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ORIGINAL ARTICLE

Comparison of the validity of stroke diagnoses in a medical quality register and an administrative health register

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Abstract

Aims: Health registers are essential sources of data used in a wide range of stroke research, including epidemiological, clinical and healthcare studies. Regardless of the type of register, the data must be of high quality to be useful. In this study, we investigated and compared the correctness and completeness of the Norwegian Patient Register (an administrative health register) and the Norwegian Stroke Register (a medical quality register for acute stroke). *Methods:* We reviewed the medical records for 5192 admissions to hospital in 2012 and defined cases of stroke in the two registers as true positive, false positive, true negative or false negative. We calculated the sensitivity, specificity, positive predictive value (PPV) and negative predictive value with 95% confidence intervals assuming a normal approximation of the binomial distribution. *Results:* The Norwegian Stroke Register was highly correct and relatively complete (sensitivity 88.1%, specificity 100% and PPV 98.6%). The Norwegian Patient Register was more complete, but less correct, when we included both the main and secondary diagnoses of stroke (sensitivity 96.8%, specificity 99.6% and PPV 79.7%); restricting the analyses to the main diagnoses of stroke resulted in less complete and more correct registrations (sensitivity 86.1%, specificity 99.9% and PPV 93.5%). ***Conclusions:*** **The Norwegian Stroke Register and the Norwegian Patient Register are adequately complete and correct to serve as valuable sources of data for epidemiological, clinical and healthcare studies, as well as for administrative purposes.**

Key Words: *Health registers, stroke diagnoses, correctness, completeness, validity, data quality*

Introduction

Administrative health registers established to monitor and manage healthcare services are often used as a basis for national statistics and can serve as an easily obtainable source of data for epidemiological studies. Medical quality registers, in contrast, are usually based on pre-defined sets of criteria for specific medical conditions or procedures. They typically include detailed information about the medical status of patients and the treatment received in hospital, in addition to several outcome measures. Their purpose is to contribute to improving the quality of care, establishing and monitoring clinical guidelines and to serve as a resource for research by providing comprehensive data on the patient group of interest.

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Register-based epidemiological studies are often of high impact because they typically have high statistical power and are free of bias from the self-selection of participants; this is regarded as a major problem in observational studies. However, the register data must be of high quality to be useful. Two frequently cited data quality attributes are completeness and correctness. Data completeness is the extent to which all the necessary data that could have been registered have actually been registered, whereas data correctness is the extent to which the registered data are in conformity with the truth [1,2].

We investigated and compared the correctness and completeness of a national administrative health register, the Norwegian Patient Register, and a national medical quality register for acute stroke, the Norwegian Stroke Register.

Methods

Norwegian Stroke Register

The Norwegian Stroke Register (hereafter referred to as the Stroke Register) was established in 2004 as a medical quality register in the Central Norway region and was approved as a national compulsory register in 2012 following the foundation of the Norwegian Cardiovascular Disease Registry [3]. Since 2012, all Norwegian hospitals have been obliged to enter into the Stroke Register medical data on all residents ⩾18 years of age admitted to hospital with acute stroke according to the World Health Organization (WHO) criteria (ICD-10 codes I61, I63 and I64) [4]. Patients admitted to hospital with acute stroke after a traumatic head injury, stroke related to intracranial tumours and ischaemic stroke following a subarachnoid haemorrhage are not included in the Stroke Register. Until 2014, hospital admissions more than seven days after the onset of stroke were also excluded.

The register contains person-identifiable information on the patients' functional status before the stroke, past medical history, the use of drugs prior to admission and at discharge, the clinical findings on admission to hospital, diagnostic procedures, treatment received during hospitalization, and dates and times for the onset of stroke, admission to hospital and discharge. Data are initially registered locally on paper forms at the hospitals by dedicated and trained doctors and nurses, who subsequently enter data into the Stroke Register using a web-based form.

Norwegian Patient Register

The Norwegian Patient Register (NPR) is a national administrative health register containing person-identifiable information on all admissions to hospital, both public and private, included in the public reimbursement policy in Norway since 2008. The register is used as basis for reimbursement to hospitals, hospital activity statistics and for research. For admissions to hospital, the NPR contains demographic, administrative and health-related data, such as the dates of admission and discharge, the main and an unlimited number of secondary discharge diagnoses according to ICD-10, and codes for diagnostic and therapeutic procedures. Data are extracted from the patient administrative systems of hospitals based on a predefined set of rules and cumulative data are then transferred to the NPR on a monthly basis.

