Quality assurance of the Western Denmark Heart Registry, a population-based healthcare register

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ABSTRACT

INTRODUCTION: During the past decade, the mandatory population-based healthcare database, the Western Denmark Heart Registry (WDHR), has provided the data for several research projects. As in most clinical registries, the data quality has not been validated thoroughly. This study was undertaken to evaluate the quality of registrations in the WDHR.

METHODS: The audit supervised procedures from involved departments that were performed in 2013. An experienced research nurse completed data collection and an experienced consultant evaluated the agreement between the WDHR and patient records. Indistinct data from patient records were determined after consulting a specialist from the department in question. Patient files were double-checked in case of disagreements between the involved systems.

RESULTS: The total proportion of errors in the referral date was 16.4% in surgery, 9.8% in percutaneous invasive procedures (PCI), 16.1% in coronary angiography (CAG) and 19.5% in computed tomography (CT)-CAG, while the errors in in-hospital dates were slightly lower. In the cardiac surgery registries, the proportion of errors was 3.3% in the history and EuroSCORE module, 1.0% in the procedure module and 2.8% in the discharge module. For PCI procedures, the errors were 3.8% in the history module, 2.2% in the procedure module and 1.6% in the discharge module. CAG and CT-CAG had slightly more errors.

CONCLUSIONS: The quality control of the WDHR revealed that overall data errors were lower than 3% and for procedure-specific registrations including indications and complications, the error rate was below 1.5%. The WDHR is valid and may be used in contemporary epidemiological studies.

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Clinical databases are important tools in quality assurance, treatment development and research. In 1993, the Danish Health Authority initiated the implementation of a national Heart Plan [1] to improve the treatment quality of cardiac diseases. Subsequently, a national heart register and the Western Denmark Heart Registry (WDHR) were established in 1999. Selected variables in the WDHR and a comparable database covering Eastern Denmark are transferred to the national Danish Heart Registry. The WDHR includes data on all adult patients in Western Denmark referred for coronary angiography (CAG), percutaneous coronary intervention (PCI) or cardiac surgery [1]. From 2008, computed tomography coronary angiography (CT-CAG) has also been included.

The WDHR covers the entire population of Western Denmark, approximately 3.0 million inhabitants, and is financed by the public owners. Owing to the use of the unique Civil Personal Registration (CPR) number [2] assigned to all Danish citizen and immigrants, it is possible to perform record linkage at the individual level across all Danish health registries [3, 4] and to obtain information on hospital admissions [5], causes of death [6] and prescribed medications [7]. The CPR system has kept records on gender, date of birth, residence, emigration date and vital status changes since 1968. Thus, Denmark has optimal opportunities for conducting registry-based research. This is further strengthened by equal access to treatment, as the Danish health service provides tax-financed universal healthcare to all Danish citizens guaranteeing free access to care at general practitioners and hospitals [1-3].

The WDHR collects referral and anamnestic information, procedural information like the use of contrast and devices (balloons, stents) in PCI, grafts, valve types, anaesthesia and intensive care together with registration of complications.

The WDHR has been the source of a comprehensive number of research projects within cardiology [8-10], cardiac surgery [11-13] and anaesthesiology [14-16], amounting to approximately 50 peer-reviewed publications. The purpose of the present study was to audit the quality of the data registered in the WDHR.

METHODS

Structure and data quality enforcement

Data regarding cardiac surgery originates from three departments, CAG from eight departments, PCI from three departments and CT-CAG from six departments. One private hospital contributes with very few procedures and was not included in the audit.

