demonstrated, most of the inequalities are established at the final stage of estimation of mortality statistics from CVD.

The preliminary results from this investigation show underestimation rather than overestimation of CVD as an underlying cause of death in Bulgaria.

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