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Potential use of routine databases in health technology assessment

J Raftery, P Roderick and A Stevens

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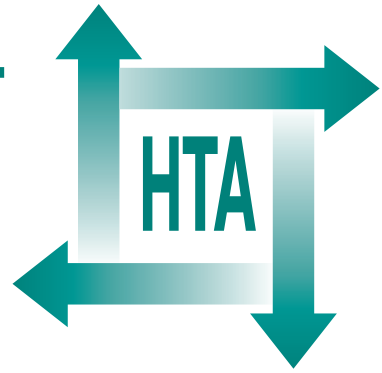

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Potential use of routine databases in health technology assessment

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Abstract

Potential use of routine databases in health technology assessment

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Objectives: To develop criteria for classifying databases in relation to their potential use in health technology (HT) assessment and to apply them to a list of databases of relevance in the UK. To explore the extent to which prioritised databases could pick up those HTs being assessed by the National Coordinating Centre for Health Technology Assessment (NCCHTA) and the extent to which these databases have been used in HT assessment. To explore the validation of the databases and their cost.
Data sources: Electronic databases. Key literature sources. Experienced users of routine databases.
Review methods: A 'first principles' examination of the data necessary for each type of HT assessment was carried out, supplemented by literature searches and a historical review. The principal investigators applied the criteria to the databases. Comments of the 'keepers' of the prioritised databases were incorporated. Details of 161 topics funded by the NHS R&D Health Technology Assessment (HTA) programme were reviewed iteratively by the principal investigators. Uses of databases in HTAs were identified by literature searches, which included the title of each prioritised database as a keyword. Annual reports of databases were examined and 'keepers' queried. The validity of each database was assessed using criteria based on a literature search and involvement by the authors in a national academic network. The costs of databases were established from annual reports, enquiries to 'keepers' of databases and 'guesstimates' based on cost per record. For assessing effectiveness, equity and diffusion, routine databases were classified into three broad groups: (1) group I databases, identifying both HTs and health states, (2) group II databases, identifying the HTs, but not a health state, and (3) group III databases, identifying health states, but not an HT. Group I datasets were disaggregated into clinical registries, clinical administrative databases and population-oriented databases. Group III were disaggregated into adverse event reporting, confidential enquiries, disease-only registers and health surveys.
Results: Databases in group I can be used not only to assess effectiveness but also to assess diffusion and equity. Databases in group II can only assess diffusion. Group III has restricted scope for assessing HTs, except for analysis of adverse events. For use in costing, databases need to include unit costs or prices. Some databases included unit cost as well as a specific HT. A list of around 270 databases was identified at the level of UK, England and Wales or England (over 1000 including Scotland, Wales and Northern Ireland). Allocation of these to the above groups identified around 60 databases with some potential for HT assessment, roughly half to group I. Eighteen clinical registers were identified as having the greatest potential although the clinical administrative datasets had potential mainly owing to their inclusion of a wide range of technologies. Only two databases were identified that could directly be used in costing. The review of the potential capture of HTs prioritised by the UK's NHS R&D HTA programme showed that only 10% would be captured in these databases, mainly drugs prescribed in primary care. The review of the use of routine databases in any form of HT assessment indicated that clinical registers were mainly used for national comparative audit. Some databases have only been used in annual reports, usually time trend analysis. A few peer-reviewed papers used a clinical register to assess the effectiveness of a technology. Accessibility is suggested as a barrier to using most databases. Clinical administrative databases (group Ib) have mainly been used to build population needs indices and performance indicators. A review of the validity of used databases showed that although internal consistency checks were common, relatively few had any form of external audit. Some comparative

audit databases have data scrutinised by participating units. Issues around coverage and coding have, in general, received little attention. NHS funding of databases has been mainly for 'Central Returns' for management purposes, which excludes those databases with the greatest potential for HT assessment. Funding for databases was various, but some are unfunded, relying on goodwill. The estimated total cost of databases in group I plus selected databases from groups II and III has been estimated at £50 million or around 0.1% of annual NHS spend. A few databases with limited potential for HT assessment account for the bulk of spending.

