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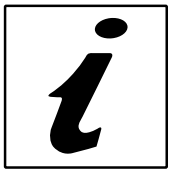
Information in practice



A survey of validity and utility of electronic patient records in a general practice

Alan Hassey, David Gerrett, Ali Wilson

Abstract

Objective To develop methods of measuring the validity and utility of electronic patient records in general practice.
Design A survey of the main functional areas of a practice and use of independent criteria to measure the validity of the practice database.
Setting A fully computerised general practice in Skipton, north Yorkshire.
Subjects The records of all registered practice patients.
Main outcome measures Validity of the main functional areas of the practice clinical system. Measures of the completeness, accuracy, validity, and utility of the morbidity data for 15 clinical diagnoses using recognised diagnostic standards to confirm diagnoses and identify further cases. Development of a method and statistical toolkit to validate clinical databases in general practice.
Results The practice electronic patient records were valid, complete, and accurate for prescribed items (99.7%), consultations (98.1%), laboratory tests (100%), hospital episodes (100%), and childhood immunisations (97%). The morbidity data for 15 clinical diagnoses were complete (mean sensitivity = 87%) and accurate (mean positive predictive value = 96%). The presence of the Read codes for the 15 diagnoses was strongly indicative of the true presence of those conditions (mean likelihood ratio = 3917). New interpretations of descriptive statistics are described that can be used to estimate both the number of true cases that are unrecorded and quantify the benefits of validating a clinical database for coded entries.
Conclusion This study has developed a method and toolkit for measuring the validity and utility of general practice electronic patient records.

Introduction

The NHS and its workforce are being made accountable for the services they provide through the emerging mechanisms of clinical governance.[1,2] These mechanisms will depend crucially on the availability of high quality health information in clinical practice,[3,4] and such data will need to be accessible through electronic patient record systems.[5]

These factors led us to consider the validity and utility of the electronic patient record system in a general practice and how these might be measured. The principal aim of this study was to measure whether the practice's electronic patient records were a true record of the health events associated with the patients of the practice.

The prime function of the medical record is to support patient care.[5] The general practice record is based on an individual and is a contemporaneous list of entries about that person's health. Record entries in computerised general practice systems generally consist of a mixture of text and Read codes. Together these form the narrative structure and content of the electronic patient record.

Measures of validity tell us whether an item measures what it is supposed to—that is, whether a measurement is true.[6] An example would be to test whether the presence of the Read code for diabetes in the database truly means that the patient has diabetes. Reliability refers primarily to the consistency or reproducibility of the data or test. The degree of reliability of the measures applied to the data will set limits on the degree of validity that is possible. Reliability is usually measured by the degrees of correlation between measures of data. Reliability and validity must both be in place to enable useful comparisons of sets of data to take place.

For the purpose of this study we extended Neal et al's definition of record validity: "Medical records, whether paper or electronic, record health events. Records are valid when all those events that constitute a medical record are correctly recorded and all the entries in the record truly signify an event."[7]

Attempts to validate electronic patient record systems have usually involved validating the database against either a paper record or patient survey.[8–13] Sensitivity and positive predictive value have been used as measures of completeness and accuracy of recording respectively.[8–10] In Britain the primary care information services (PRIMIS) project was designed to help primary care organisations improve patient care through the effective use of their clinical computer systems.[14] PRIMIS uses a methodology based on standard MIQUEST queries[15] to interrogate practice clinical databases. These queries include validation checks, but they are primarily useful as a tool for assuring the reliability of health data and facilitating the analysis of aggregated anonymised datasets. We could find no

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Further details of the 15 clinical diagnoses used to validate electronic patient records appear on the BMJ's website

Promotion of an information culture at Fisher Medical Centre

- Promoted "paperless" clinical practice among all clinical and administrative staff—made computer terminals available to all staff working in the practice
- Provided education, training, and support on using electronic patient record systems
- Shared expertise in the development and application of data collection templates with other practices via user groups and primary care group
- Applied PRIMIS/MIQUEST toolkit to practice databases and extracted anonymised, aggregated datasets for analysis (to measure reliability of data collection)
- Used the EPR-Val toolkit to measure validity and utility of practice electronic patient records
- Fed back the analysis results to make the data relevant to the clinical practice of each health professional (teaching, audit, research, clinical governance)

other published accounts of attempts to validate electronic patient records based solely on the contents of the clinical database.