ORIGINAL ARTICLE

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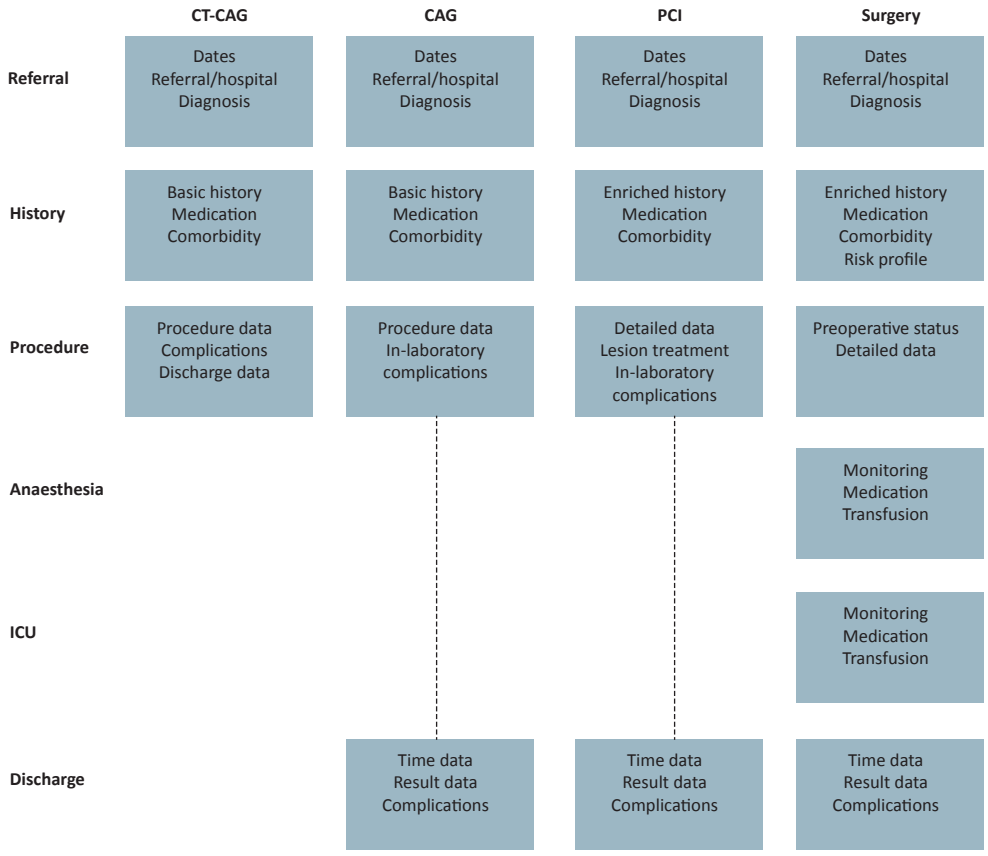
FIGURE 1

The data entry forms. Patient information based on civil registration number. Imported from the civil personal registration system – civil status, address.



CAG = coronary angiography; CT-CAG = computed tomography-coronary angiography; ICU = intensive care unit; PCI = percutaneous invasive procedures.

The doctors responsible for the individual procedures enter data into a web-based data system using the civil registration numbers. The proportion of registrations is aligned annually with the Danish National Patient Registry [7], and agreement has exceeded 98% in recent years. The overall data quality is monitored and reported in quarterly and annual reports. The data entry forms are shown in **Figure 1**. The data quality is confirmed by validation rules at data entry, pre-specified limits and correct sequence of time data. Further validations and random spot checks are performed through research projects and by the data management group [11]. However, the system has a potential inherent error as data from the referral and history module may be transferred from visit to visit if the doctors copy the previously registered by a single "Accept" procedure. Thus, incorrect data may not be corrected and changes in patients' status since their last visit may not be recorded.

Despite the comprehensive use of WDHR data in research and quality assurance, only minor audits have been conducted [11].

Audit procedure

Due to minor changes of the database in 2012 and 2014, the audit concerned data from procedures performed in 2013. The study was conducted as a quality assurance project at the involved departments. No patient consent or approval from the local ethics committee was required according to Danish law.

The power calculation was based on the premise that a 3% error in registration is acceptable. To detect a difference from 3% to 6%, the total number needed with $\alpha = 0.05$ and $\beta = 0.10$ was 454. Thus, 128 (5%) of all surgical procedures, 164 PCI (3%) and 174 CAG (1%) were included. The CT-CAG was not originally part of the audit; still, 190 procedures were included. The proportion of included procedures was equal for all departments. All variables transferred to the Danish Heart Registry and selected variables of interest for research and development were evaluated. An electronic randomisation module randomly selected the procedures for the audit among all procedures from 2013.

Evaluation principle

An experienced research nurse completed the data collection, and an experienced consultant evaluated the agreement between the WDHR and the patient records. Indistinct data from patient records were determined by consulting a specialist from the specific department. Patient records were double-checked in case of disagreement between the WDHR and patient files.