Conclusions: Suggestions for policy include clarification of responsibility for the strategic development of databases, improved resourcing, and issues around coding, confidentiality, ownership and access, maintenance of clinical support, optimal use of information technology, filling gaps and remedying deficiencies. Recommendations for researchers include closer policy links between routine data and R&D, and selective investment in the more promising databases. Recommended research topics include optimal capture and coding of the range of HTs, international comparisons of the role, funding and use of routine data in healthcare systems and use of routine database in trials and in modelling. Independent evaluations are recommended for information strategies (such as those around the National Service Frameworks and various collaborations) and for electronic patient and health records.

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List of abbreviations

ADR	adverse drug reaction
AIC	Adverse Incident Centre
AWPS	All Wales Perinatal Survey
BCG	Bacille Calmette–Guérin
BCIS	British Cardiovascular Intervention Society
BINOCAR	British Isles Network of Congenital Anomalies Register
BNF	British National Formulary
BPEG	British Pacing and Electrophysiology Group
BSS	Breast Screening System
BTW	Breast Test Wales
CAD	Chromosome Abnormality Database
CAR	Congenital Anomalies Register
CARE	Craniofacial Anomalies Register
CARIS	Congenital Anomalies Register and Information Service
CCAD	Central Cardiac Audit Database
CCRG	Childhood Cancer Research Group
CDS	Community Dental Service
CDSC	Communicable Disease Surveillance Centre
CEMD	Confidential Enquiries into Maternal Deaths
CEPOD	Confidential Enquiry into Peri-Operative Deaths
CESDI	Confidential Enquiry into Stillbirths and Deaths in Infancy
CHD	coronary heart disease
CHI	Commission for Health Improvement; Community Health Index
CHRIS	Central Health Registry Inquiry System
CISH	Confidential Inquiry into Suicides and Homicides
CIU	Cancer Intelligence Unit
CMDS	Contract Minimum Dataset
CMO	Chief Medical Officer
CMPD	Case Mix Programme Database
CMR	Continuous Morbidity Recording
COIN	Cancer and Oncology Information Network
COPPISH	Core Patient Profile Information in Scottish Hospitals
CRAG	Clinical Resource and Audit Group
CRC	Cancer Research Campaign
CRIR	Committee for Regulating Information Requirements
CSA	Central Services Agency
CSM	Committee on Safety of Medicines
CSR	Cardiac Surgical Register
DAP	Drug Analysis Print
DAR	Data Analysis Report
DCO	death certificate only
DHSS	Department of Health and Social Services
DI	donor insemination
DIN	Doctors' Independent Network
DPH	Director of Public Health
DQI	Data Quality Indicator

continued

List of abbreviations *continued*

DRG	diagnosis related group
DVR	Data Validation Report
EDI	electronic data interchange
EDTA	European Dialysis and Transplant Association
EHR	electronic health record
EPIC	Epidemiology and Pharmacology Information Core
EPR	electronic patient record
ESRF	end-stage renal failure
EUROCAT	European Registration of Congenital Anomalies and Twins
FACE	Functional Analysis of Care Environments
GHS	General Household Survey
GPRD	General Practice Research Database
GRCA	Glasgow Register of Congenital Anomalies
GRO	General Register Office
GRO(S)	General Register Office for Scotland
GUM	genitourinary medicine
HDU	high dependency unit
HEMS	Health Education Monitoring Survey
HES	Hospital Episode Statistics
HFEA	Human Fertilisation and Embryology Authority
HIB	*Haemophilus influenzae* B
HIPE	Hospital Inpatient Enquiry
HLA	human leucocyte antigen
HRC	Human Rights Convention
HRG	Healthcare Resource Group
HSA	Health Statistics and Analysis Unit
HSE	Health Survey for England
HT	health technology
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
ICU	intensive care unit
INBT	Institute of Biomedical Technology
IPPR	Itemised Prescribing Payment Report System
ISD	Information and Statistics Division
ISD Scotland	Information and Statistics Division, NHS Scotland
IT	information technology
IUD	intrauterine device
IVF	*in vitro* fertilisation
MCA	Medicines Control Agency
MCCR	Merseyside and Cheshire Cancer Registry
MCHRC	Maternal and Child Health Research Consortium
MDA	Medical Devices Agency
MEMO	Medicine Monitoring Unit
MINAP	Myocardial Infarction National Audit Project
MMR	measles, mumps and rubella
MPEU	Mersey Perinatal Epidemiology Unit
MRC	Medical Research Council
MRI	magnetic resonance imaging
MV	microscopically verified
NAO	National Audit Office
NASDAB	National Amputee Statistical Database
NCAS	National Congenital Anomaly System