Subjects and methods

The study practice, Fisher Medical Centre, is based in Skipton, serving 13 500 patients in the Yorkshire Dales. The practice has used the EMIS clinical system since 1990 and has been "paperless" since 1994. Patient data are entered by general practitioners, practice nurses, administrative staff, and attached community nurses. All patient events and contacts with the practice should be recorded by direct entry, electronic scanning of letters, or clinical messaging from local NHS providers (such as laboratory reports). Much time and effort have been spent fostering an "information culture" in the practice over the past six years (see box).[16] The practice clinical database should be valid, complete, and accurate since 1994.

We performed our study (which was approved by the local ethics committee) in two stages. The first stage was to build confidence in the validity of the clinical database across the main functional areas of the electronic patient records (table 1). We sampled practice activity retrospectively, so staff were not alerted to the study beforehand and had no chance to change their recording behaviour. We sampled the details of all patient events and contacts with the practice over a typically busy week. We selected the study week at random but excluded weeks containing a bank holiday. We validated the practice database for registrations and items of service against the local health authority's database over three months. We also measured the completeness and accuracy of practice prescribing with a one month retrospective survey of the town's busiest local pharmacy. All prescriptions are issued via the practice computer except those issued when working for the general practice cooperative or on house calls. We surveyed the pharmacy to measure the number of practice prescriptions dispensed by them and checked all handwritten prescriptions against the practice electronic patient records. Finally, we compared the separate record systems used by the practice's health visitors for preschool children with the practice system to identify and check the vaccination status of all 3 year old children in 1999.

In the second stage of our study we measured the validity of the clinical entries in the practice's electronic patient records. The principal innovation in our study was to consider the Read codes in the records as tests for the true presence or absence of the associated conditions in the database. The method was based on using Read coded entries over the previous five years (or previous year for asthma and ischaemic heart disease) to validate available criteria in the electronic records for 15 clinical diagnoses (for details, see extra information on the *BMJ*'s website). These criteria would act as the standard for each diagnosis. We developed search strategies for these conditions and tested them against a standard PRIMIS toolkit.[14] We chose the 15 diagnoses on the basis that they represented important causes of morbidity across the spectrum of chapter headings in ICD-9 (international classification of diseases, ninth revision), that they could be validated against other criteria in the patient record (drug treatment or diagnostic test), and that comparative data were available from other published studies.

Statistical analysis

We used standard statistical tests to compare the practice database with the validating criteria and other data sources such as the *Morbidity Statistics from General Practice: Fourth National Study*.[17] We measured the completeness and accuracy of the electronic patient records in terms of sensitivity and positive predictive value respectively. These statistics can be calculated from a simple 2×2 table and can be applied to any "test" as a measure of its usefulness.[18,19] The figure shows a worked example for diabetes.

The power of a test can be understood in terms of its ability to change the prior (pre-test) probability that a patient does or does not have the test condition.[20,21] The positive predictive value gives the power of a test to change the probability that the patient has the test condition. The likelihood ratio for a positive test is the

Table 1 Functional areas of the general practice's electronic patient records and the criteria used to validate them

Functional area	Validating criteria
Practice links with local health authority	Matching of patient lists against the health authority database
Appointment system	Validate against consultation records
Consultation event records	Validate place of consultation against patient contact lists. Check referral letters, reports, and incoming letters against record entries
Practice links with pathology laboratory	Validate against paper records and reports
Prescribing	Pharmacy survey of prescribed items, validate against hospital letters and discharge summaries
Search, call, and recall	Validate immunisation records against local NHS community trust database
Morbidity registers	Triangulate diagnostic codes against other diagnostic criteria (drugs or tests) for test conditions

		Diabetes		
		Present	Absent	Total
Read code	Present	286	2	288
	Absent	5	13 300	13 305
	Total	291	13 302	13 593

cell a	True +ve	False +ve
cell c	False -ve	True -ve

cell b

cell d

Statistic value (95% CI)