Most variables in the WDHR are mandatory. A few are optional, mainly for technical and logistic reasons. Furthermore, the patient records do not necessarily contain information relating to the relevant WDHR variables. Thus, one of six results were possible (**Table 1**); when information was available in the patient records as well as in the WDHR, the distinction was simply correct or erroneous. If WDHR data could not be verified from the patient records (line five), they were considered "correct". If a variable was recorded as unknown in the WDHR (line six), the patient record was always consulted for research and development purposes. Therefore, it was considered correct in the audit. Divergence between the WDHR and the patient records is presented as a percentage of the total differences, percentage with no information in the WDHR and percentage of errors.

Values ± 1 day were accepted as correct for referral, procedure and discharge date, respectively, except referral dates for CT-CAG, where ± 5 days were accepted.

Smoking is registered in the WDHR as current, previous, never or unknown. These categories are not followed consistently in the patient records. Consequently, the audit considered smoking as current smoker or non-smoker. Diabetes was considered as without, insulin- and non-insulin treated . An error was present if height and weight diverged by more than 5 kg/cm. Ejection fraction was considered erroneous if data diverged by more than 5%. The creatinine level is registered in the CT-CAG module. Values ± 10 µmol/l were considered correct. All other data in the history module and the EuroSCORE module were dichotomous (yes/no) registrations.

Values within ± 10 min. were accepted as correct in catheter insertion in PCI/CAG, anaesthesia induction time in surgical procedures and the duration of extracorporeal circulation time (ECC), and ± 5 min. was accepted as correct for cross clamp time (CC). The acceptable deviation in the ICU discharge time was 2 h.

The PCI and CAG module have six different procedure indications regarding ST-segment elevation myocardial infarction (STEMI) and one for unstable angina, but it may be difficult to distinguish between these indications. Thus, all these indications were considered correct if the patient was treated for STEMI or unstable angina. Similarly, control after coronary artery bypass grafting (CABG) was considered correct when the patient files described stable angina and conversely. Cases were accepted as correct when "Other" was registered in the WDHR even though a specific indication was available according to the patient records. Kiloelectron volt (keV) and radiation in CT-CAG procedures were considered correct if data diverged by less than ± 10 keV/µGray × cm.

TABLE 1

The possible outcomes of audited registrations.

WDHR	Patient records	Result audit
Yes	Yes	Correct
No	No	Correct
No	Yes	Error
Yes	No	Error
Yes or no	No info	Likely correct
No info	Yes or no	Likely correct

WDHR = West Danish Heart Registry.

Trial registration: not relevant.

RESULTS

A total of 225,248 CAG, 50,750 CT-CAG, 85,633 PCI and 38,841 surgical procedures were registered in the WDHR by the end of 2015.

Referral

The total proportion of referral date errors was 16.4% for surgery, 9.8% for PCI, 16.1% for CAG and 19.5% for CT-CAG. The total proportion of errors concerning in-hospital date was 6.3%, for surgery, 4.3% for PCI and 8.0% for CAG. A negligible number of dates registered in the WDHR could not be verified in the patient records.

Cardiac surgery

The number of differences and error percentages are given in **Table 2**. Overall, the fraction of errors in the history and EuroSCORE module was 3.3% with the largest fraction of errors in left ventricular ejection fraction (11.8%). Errors in the procedure-related factors in the EuroSCORE module ranged from 0.0% to 0.8%.

All surgical procedure dates were registered correctly. Similarly, all CABG procedures were registered correctly, except for a small difference in the numbers of peripheral anastomosis. One patient (0.8%) was incorrectly registered with aortic valve surgery, none with mitral valve surgery (MVR) and one patient (0.8%) with procedures other than the above. Two patients had errors in the biological/mechanical valve, while one MVR had an error regarding replacement/repair. In patients undergoing other procedures than those mentioned above, disagreement was found in one case. No error

TABLE 2

Audit result of cardiac surgery procedures divided into modules.