continued

List of abbreviations *continued*

NCCHTA	National Coordinating Centre for Health Technology Assessment
NCEPOD	National Confidential Enquiry into Perioperative Deaths
NCR	National Cancer Registry
NDSCR	National Down Syndrome Cytogenetic Register
NHSCR	National Health Service Central Registry
NHSE	NHS Executive
NHSIA	National Health Service Information Authority
NHSiS	National Health Service in Scotland
NICE	National Institute for Clinical Excellence
NICR	Northern Ireland Cancer Registry
NOIDS	Notification of Infectious Diseases
NPMS	National Prospective Monitoring System
NRCT	National Registry of Childhood Tumours
NSAID	non-steroidal anti-inflammatory drug
NTD	National Transplant Database
NWCS	NHS-Wide Clearing Service
NWRCR	North Western Regional Cancer Registry
NYCRIS	Northern and Yorkshire Cancer Registry and Information Service
OCIU	Oxford Cancer Intelligence Unit
OCMR	Oxford Congenital Malformation Registry
ONS	Office for National Statistics
OPCS	Office of Population Censuses and Surveys
PACE	Population-Adjusted Clinical Epidemiology
PACT	prescribing analysis and cost
PAS	Patient Administration System
PATS	Patient Analysis and Tracking System
PCA	Prescribing Cost Analysis
PCDID	Primary Care Drug Information Database
PCG	Primary Care Group
PCT	Primary Care Trust
PEDW	Patient Episode Database for Wales
PHLS	Public Health Laboratory Service
PMDS	Prescribing Monitoring Document System
PORT	Patient Outcome Research Teams
PPA	Prescription Pricing Authority
PPD	Pharmacy Practice Division
PPS	Prescription Pricing Services
PTCA	percutaneous transluminal coronary angioplasty
PTI	Practice Team Information
RCT	randomised controlled trial
RRF	Rapid Report Form
SASM	Scottish Audit of Surgical Mortality
SCR	Scottish Cancer Registry
SCRUGS	Scottish Care Resource Utilisation Groups
SCTS	Society of Cardiothoracic Surgeons
SEAG	Scientific and Ethical Advisory Group

continued

List of abbreviations *continued*

SERNIP	Safety and Efficacy Register of New Interventional Procedures
SHFA	Scottish Hip Fracture Audit
SHRUGS	Scottish Health Resource Utilisation Groups
SMMIS	St Mary's Maternity Information System
SMR	Scottish Morbidity Record
SNLG	Scotland and Newcastle Lymphoma Group
SOCRATES	Scottish Open Cancer Registration and Tumour Enumeration System
SPSS	Statistical Package for the Social Sciences
SRL	Scottish Record Linkage
SSBID	Scottish Stillbirth and Infant Death Survey
SSD	Social Survey Division
STAG	Scottish Trauma Audit Group
STD	sexually transmitted disease
TARN	Trauma Audit Research Network
TCR	Thames Cancer Registry
UKACR	UK Association of Cancer Registries
UKCCSG	UK Children's Cancer Study Group Register
UKCF	UK Cystic Fibrosis
UKCFDC	UK Cystic Fibrosis Data Centre
UKHCDO	UK Haemophilia Centre Directors' Organisation
UKHVR	UK Heart Valve Registry
UKTSSA	UK Transplant Support Service Authority
USS	ultrasound scanning
WCISU	Welsh Cancer Intelligence and Surveillance Unit
WHCSA	Welsh Health Common Services Authority
WHIS	Welsh Health Information Services
WMCIU	West Midlands Cancer Intelligence Unit
WOSCOPS	West of Scotland Coronary Prevention Study Group

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Introduction

This report defines health technology assessment to include the investigation of (i) effectiveness, (ii) diffusion and equity and (iii) cost – all as applied to the range of health technologies (HTs) including pharmaceuticals, devices, procedures and settings. Key characteristics of routine data are regular collection, standard definitions, obligatory completion and representative coverage.