Sensitivity (%) = 98.3 (98.1 to 98.5)
Specificity (%) = 100.0 (100.0 to 100.0)
Likelihood ratio positive = 6536.72
Likelihood ratio negative = 0.017
Positive predictive value (%) = 99.3 (99.3 to 99.4)
Negative predictive value (%) = 100.0 (99.9 to 100.0)
Accuracy (%) = 99.9
Prevalence (%) = 2.1
Post-test probability positive (%) = 99.3
Post-test probability negative (%) = 0.0
TPFN ratio = 57.20
DBFind$^{10\,000}$ = 3.7

2×2 table to calculate sensitivity and positive predictive value of practice database for diabetes

odds that the test will be positive in a patient with the condition compared with a patient without the condition. The pre-test probability for any test condition is the prevalence of that condition in the community. Likelihood ratios are an accepted method of "testing tests."[22 23] In this study they represent a quantifiable measure of the validity of the Read coded entry to predict the true presence or absence of the associated condition.

We checked valid data against recognised diagnostic standards for each condition to confirm existing diagnoses and identify potential further cases. The difference between the number of conditions existing in the database and the total number identified was made comparable through development of two new descriptive statistics, the TPFN ratio and the DBFind$^{10\,000}$ (see box for details). We developed a toolkit in Excel (EPR-Val) to calculate the full range of statistics (including the TPFN ratio and DBFind$^{10\,000}$) from the test data.

Results

Validity of the main functional areas of the electronic patient records

The practice list and all claims payments were fully reconciled with the health authority over three months in 1999. These payments are an important check on validity because they include procedures that can be carried out only on patients of the appropriate age and sex. During the study week, we checked all appointments and visits with practice clinicians against the database to confirm that every appointment had a consultation entry: 98.1% of 1029 consultations were recorded in the clinical records. Of the 20 not recorded, 12 were "Did not attend," and eight consultations were missed. During the study week, the practice received 202 hospital letters, 358 pathology reports, and 12 contact sheets from the general practice cooperative and made 44 referrals. There were several minor transcription errors, but clinical details were correctly recorded in every case.

When we surveyed Skipton's busiest pharmacy we found a total of 639 practice prescriptions were dispensed by them over one month, 629 computer generated and 10 handwritten prescriptions. Of the handwritten ones, eight were properly recorded in the computer clinical record and two were missed. Overall 99.7% of prescriptions tracked were recorded by the electronic patient record during that month.

When we checked the vaccination status of all 3 year old children in 1999 we produced a list of 144 children. The records matched with the separate record systems used by the practice's health visitors in 140 (97%) cases, the remaining four children had just registered with the practice and were unknown to the health visitors.

Validity of clinical entries in electronic patient records

We ran a series of standard MIQUEST validation queries, which included checks on codes that are sex specific. Two men were recorded as having had cervical smears, but there were no other unreconciled procedural coding errors. This gave us the confidence in our coding to populate the 2×2 contingency tables (details available on the *BMJ*'s website) and calculate the statistics for each of the 15 diagnoses (table 2). These results show that the practice database was valid, complete, and accurate. The results for obesity are an exception and reflect a coding practice of recording body mass index rather than the diagnosis of obesity. The likelihood ratios indicated that the presence of the Read codes for the 15 conditions indicated a true diagnosis in 96% of cases. The absence of the Read code indicated the true absence of those conditions in 99.5% of cases (table 2).

The TPFN ratios and DBFind$^{10\,000}$ results for asthma, iron deficiency anaemia, hypothyroidism, and ischaemic heart disease indicate high priority areas for the practice to identify previously undiagnosed true cases of these conditions in the database.

Calculating and using the TPFN ratio and DBFind$^{10\,000}$ statistics

- TPFN ratio is the ratio of true positive cases to false negatives in the database. The TPFN ratio is used to estimate both the number of true cases that are unrecorded in the database and quantify the benefits of validating the database for any coded entry. For example, if the TPFN ratio is 50, the prevalence of condition x is 1%, and the practice list size is 4000, then the total expected number of cases of $x = 40$. Since the total expected number of cases is less than the TPFN ratio, searching the database is unlikely to yield a single extra case of condition x
- DBFind$^{10\,000}$ = (number of false negatives/total number of patients in database)×10 000. This is the number of false negatives in a database of 10 000 patients. For example, if there are 20 false negatives in a practice list size of 4000, then the number of false negative cases in a database of 10 000 patients is (20/4000)×10 000 = 50
- The lower the TPFN ratio and higher the DBFind$^{10\,000}$ results, the greater the number of false negative cases in the database. This enables users to prioritise where they would achieve the best rate of return from validating their clinical databases in line with national and local priorities