Factor	Audit difference, n	No data, n		Errors, n (%)
		WDHR	file	
History and EuroSCORE module				
Smoking	14	0	9	5 (3.9)
Diabetes mellitus	10	1	5	4 (3.1)
Height	21	12	5	4 (3.1)
Weight	19	9	5	5 (3.9)
Chronic obstructive lung disease	8	0	0	8 (6.3)
Peripheral artery disease	9	2	0	7 (5.5)
Previous central nervous disease	10	5	0	5 (3.9)
Previous surgery	6	3	0	3 (2.4)
S-creatinine concentration > 200 µmol/l	6	0	5	1 (0.8)
Active endocarditis	3	3	0	0
Critical preoperative state	5	0	0	5 (3.9)
Unstable angina pectoris	33	29	0	4 (3.1)
Left ventricular function	26	0	11	15 (11.8)
Recent myocardial infarction	9	0	2	7 (5.5)
Acute surgery	1	0	0	1 (0.8)
Procedure other than CABG	1	0	0	1 (0.8)
Aortic surgery	0	0	0	0
VSD surgery	19	0	18	1 (0.8)
Procedure and perfusion modules				
Procedure date	0	0	0	0
Coronary artery bypass grafting	0	0	0	0
No of peripheral grafts	2	0	0	2 (1.6)
Aortic valve surgery: AVR	1	0	0	1 (0.8)
Procedure code AVR	2	0	0	2 (4.3)
Mitral valve	1	0	0	1 (6.3)
Other procedures	1	0	0	1 (4.8)
On-pump surgery	0	0	0	0
Extracorporeal circulation time	18	15	0	3 (2.7)
Cross clamp time	17	15	0	2 (1.8)
Anaesthesia and ICU, anaesthesia start	6	5	0	1 (0.8)
Inotropes during anaesthesia	13	2	0	11 (8.7)
Haemostats during anaesthesia	17	6	0	11 (8.7)
Referral time to ICU	6	2	0	4 (3.1)
Inotropes in ICU	14	2	0	12 (9.4)
Postoperative bleeding	16	6	0	10 (7.9)
Extubation time	23	15	0	8 (6.3)
Discharge time from ICU	11	4	0	7 (5.5)
Discharge module				
Perioperative stroke	6	5	0	1 (0.8)
Sternal infection	5	1	1	3 (2.4)
Re-surgery due to bleeding	3	1	0	2 (1.6)
Dialysis	6	1	3	2 (1.6)
Myocardial infarction	2	1	0	1 (0.8)
Discharge date	14	0	0	12 (9.4)

AVR = aortic valve replacement; CABG = coronary artery bypass grafting; ICU = intensive care unit; VSD = ventricular septum defect; WDHR = West Danish Heart Registry.

was found in the registration of on/off pump surgery. The proportion of ECC and CC time that could not be verified in the patient records was 13.3%. Error was found in 2.7% in ECC time and 1.8% in CC time. Only one patient had an ECC time divergence exceeding 10 min. Overall, the number of errors was 1.0% in the surgical procedure module and 1.3% in the perfusion module. The overall fraction of errors in the discharge module was 2.8%, dominated by errors concerning the discharge date. Disregarding the discharge date, the

TABLE 3

Audit of cardiologic procedures divided into type and selected variables.

Factor	Audit difference, n	No data, n		Errors, n (%)
		WDHR	file	
PCI modules				
Smoking	39	7	25	7 (4.3)
Diabetes mellitus	12	1	6	5 (3.0)
Height	35	3	25	7 (4.3)
Weight	35	4	25	6 (3.7)
Ejection fraction	52	29	17	6 (3.7)
Procedure indication	3	0	0	3 (1.8)
Procedure start time	11	0	7	4 (2.4)
Procedure codes	8	1	0	7 (4.3)
No treated lesions	4	0	1	3 (1.8)
No treated vessels	13	0	9	4 (2.4)
No of stents	7	0	3	4 (2.4)
In-laboratory complications	54	0	53	1 (0.6)
Procedure complications: discharge	58	2	52	4 (2.4)
Complication catheter insertion site	55	0	51	4 (2.4)
Discharge time	1	0	1	0
CAG modules				
Smoking	56	34	10	12 (6.9)
Diabetes mellitus	86	77	4	5 (2.9)
Procedure indication	18	8	2	8 (4.6)
Priority level	12	0	2	10 (5.7)
Procedure codes	5	0	4	1 (0.6)
Stenosis main stem	0	0	0	0
In-laboratory complications	73	0	69	4 (2.3)
Procedure complications: discharge	79	0	77	2 (1.1)
Complication catheter insertion site	62	0	60	2 (1.1)
Discharge time	25	1	1	23 (13.1)
CT-CAG modules				
Diabetes mellitus	100	98	1	1 (0.5)
Cholesterol-lowering treatment	46	37	3	6 (3.2)
Creatinine level	35	10	19	6 (3.2)
Left ventricular function	28	15	5	8 (4.2)
Procedure date	11	0	0	11 (5.8)
Procedure indication	4	2	0	2 (1.1)
keV	62	19	0	43 (22.6)
µGray × cm	34	20	0	14 (7.4)