Study population

We included all admissions to hospital with a diagnosis of acute stroke in the Stroke Register (n=870) and the NPR (n=1253) from 1 April to 31 December 2012 in four hospitals in Central Norway (St. Olav's University Hospital, Levanger Hospital, Ålesund Hospital and Kristiansund Hospital). The total number of cases of stroke was 1259. The four hospitals were chosen as they had reported data to the Stroke Register since 2004 and had, by 2012, acquired experience and established well-functioning data collection routines. All patients were over the age of 18 years with no upper age limit. We defined acute stroke as haemorrhagic stroke (ICD-10 code I61), ischaemic stroke (ICD-10 code I63) and unspecified stroke (ICD-10 code I64).

To detect possible cases of stroke not included in the registers (false negative (FN) strokes) and to obtain an estimate of true negative (TN) strokes, we also investigated all admissions to hospital during the study period with the following main diagnoses: (a) transient ischaemic attack (TIA) (ICD-10 code G45) (n=417); (b) stroke sequelae (I69) or other cerebrovascular disease such as non-traumatic intracranial bleeding (I62), occlusion or stenosis of pre-cerebral or cerebral arteries without stroke (I65 and I66) and other specific cerebrovascular diseases (I67 and I68) (n=177); and (c) stroke mimicking diagnoses such as epilepsy (G40), migraine (G43), headaches (G44), vertigo (R42), delirium (F05) and benign or malignant neoplasms of the brain (D33, D43 and C71) (n=867). In addition, we included a random sample of 25% of admissions to hospital with these disorders as any of the secondary diagnoses (n=669). Finally, we included a 3.45% random sample (n=1803) of all other admissions to hospital during the study period. Figure 1 shows a flow chart and graphic presentation of the sample.