Aims

The aims of this study were to:

1. develop criteria for classifying databases in relation to their potential use in HT assessment
2. list the databases of relevance in the UK
3. apply the criteria for classifying databases to that list
4. explore the extent to which prioritised databases could pick up those HTs being assessed by the National Coordinating Centre for Health Technology Assessment (NCCHTA)
5. investigate the extent to which these databases have been used in HT assessment
6. explore the degree to which databases, so used, have been validated
7. estimate the cost of the prioritised databases
8. make suggestions for facilitating the use of routine data for HT assessment.

Methods

A 'first principles' examination of the data necessary for each type of HT assessment was central to aim 1, supplemented by literature searches and a historical review.

A long list (aim 2) was developed using selected literature and by networking with people with relevant experience.

The principal investigators applied the criteria to the long list (aim 3) using annotations of each. Comments of the 'keepers' of the prioritised databases were incorporated.

For aim 4, details of 161 topics funded by the NHS R&D Health Technology Assessment (HTA) programme were reviewed iteratively by the principal investigators.

Uses of databases in HT assessments (aim 5) were identified by literature searches, which included the title of each prioritised database as a keyword. Annual reports of databases were examined and 'keepers' queried. Each identified use was checked by the three principal investigators.

The validity of each database (aim 6) was assessed using criteria based on a literature search and involvement by the authors in a national academic network. The 'keepers' of databases were queried.

The costs of databases (aim 7) were established from annual reports, enquiries to 'keepers' of databases and 'guesstimates' based on cost per record.

The proposals under aim 8 were based on the above and discussion between authors.

Results

To be of value in HT assessment, databases must at least identify a well-defined HT. Additional dimensions depend on the type of HT assessment. For assessing effectiveness, equity and diffusion, routine databases were classified into three broad groups:

- group I databases, identifying both HTs and health states
- group II databases, identifying the HTs, but not a health state
- group III databases, identifying health states, but not an HT.

Group I datasets were disaggregated into clinical registries, clinical administrative databases and population-oriented databases. Group III were disaggregated into adverse event reporting, confidential enquiries, disease-only registers and health surveys.

Databases in group I can be used not only to assess effectiveness but also to assess diffusion and equity. Databases in group II can only assess diffusion. Group III has restricted scope for assessing HTs, except for analysis of adverse events.

For use in costing, databases need to include unit costs or prices. Some databases included unit cost as well as a specific HT.

A long list of around 270 databases was identified at the level of the UK, England and Wales or England (over 1000 including Scotland, Wales and Northern Ireland).

Allocation of these to the above groups identified around 60 databases with some potential for HT assessment, roughly half to group I. Eighteen clinical registers were identified as having the greatest potential although the clinical administrative datasets had potential mainly owing to their inclusion of a wide range of technologies. Only two databases were identified that could be directly used in costing.

The review of the potential capture of HTs prioritised by the UK's NHS R&D HTA programme showed that only 10% would be captured in these databases, mainly drugs prescribed in primary care.

The review of the use of routine databases in any form of HT assessment indicated that clinical registers were mainly used for national comparative audit. Some databases have only been used in annual reports, usually time trend analysis. A few peer-reviewed papers used a clinical register to assess the effectiveness of a technology, particularly those with relatively simple outcomes (conceptions from *in vitro* fertilisation or graft failure in organ transplants). The authorship of such studies suggests that accessibility is a barrier to using most databases.

Clinical administrative databases (group Ib) have been mainly used to build population needs indices and performance indicators.

A review of the validity of used databases showed that although internal consistency checks were common, relatively few had any form of external audit. Some comparative audit databases have data scrutinised by participating units. Issues around coverage and coding have, in general, received little attention.

NHS funding of databases has been mainly for 'Central Returns' for management purposes, which excludes those databases with the greatest potential for HT assessment. Funding for these was various, but some are unfunded, relying on goodwill. The estimated total cost of databases in group I plus selected databases from groups II and III has been estimated at £50 million or around 0.1% of annual NHS spend. A few databases with limited potential for health technology assessment account for the bulk of spending.

Conclusions and recommendations for further research

Proposals for policy include clarification of responsibility for the strategic development of databases, improved resourcing, and issues around coding, confidentiality, ownership and access, maintenance of clinical support, optimal use of information technology, filling gaps and remedying deficiencies.