CAG = coronary angiography; CT-CAG = computed tomography coronary angiography; PCI = percutaneous invasive procedures; WDHR = West Danish Heart Registry.

fraction of errors in postoperative complications was 1.4%. In general, the fraction of errors was higher in the anaesthesia and intensive care modules of which several data fields are not mandatory. Moreover, audit was difficult as treatments and observation are often registered in two independent modules.

Percutaneous invasive procedures

The overall proportion of errors in the history module was 3.8% (**Table 3**). The fraction of errors in the procedure module was 2.2%, and 1.6% in the discharge module. The proportion of errors was relatively uniform with few exceptions like smoking, height and procedure codes being marginally higher (4.3%). The procedure module data; indication, treated lesions and in-laboratory complications all had errors below 1.8%.

Coronary angiography

The individual departments have fewer patients audited, and differences in local policies and logistics may result in a higher proportion of errors in CAG registrations. The total proportion of errors in the CAG history module was 4.9% (Table 3). The procedure module had overall errors in 2.6%, the discharge module in 5.1% of registrations. The high number was driven by errors in the discharge date, while the number of errors in procedure-related complications was 1.1%.

Computed tomography-coronary angiography

The overall fraction of errors in the CT-CAG module was 6.0%. If data on keV registration are excluded, the overall fraction of error was 3.6%. As is the case for the other modules, the history modules carry the highest number of errors, while the procedure module carries the lowest number.

DISCUSSION

Multiple data are routinely collected for quality control, administrative and research purposes in the WDHR. Validating this mandatory population-based healthcare database, we found the number of overall data errors to be below 3% and in procedure-specific registrations like indications and complications, the error rate was below 1.5%.

Like the majority of WDHR articles [11, 12, 16], all large clinical registries developed during the past decades [17-19] have focused mainly on the number of registrations rather than on correctness. In many studies, audit and verification have included vital parameters, but to our knowledge, this audit is the first systematic audit performed on a large quality registry. The results are acceptable and data may be used for contemporary epidemiological studies. However, some challenges need to be addressed.

Inherence of data fields or part of registry forms is enforced in order to avoid double registration and to reduce the time spent on registration. The weakness is that a system which should detect changes from one registration to the next may therefore fail, which leads to the conclusion that the system is never better than those who enter the data.

Another important challenge is that because it stores all relevant information in one place, the registry is considered part of the patient files in some institutions, making future control difficult. One department relies solely on the WDHR, and performing an audit is thus not feasible.

When registering comorbidity, the registrants may have a biased behaviour and register more severe comorbidity. Overall, we could not demonstrate differences in "positive/negative" errors. However, there was a trend in EuroSCORE factors as 24 of 35 errors increased comorbidity compared with 11 which decreased comorbidity ($p = 0.028$).

The timing of registration may be important. The WDHR is constructed and managed as a real-time system and most handle the registration at the time of the procedure, whereas others register later. This may result in faulty conclusions when doing an audit as it may be difficult to establish the timing of a measurement or an event.

The cardiology part of the WDHR is similar to that of the Swedish Coronary Angiography and Angioplasty Register (SCAAR) established in 1989. The SCAAR registry does not include surgery and transcatheter aortic heart valve, but can be linked through The Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended

Therapies (SWEDEHEART) system. The German Institut fur Herzinfarkt Forschung, the British National Audit of Percutaneous Coronary Interventions and the US National Cardiovascular Data Registry registries cover PCI solely in contrast to the WDHR and the SWEDEHEART.

Compared with other systems, the benefit of the WDHR is the combining of different cardiac interventional procedures and a distinctive ability to do follow-up by combining the WDHR with the Danish National Registry of Patients and the Danish Register on Causes of Death [5, 6].

Limitations of the study

The number of audited registrations is limited, but should be sufficient to reveal major differences and errors. This audit was done by one person only, which improves its consistency. Furthermore, all discrepancies were double-checked which enhanced the findings of the audit.