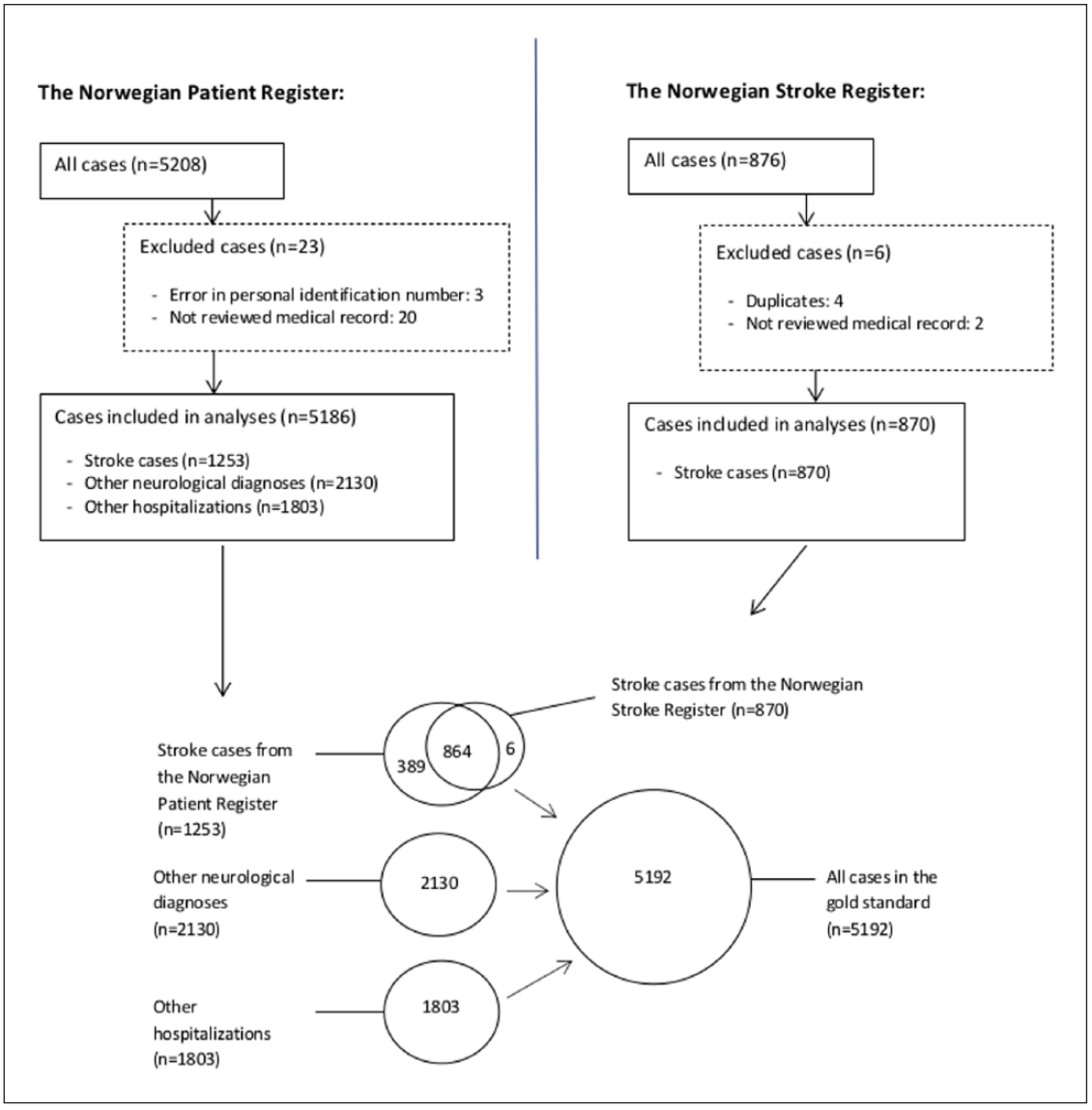

Figure 1. Flow chart and graphic presentation of the sample.

Review of medical records

Hospital medical records were reviewed to establish a gold standard. The review was performed for the whole study population (n=5192 admissions to hospital) by two experienced stroke nurses and one of the authors (TV) according to a pre-defined form. The reviewers had access to all relevant information in the electronic medical records, such as medical history, clinical presentation, and findings on clinical, laboratory and imaging examinations. Diagnostic images were not re-interpreted. Based on the WHO criteria for acute stroke [4], the gold standard was established by classifying patients as probable stroke, possible stroke or no stroke. Reviewers were blinded to the registrations in the NPR and the Stroke Register during the review. All cases classified as possible stroke were re-examined by a stroke doctor to determine whether a stroke had occurred; however, a few cases (n=12) remained uncertain even after the second review. These cases were categorized as 'not stroke' in our analyses.

Following the initial data analyses, all misclassified cases (false positive (FP) and FN) in the Stroke Register were reviewed again by two of the authors (GR and TW) with expert knowledge of the Stroke Register's inclusion criteria.

Statistical analysis

On the basis of the established gold standard we classified cases in the two registers as true positives (TP), true negatives (TN), FP or FN. We defined data

Table I. Total number of admissions to hospital, admissions to hospital included in the study population and weight by discharge diagnoses.

	Total number of admissions to hospital[a]	No. (% of total) admissions to hospital in the study population	Weight
Cases of stroke (ICD-10, codes I61, I63 and I64)	1259	1259 (100)	1
Other neurological diagnoses			
TIA (ICD-10 codes G45)			
Primary diagnosis	417	417 (100)	1
Secondary diagnosis	316	79 (25)	4
Stroke sequelae or other cerebrovascular diseases (ICD-10 codes I62, I65, I66, I67, I68 and I69)			
Primary diagnosis	177	177 (100)	1
Secondary diagnosis	1396	349 (25)	4
Stroke mimics (ICD-10 codes G40, G43, G44, R42, F05, D33, D43 and C71)			
Primary diagnosis	867	867 (100)	1
Secondary diagnosis	964	241 (25)	4
Other admissions to hospital	52,233	1803 (3.45)	28.97
Total	57,629	5192	

[a]Total number of admissions to hospital for residents ⩾18 years discharged from St Olav's University Hospital, Levanger Hospital, Ålesund Hospital and Kristiansund Hospital during the period 1 April to 31 December 2012. Data source: Norwegian Patient Register.

completeness as equivalent to the sensitivity (TP/(TP+FN)), i.e. the proportion of cases of true stroke according to the gold standard that were also present in the registers. We defined data correctness as equivalent to the positive predictive value (PPV) (TP/(TP+FP)), i.e. the proportion of cases of stroke present in the registers that were cases of true stroke according to the gold standard [2]. In addition, we calculated the specificity (TN/(TN+FP)), i.e. the proportion of non-stroke cases correctly identified as such, and the negative predictive value (NPV) (TN/(TN+FN)), i.e. the proportion of non-stroke cases not present in the registers. The 95% confidence intervals (CI) were calculated assuming a normal approximation of the binomial distribution.