Recommendations for researchers include closer policy links between routine data and R&D, and selective investment in the more promising databases. Recommended research topics include optimal capture and coding of the range of HTs, international comparisons of the role, funding and use of routine data in healthcare systems and use of routine databases in trials and in modelling. Independent evaluations are recommended for information strategies (such as those around the NSFs and various collaborations) and for electronic patient and health records.

Chapter 1
Introduction

Routine data and health technology assessment

Routine data have been underused in health technology (HT) assessment. A vicious circle applies: 'as the data are poor, they cannot be used; lack of use ensures they remain limited and of poor quality'. One of the purposes of this report is to help promote a virtuous circle: 'good quality data which, because used, must be improved'.

The term 'routine data' as used here (see definition in Chapter 3, p. 15) includes not only administrative data, but also disease and health technology registers, adverse event reporting and regular health-related surveys. Regular collection and the use of standardised definitions are key attributes.

The international 'effectiveness revolution' in healthcare cries out for improved information on the efficacy, effectiveness, use and costs of each HT. As healthcare is made up of multiple and varied HTs – with thousands of diseases and often many interventions for each – the number of HTs is very large.

For efficacy analysis, conventional scientific wisdom favours ever more and larger randomised controlled trials (RCTs) collecting 'customised' or specially designed data. Random allocation and blinding of assessment in RCTs minimise bias and control for confounders, both known and unknown. However, there are limitations to trials. First, the scale and pace of HT development are greater than the capacity to fund and carry out RCTs. Second, RCTs may occasionally be inappropriate, impossible or inadequate.*[1]

Observational studies provide the main alternative to RCTs in assessing efficacy. Some largely rely on routine data. For example, disease/technology registers and adverse event reporting systems are better than trials in detecting serious adverse events which tend to be rare and delayed. Comparative assessment of different technologies using observational data can reduce the risk of bias by risk adjustment, a growing feature in disease and technology registers.

Although routine data may have a limited role in evaluating the efficacy of HTs, they often make an important contribution to randomised trials. The 'flagging' of patients' outcomes in trials, for both mortality and to a lesser extent incidence (such as in cancer), is widely used in trials.[2] Routine data can provide information on health service resource use, which may be important as a proxy outcome (e.g. re-admission, hospitalisation) and to estimate costs.

Even when RCTs are appropriate, they do not always provide generalisable information on **effectiveness** (how well the HT performs in everyday practice) as opposed to **efficacy**. RCTs often have restrictive criteria for entry at the level of patient and centre. Those patients who might be at risk of harm from the intervention or those who might not comply tend to be deliberately excluded; a recent systematic review has shown that as few as 20% of the relevant patients have been included on some major clinical trials.[3] RCT efficacy estimates may not apply to groups excluded from trials. For example, the balance of risk and benefit may differ when the technology is applied in everyday practice, owing to levels of operator skill or monitoring requirements. The resources used in centres involved in trials may also differ from those used in routine practice. Assessment of effectiveness requires data on the patients actually treated, their severity and co-morbidities, plus in some instances how the technology was delivered (if different from the trial situation), and the resulting outcomes. Routine data potentially have an important role to play in assessing effectiveness.

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* Black[1] has suggested four limitations of clinical trials, in that they may be:

1. unnecessary if the effect of the intervention is dramatic, or
2. inappropriate or infeasible owing to infrequent outcomes, effects taking a long time or because randomisation may reduce the effect of the intervention, or
3. impossible owing to lack of individual equipoise, ethical objections to randomisation, political or legal obstacles, geographical barriers or contamination, or
4. inadequate owing to lack of generalisability because of atypical clinicians, patients or treatments.

Although assessment of the efficacy and effectiveness of HTs is paramount, HTs can also be assessed in relation to diffusion, equity and cost. These assessments offer greater scope for using routine data. Diffusion of HTs is closely related to assessment of equity of use, in that both require data on the use of technologies by time and by place or group. The current health and healthcare 'variations' literature is noteworthy for being almost entirely based on routine data.[4–6]

Costing also relies largely on routine data. In addition to the direct cost of HTs, economic evaluation requires data on the knock-on effects with resource consequences, such as subsequent health service use averted by an effective technology. Since such effects often happen outside the time frame of clinical trials they tend to be assessed using modelling, which often relies on routine data. Routine data can be used not only to supplement trial data collected from patients, but also to validate such information. Estimation of the cost impact of particular HTs has an important policy role, not least by NICE in relation to its guidance on new health technologies.*

Routine data problems

Improvement of routine databases requires the acknowledgement of their flaws. These include the following.