CONCLUSIONS

The quality control of the population-based healthcare database, the WDHR, revealed that overall data errors were below 3% and in procedure-specific registrations including indications and complications below 1.5%. The WDHR is valid and may be used for contemporary epidemiological studies.

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LITERATURE

1. Schmidt M, Maeng M, Jakobsen CJ et al. Existing data sources for clinical epidemiology: The Western Denmark Heart Registry. Clin Epidemiol 2010;2:137-44.
2. Pedersen CB. The Danish Civil Registration System. Scand J Public Health 2011;39:22-5.
3. Pedersen CB, Gøtzsche H, Møller JO et al. The Danish Civil Registration System. A cohort of eight million persons. Dan Med Bull 2006;53:441-9.
4. Frank L. Epidemiology: when an entire country is a cohort. Science 2000; 287:2398-9.
5. Andersen TF, Madsen M, Jorgensen J et al. The Danish National Hospital Register. A valuable source of data for modern health sciences. Dan Med Bull 1999;46:263-8.
6. Juel K, Helweg-Larsen K. The Danish registers of causes of death. Dan Med Bull 1999;46:354-7.
7. Sørensen R, Hansen ML, Abildstrom SZ et al. Risk of bleeding in patients with acute myocardial infarction treated with different combinations of aspirin, clopidogrel, and vitamin K antagonists in Denmark: a retrospective analysis of nationwide registry data. Lancet 2009;374:1967-74.
8. Jensen JK, Jensen LO, Terkelsen CJ et al. Incidence of definite stent thrombosis or in-stent restenosis after drug-eluting stent implantation for treatment of coronary in-stent restenosis: from Western Denmark Heart Registry. Catheter Cardiovasc Interv 2013;8:260-5.

9. Jensen LO, Thayssen P, Maeng M et al. Randomized comparison of a sirolimus-eluting Orsiro stent with a biolimus-eluting Nobori stent in patients treated with percutaneous coronary intervention: Rationale and study design of the Scandinavian Organization for Randomized Trials with Clinical Outcome VII trial. Am Heart J 2015;170:210-5.
10. Jensen LO, Terkelsen CJ, Horváth-Puhó E et al. Influence of multivessel disease with or without additional revascularization on mortality in patients with ST-segment elevation myocardial infarction. Am Heart J 2015;170:70-8.
11. Munkholm SB, Jakobsen CJ, Mortensen PE et al. Validation of post-operative atrial fibrillation in the Western Denmark Heart Registry. Dan Med J 2015;62(12):A5162.
12. Mikkelsen MM, Johnsen SP, Nielsen PH et al. The Euroscore in Western Denmark. A population based study. J Cardiothor Vasc Anesth 2012;26: 258-64.
13. Kremke M, Tang M, Lawaetz K et al. Antiplatelet therapy at the time of coronary artery bypass grafting - a multicenter cohort study. Eur J Cardiothorac Surg 2013;44:e133-e140.
14. Jakobsen C-J, Berg H, Hindsholm KB et al. The influence in outcome of Propofol versus Sevoflurane anaesthesia in 10,535 single cardiac procedures: J Cardiothor Vasc Anesth 2007;21:664-71.
15. Nielsen DV, Fedosova M, Hjortdal VE et al. Is single-dose prophylactic gentamicin associated with acute kidney injury in patients undergoing cardiac surgery? A matched-pair analysis. J Cardiothor Surg 2014;148: 1634-9.
16. Nielsen DV, Madsen M, Johnsen SP et al. Health Outcomes with and without use of inotropic therapy in cardiac surgery; results of a propensity-score-matched analysis. Anesthesiology 2014;120:1098-108.
17. Black N. High-quality clinical databases: breaking down barriers. Lancet 1999;353:1205-6.
18. Stowa PJ, Graeme K, Hart GK et al. Development and implementation of a high-quality clinical database: the Australian and New Zealand Intensive Care Society Adult Patient Database. J Crit Care 2006;21:133-141.
19. David A, Harrison DA, Welch CA et al. The epidemiology of severe sepsis in England, Wales and Northern Ireland, 1996 to 2004: secondary analysis of a high quality clinical database, the ICNARC Case Mix Programme Database. Crit Care 2006;10:R42.