When calculating the estimated measures of sensitivity, specificity, PPV and NPV, we applied weights based on the proportion of sampled cases in each category. For instance, we sampled 25% of all admissions to hospital with TIA as any secondary diagnosis, hence any case of stroke detected among these cases was given a weight of 4 in our analyses to estimate how many cases of stroke we would have found if we had investigated all admissions to hospital in this group. Table I provides an overview of the sample proportions.

All statistical analyses were performed using IBM SPSS Statistics version 21.

This study was approved by the Norwegian Data Protection Authority and the Norwegian Directorate of Health and did not require patient consent. The regional research ethical review board considered the study to be a quality enhancement study and thus referred our application to the Directorate of Health and the Data Protection Authority.

Table II. Distribution of true and false positives and negatives in the Stroke Register and the Norwegian Patient Register according to classifications in the gold standard.

	Gold standard[a]		
	Stroke	No stroke	Total
Norwegian Stroke Register			
Stroke	858 (858)	12 (12)	870 (870)
No stroke	107 (116)	4215 (56,643)	4322 (56,759)
Total	965 (974)	4227 (56,655)	5192 (57,629)
Norwegian Patient Register (main and secondary diagnoses combined)			
Stroke	999 (999)	254 (254)	1253 (1253)
No stroke	21 (33)	3918 (56,343)	3939 (56,376)
Total	1020 (1032)	4172 (56,597)	5192 (57,629)
Norwegian Patient Register (main diagnoses only)			
Stroke	883 (883)	61 (61)	944 (944)
No stroke	130 (142)	4118 (56,543)	4248 (56,685)
Total	1013 (1025)	4179 (56,604)	5192 (57,629)

[a]Numbers in parentheses are estimations based on weights (see Table I) used when calculating sensitivity, specificity, positive predictive value and negative predictive value.

Results

Cases of stroke in the Norwegian Stroke Register

We found 858 TP cases of stroke and 12 FP cases of stroke in the Stroke Register. Furthermore, we identified 107 cases of stroke not registered in the Stroke Register (Table II). Estimated measures of completeness and correctness of the Stroke Register indicated a sensitivity of 88.1% (95% CI 86.4–90.4%), a specificity of 100% (95% CI 100–100%) and a PPV of 98.6% (95% CI 97.4–99.4%) (Figure 2).

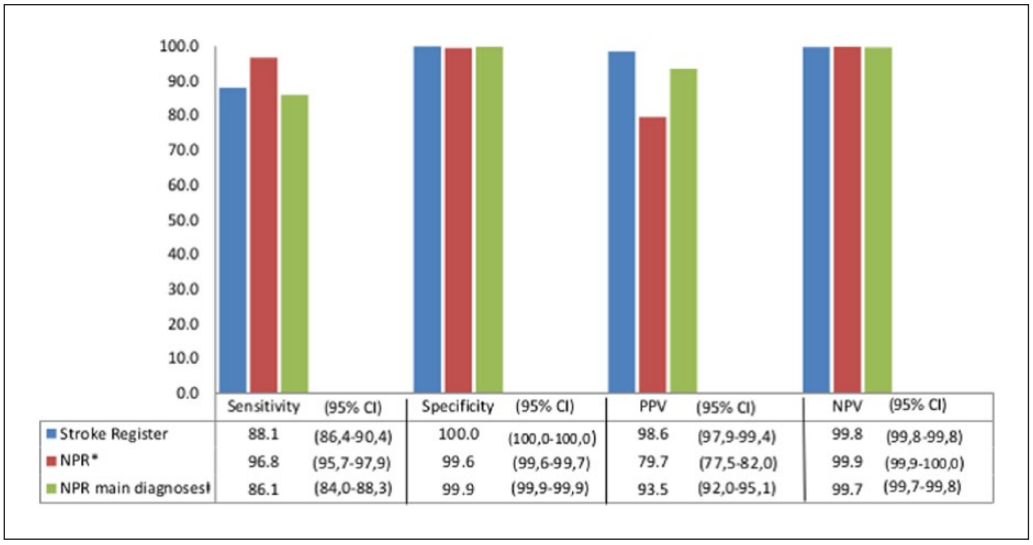

Figure 2. Estimated sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) with 95% confidence intervals (CI) for the Norwegian Stroke Register and the Norwegian Patient Register (NPR) (main and secondary diagnoses combined, and main diagnoses only).
*The Norwegian Patient Register, main and secondary diagnoses combined.
†The Norwegian Patient Register, main diagnoses only.