Problems of a historically 'information-free' culture

Healthcare systems tend to have weak information,[7] despite the multiplicity of detail collected. The scale and diversity of healthcare systems have hitherto limited data collection to highly aggregated returns. Most healthcare systems have some data on the number of people admitted to hospital or drugs prescribed, often for reasons to do with payment, but few have data on the effects of treatments. Data are often compiled at the level of provider unit rather than at patient or population level.

Assessment of HTs in any of the dimensions of efficacy, effectiveness, diffusion, equity or cost requires much more data than have tended to be collected historically. The quantity and quality of existing administrative databases depend partly on how particular healthcare systems are organised, with more administrative data in more market-oriented systems. Systems such as the NHS, which does not generally require data for payment, collect fewer data. Nor has information technology (IT) played its full potential: a recent estimate put healthcare investment in IT at 2–3% compared with around 15% in banks.[8]

Data collection problems

The gap between data and information applies to healthcare in an extreme way. Although details of patients' conditions and treatments are noted in consultations, they generally do not become available as 'data' for analysis. A considerable amount of patient-specific information is recorded in the course of healthcare delivery, such as patients' characteristics, disease severity, co-morbidity and diagnostic and treatment data (plus some information on outcomes). These are usually held in bulky paper files termed 'casenotes'. In addition to the familiar distinction between data and information, a further distinction can be made between 'data' (given) and 'capta' (captured or taken). Health services capture enormous amounts of detail (capta), often in casenotes but these seldom get translated into data, let alone into information. Casenotes in England still tended to be handwritten in the mid-1990s,[9] specific to the place of treatment, and are difficult to interpret. Progress with electronic patient records and health records has been slow.[10,11] Problems include lack of standard formats, variation between doctors in completeness and accuracy of data, and poor integration with other professions' entries (nurses, physiotherapists) or with settings of care. A high proportion of casenotes has been untraceable in various studies.

Confidentiality

Healthcare records can have significance well beyond healthcare, affecting the extent to which

* The National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) illustrate the roles of different types of data in the range of HT assessments. New HTs are identified by the National Horizon Scanning Centre and some are referred to NICE for assessment. NICE guidance is based partly on the results of clinical trials, partly on models which make explicit assumptions in extrapolating the trial evidence on effectiveness and costs. NICE guidance is also charged with assessing equity and the cost impact of its guidance, both of which rely largely on routine data. CHI is charged with monitoring the adherence to NICE guidance, either using existing routine databases or by developing new ones. Meanwhile, further clinical trials are being conducted, requiring NICE to review its guidance regularly. In this process, clinical trial data and routine data mutually influence each other in assessing efficacy, effectiveness, diffusion, equity and cost.

people can plan their lives. Dramatic advances in diagnostic and prognostic markers of future health states, not least in genetics, could undercut social arrangements for risk sharing such as life assurance and health insurance.

Data on the use of certain health services have long been deliberately anonymised (returns for sexually transmitted diseases, for example) to prevent stigmatisation and encourage uptake. Most databases, however, cannot be anonymised if they are to be used for administrative purposes, let alone for research. Increased legal protection of the privacy of individuals, particularly in Europe, has raised major issues around the confidentiality of healthcare records and the degree to which consent is required before data can be entered.