Table 2 Summary statistics produced by EPR-Val toolkit for 15 test diagnoses

Test condition	Prevalence (%)*	Sensitivity (%)	PPV and PTP+ve (%)	LR+ve	LR–ve	PTP–ve (%)	TPFN ratio	DBFind$^{10\,000}$
Breast cancer	0.4	94.7	100	∞	0.053	0.0	18.0	2.2
Prostate cancer	0.2	100	96.0	13577	0.00	0.0	∞	0
Diabetes	2.1	98.3	99.3	6536	0.017	0.0	57.2	3.7
Obesity	6.0	2.1	89.5	134	0.979	5.8	0.02	583.7
Hypothyroidism	1.7	82.1	97.5	2196	0.179	0.3	4.6	30.9
Hyperthyroidism	0.4	97.9	95.9	6632	0.021	0.0	47.0	0.7
Gout	1.6	93.7	97.6	2507	0.063	0.1	14.8	10.3
Iron deficiency anaemia	1.4	77.6	96.8	2080	0.224	0.0	3.5	31.6
Glaucoma	0.8	96.4	95.5	2601	0.036	0.0	26.8	2.9
Epilepsy	0.6	94.0	95.2	3179	0.060	0.0	15.8	3.7
Parkinson's disease	0.2	86.7	96.3	11760	0.133	0.0	6.5	2.9
Ischaemic heart disease	5.2	95.5	97.1	615	0.045	0.2	21.3	23.5
Hypertension	6.6	97.8	98.9	1242	0.022	0.2	43.6	14.7
Asthma	5.3	87.3	86.3	112	0.128	0.7	6.8	67.7
Rheumatoid arthritis	0.7	98.9	92.2	1670	0.011	0.0	94.0	0.7
Average for all diagnoses	—	87	96	3917	0.1314	0.05	35.7	51.9

*Five year prevalence (except for hypertension and asthma, with 1 year prevalence). PPV=positive predictive value. LR+ve=likelihood ratio positive. LR–ve=likelihood ratio negative. PTP+ve=post test probability positive. PTP–ve=post test probability negative. TPFN=true positive to false negative ratio. DBFind$^{10\,000}$=(false negatives/total in database)×10 000. ∞=infinite value (resulting from dividing by 0).

Discussion

The first stage of this study established a method for validating a general practice electronic patient record system. The study period covered just one week, and other random checks might be important for particularly busy times. However, we are confident that our sample was representative of typical practice activity. The practice database was generally valid for prescribed items, consultations, laboratory tests, hospital episodes, and childhood immunisations. The results compare favourably with those of other published studies.[9 13 17]

The second stage of the study measured the validity and utility of the clinical database for 15 diagnoses. The morbidity data associated with these conditions were highly valid and reliable. The prevalences of these diagnoses in this study were generally higher than those reported in the *Morbidity Statistics from General Practice: Fourth National Study*[17] (see table 3).

Our study assessed the power of a diagnostic code (Read code) to alter the probability that a patient actually had a test diagnosis through the calculation of a range of statistics. Sensitivity, positive predictive value, and likelihood ratio are useful in combination to assess the overall validity of clinical diagnostic coding in an electronic patient record because of their different strengths and weaknesses.[18–20] We suggest that overall validity of electronic patient records should be assessed with these measures in combination.

Health workers could use the method and toolkit described here to quantify the validity of their electronic patient record systems. The derived statistics TPFN ratio and DBFind$^{10\,000}$ facilitate the estimation of the true prevalence of medical conditions in the database, based on setting clinical criteria, and help quantify the benefits of validating the database for each condition. Users could then prioritise where they would achieve the best rate of return from developing and validating their clinical systems in line with national and local priorities.

The statistical tests applied in this study are sensitive enough to enable health professionals to measure the degree of confidence they can have in clinical coding at the level of a single practice. A validation toolkit (EPR-Val) was developed as part of the research project. This provides a full range of statistical tests (including the TPFN ratio and DBFind$^{10\,000}$), and we have made it freely available on the *BMJ*'s website.