Table III. Characteristics of the 254 false positive cases of stroke in the Norwegian Patient Register.

	No. (%) all cases of stroke	No. (%) main diagnoses	No. (%) secondary diagnoses
Transient ischaemic attack	13 (5.1)	9 (15.0)	4 (2.1)
Previous stroke	92 (36.2)	11 (18.3)	81 (41.8)
Rehabilitation after stroke	71 (28.0)	17 (28.3)	54 (27.8)
Not fulfilled the WHO stroke criteria	38 (15.0)	8 (13.3)	30 (15.5)
Stroke mimics	5 (2.0)	3 (5.0)	2 (1.0)
Error in coding	13 (5.1)	2 (3.3)	11 (5.7)
Old stroke not previously diagnosed	3 (1.2)	–	3 (1.5)
Other	19 (7.5)	10 (16.7)	9 (4.6)
Total	**254 (100)**	**60 (100)**	**194 (100)**

Patient characteristics are based on information gathered from the hospital medical records during the review process.

The majority of the FN cases of stroke in the Stroke Register (87.9%) had a diagnosis of stroke in the hospital discharge note (data not shown). There was no difference with regard to hospital, sex or age group between the FN and TP cases. However, there was a substantially higher in-hospital mortality among the FN cases compared with the TP cases (25.2 and 6.6%, respectively; χ^2 test $p<0.001$).

Cases of stroke in the Norwegian Patient Register

When investigating both main and secondary diagnoses of acute stroke in the NPR, we identified 999 TP and 254 FP cases of stroke according to the gold standard (Table II). A total of 21 defined cases of stroke in the gold standard were not registered with a stroke diagnosis in the NPR and were categorized as FN.

The results indicated a sensitivity of 96.8% (95% CI 95.7–97.9%) and a specificity of 99.6% (95% CI 99.6–99.7%). The PPV was lower: 79.7% (95% CI 77.5–82.0%) (Figure 2). Restricting the analyses to only the main diagnoses of acute stroke, however, we found that the sensitivity was lower and the PPV was higher: 86.1% (95% CI 84.0–88.3%) and 93.5% (95% CI 92.0–95.1%), respectively. The specificity remained almost perfect at 99.9% (95% CI 99.9–99.9%).

The majority of the FP cases of stroke were registered in the NPR with a secondary diagnosis of stroke. The most common cause of FP misclassification were cases of previous stroke that often should have been coded as sequelae (36.2%) and admission to hospital for rehabilitation after stroke (28.0%) (Table III). In 38 (15.0%) cases we found that the description in the medical records did not fulfil the WHO stroke criteria; these cases of stroke were characterized by, for

instance, focal symptoms lasting less than 24 hours and no evidence of stroke found on nuclear magnetic resonance imaging or computed tomography.

Discussion

We found that the Stroke Register was highly correct (PPV 98.6% and specificity 100%) and relatively complete (sensitivity 88.1%). The NPR was more complete (sensitivity 96.8%), but less correct (PPV 79.7% and specificity 99.6%) when we included both main and secondary diagnoses of stroke. When restricting the analyses to the main diagnoses of stroke, however, the results for the NPR became more similar to the results in the Stroke Register: less complete (sensitivity 86.1%) and more correct (PPV 93.5% and specificity 99.9%) registrations.

Although we only found a few FP cases of stoke in the Stroke Register, approximately 11% of all cases of stroke defined in the gold standard were not included in the Stroke Register and were thus FN cases. Nearly 88% of these cases were registered with a diagnosis of acute stroke in the hospital discharge note; 10% had a diagnosis of TIA. Of particular interest, there was substantially higher in-hospital mortality among the patients with an FN diagnosis compared with the patients with a TP diagnosis (25.2 and 6.6%, respectively), indicating that patients with fatal stroke are more likely to be missed in the registration process. This may be due to the death of the patient before they could be transferred to a stroke unit (where most dedicated registrars work), or to an initial uncertainty leading to a delayed diagnosis of stroke. Establishing routine inspections of the patient administrative systems in hospitals to identify all possible strokes with a particular emphasis on fatalities will probably improve the completeness in the Stroke Register. As mortality is one of the most important quality indicators in a healthcare quality register, we recommend that future studies should analyse the mortality data in the Stroke Register in depth. Overall, the misclassifications in the Stroke Register appear to be largely due to errors in collecting and reporting data to the register.

Approximately 64% of the FP cases of stroke in the NPR appeared to be patients who had had a stroke previously; almost half of these patients were in rehabilitation after a recent episode of stroke, but were given a diagnostic code for acute stroke in the hospital medical records. To a large extent, we found that the contents in the NPR matched the contents in the hospital medical records and, consequently, that the misclassifications mainly were due to factors affecting the coding process at the hospitals and not to register-specific data collection procedures. Norway relies on a diagnosis-related group reimbursement system. It can be questioned whether such reimbursement systems influence the coding practice; however, we did not investigate the issue in this study. Nevertheless, it is likely that the reimbursement system is an incentive to accomplish completeness in registrations. There is also a theoretical possibility that it inspires excessive coding, contributing to the relatively large number of FP cases of stoke found among the secondary diagnoses in the NPR, but further investigations are needed to resolve this matter.

Considering the different data collection procedures, these findings are not unexpected. The administrative health register collects data by automatic extraction from the patient administrative systems of the hospitals, which ensures completeness based on what is, in fact, registered at the hospitals. The medical quality register uses a manual data collection procedure involving an initial screening by trained personnel before reporting cases into the register, thus largely avoiding the problem with FP cases of stroke. Manual reporting systems, however, make complete registrations demanding to achieve, as they require personnel, resources, knowledge and motivation to collect the data.

Several studies have investigated the validity of stroke diagnoses in hospital discharge registers or national administrative health registers [5–13], with results indicating sensitivity in the range 70–90% and PPV in the range 60–100%, placing our results for the NPR in the upper range of these studies. To our knowledge, only three studies have investigated the validity of a stroke-specific quality register. In a 1992 study, a sensitivity of 96% and a PPV of 100% were reported for the Northern Sweden MONICA Registry [14], whereas a recent study found that the Danish Stroke Registry had a sensitivity of 97% and a PPV of 90% [15]. The sensitivity and PPV of the Michigan Stroke Registry were reported to be 68.8 and 87.7%, respectively, in a 2014 study [16]. The results from the present study indicate a lower sensitivity for the Stroke Register than in these two European studies and a higher sensitivity than that found in the US study. However, differences in sample attributes, sample sizes, gold standards and methods of validation make direct comparisons between studies difficult.

The strength of this study is that it is population-based and considerable in size, covering all cases of acute stroke at four different hospitals in Central Norway during the study period. Our study design made it possible to estimate the number of FN cases of stroke in the study period. However, the gold standard was not classified according to stroke subtypes and, consequently, we could not assess the validity of the stroke subtypes. We did not perform an

inter-rater reliability assessment, yet it is known that different raters may conclude or interpret information in medical records differently [17,18]. The results from this study are based on the information available for our raters through retrospective review of the medical records. The study included all admissions to hospital during a defined time period from a university hospital, a large regional hospital and two local hospitals in Central Norway. This region is representative of the Norwegian population in most respects, such as age and gender distribution, morbidity and mortality. However, this does not necessarily mean that the coding practice in the four hospitals studied can be generalized to all hospitals in Norway.

Conclusions

The administrative health register and the medical quality register displayed similar results with regard to completeness and correctness. Both the Stroke Register and the NPR may serve as valuable sources of data for epidemiological, clinical and healthcare studies, as well as for administrative purposes.

The misclassifications in the Stroke Register were mainly related to data collection procedures, whereas the contents of the NPR reflected to a large extent the coding in the hospital medical records. More complete data in the medical quality register may be achieved by improved compliance with the data collection protocol with a particular focus on fatalities, whereas more correct data in the administrative register requires a focus on coding procedures at the hospitals.

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Conflict of interest

None declared.

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