In conclusion, we have developed a new approach to the validation of clinical databases in general practice. We have validated a general practice electronic patient record system and developed a standard method and toolkit for quantifying the validity and utility of data in clinical databases. The results of this study are relevant to all those involved in patient care and performance management in the "New NHS."

Table 3 Comparison of disease prevalences from the fourth morbidity statistics from general practice, 1991-2, (MSGP4)[17] and from Fisher Medical Centre (FMC)

Condition	MSGP4*	FMC†
Breast cancer	30	31
Prostate cancer	11	13
Diabetes	111	157
Obesity	82	438
Hypothyroidism	50	127
Hyperthyroidism	9	26
Gout	40	119
Iron deficiency anaemia	54	104
Glaucoma	21	60
Epilepsy	36	45
Parkinson's disease	15	16
Ischaemic heart disease	200	386
Hypertension	412	482
Asthma	400	391
Rheumatoid arthritis	38	51

*Rates are per 10 000 patient years at risk. †Rates are 5 year prevalences per 10 000 patients (except for hypertension and asthma, with 1 year prevalence).

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Contributors: All three authors conceived and planned the study. AH and DG developed the toolkit and performed the analysis. AH was the main author of the paper, with revisions from AW and DG. DG will act as guarantor for the paper. In addition, Dr David Pearson helped in the planning of this study

What is already known on this topic

Delivering the performance management agenda in the NHS will depend on the availability of high quality information in general practice

Record entries in GP systems generally consist of a mixture of text and Read coded entries

Sensitivity and positive predictive value have been used to measure the completeness and accuracy of data recording in electronic patient record systems

What this study adds

This study has developed a standard method and toolkit for measuring the validity and utility of electronic patient record systems

The principal innovation in this study is to consider the Read codes in the records as tests for the true presence of the associated diagnoses

This study has developed a new approach to the validation of electronic patient record systems.

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A memorable patient

My room

As a not so junior junior doctor training part time in psychiatry, I have rotated through a fair number of doctors' offices. For several years when I was a clinical assistant, my personal effects had to be confined to a pair of grey plastic trays. Part share of an office is more usual.

The presence of a colleague is very inhibiting to work, particularly the dictation of letters. However, gossiping about colleagues, letting off steam about the job (not to mention my own friends and family), and occasionally even pondering the whole nature of psychiatric illness have helped keep me relatively cheerful.

Through sessions at peripheral clinics and day hospitals, you often share a room with colleagues who, like Major Major from *Catch 22*, are always out when you are in. Here rooms can accumulate mystery detritus: half eaten packets of biscuits, journals, clothing, bicycle pumps. Often these turn out to belong to no one, but the other occupants, like you, don't feel proprietorial enough to bin them.

Essential equipment is seating, a telephone, a pen, and a Dictaphone. The office should have space to interview patients with carers or host tutorial groups and should also provide peace and quiet to let you catch whether the hesitant, mumbling person before you is thought-disordered or deluded rather than just shy. A hook on the door, a filing cabinet, a kettle, and a green view are luxury items. One of these years, a computer might appear.

Recently, as part of my special interest sessions, I took a patient from an adjacent ward to my room to ask about his experience of electroconvulsive therapy. Perhaps not surprisingly, he was more interested in talking about antidepressants. An overdose attempt with his latest tablet had provoked acute retention of urine, and he was still encumbered with a catheter. He pointed to mugs, pens, paper hankies, the desk lamp, and calendar, all of which bore the trade names of antidepressants he had heard of. Did I recommend them, were they better than some of the older drugs that had helped him in the past?

I, of course, demurred, suggesting he discuss these concerns with his own consultant. Realising my room had been annexed as advertising space for the pharmaceutical industry, I swept the free gifts into the waste bin. The desk lamp didn't even work.

Drug companies have to be profitable. Who else is going to come up with safe and effective agents without side effects for my patients? Still, rather than give free product endorsements, I have decided to cover the walls with a heroes gallery of public figures who have spoken openly about their experience of mental illness. Any suggestions?

Elizabeth H Hare *specialist registrar in psychiatry, Edinburgh*