Inadequate coding

If the 'capta' in casenotes are to be turned into useful data, standardised coding systems of diseases (both for patient characteristics and outcomes) and technologies are essential. The International Classification of Diseases (ICD) was originally developed for classifying causes of death, but from 1948 was extended to cover morbidity.[12] ICD, which has to be regularly updated to keep up with new diseases (currently on ICD-10), has a major advantage of being international. Standard definitions have also been developed to classify surgical interventions, though national differences exist. The UK uses OPCS4, originally developed by the Office of Population Censuses and Surveys[13] but maintained by the NHS Information Authority, which acknowledged in 2000 that it was due for replacement.* Pharmaceuticals are coded via the British National Formulary (BNF), whose chapter headings can be mapped to the WHO classification and European Union classifications but not directly to ICD headings.†

Coding systems require means of translating the nomenclature or terms used by doctors to describe diseases, conditions and treatments into standard codes.‡ Several systems, including Read in the UK and SNOMED in the USA, aim to achieve this by way of an electronic thesaurus. SNOMED and Read codes were merged to provide a new international terminology of health from 2001.[15]

Although an electronic thesaurus can cover the full range of HTs, coding systems are generally lacking for HTs other than surgical and pharmacological interventions. A coding system for medical devices has only recently been developed. No such systems exist for outpatients, for diagnostics and imaging, for the range of types of contact in primary and community health services or for the organisation of healthcare delivery.

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* The *Office of Population Censuses and Surveys Classification of Surgical Operations and Procedures*, 4th Revision (OPCS4), published in 1987, evolved from a series of classifications revised since the earliest classification of surgical operations, was published in Britain by the Medical Research Council (MRC) in 1944. Subsequent updates were made to the fourth revision in 1987, 1988 and 1989. Use of OPCS4 is mandatory in contract minimum datasets and Central Returns in the NHS England. The classification is maintained and published by the NHS Information Authority, which has acknowledged: "The classification is no longer meeting the needs of the user as current practice has been significantly developed since the last revision of OPCS4. Following a strategic review of OPCS4 and final report issued in April 1998, a further project was completed to look at the feasibility of basing future development on Clinical Terms. The final report was produced in March 1999. The NHS Information Authority is currently in discussion with the Information Policy Unit on the need to take forward work on an OPCS4 replacement." See http://www.coding.nhsia.nhs.uk/clin_class/class_faq.asp#6

† In the USA, the Healthcare Financing Administration has developed a new procedural coding system linked to ICD 10 (ICD-10-PCS). Hitherto the USA used the American Medical Association's Common Procedural Terminology, CPT-4.[14] The European Union has established a centre for standardisation of coding systems (Centre Européen de Normalisation), which aims to develop new systems. Prior to selling medical devices within the European Union, manufacturers must assign a risk class to each device and follow other safety and performance requirements defined by the European Medical Devices Directives. To assist manufacturers who want to self-certify their products by meeting the classification requirements of the Directives, the Institute of Biomedical Technology (INBT), a non-profit organisation with headquarters in Greece, has produced a medical device classification guide for determining the risk level of a device.

‡ An alternative view sees three distinct processes in information handling: terming (SNOMED Clinical Terms), classifying (ICD-10 and OPCS4) and grouping (Healthcare Resource Groups). These can be described in terms of 'granularity'. The finest granularity offering the greatest detail for recording patient care is a natural clinical terminology, such as SNOMED Clinical Terms. This can underpin and populate the electronic patient record (EPR) by providing a common computerised language. A coarser granularity is found at classification level to support statistics and management. The coarsest granularity is found at grouping level to support aggregation for costing and other analysis.

Even when coding systems exist, they are limited not only by the quality of the underlying data, but also by the lack of detail in most standard coding definitions. For example, ICD does not cover disease severity and, in practice, many conditions are coded as 'unspecified'.* Although procedure codes (such as OPCS) specify surgical interventions, detail is lacking on the specific surgical technologies used.

The extent to which health states can be included in medical records must be limited, partly owing to problems of the coding systems (no severity, quality of life measurement, or disease-specific symptom profiles), and duration (longer term outcomes matter). Most coding systems lack the relevant domains to include such detail even if available.

Standard classification systems are inevitably poor at identifying new technologies. All standard coding systems inevitably lag new diseases and procedures.† For example, coronary stenting was not picked up as a distinct technology in routine hospital statistics despite its high cost and questions over its effectiveness.[16]

Perceived lack of value

Most NHS administrative databases are regarded as unreliable by clinicians, and are consequently seldom used in clinical practice. Reliability of routine data can, however, be plausibly expected to vary by data heading. To meet legal and administrative requirements, certain minimum data have to be reliable (patient identification, date of entry and exit from care), but additional data may be less reliable owing to lack of clear or standard definition (for example, health states and treatments). Any perceived lack of reliability of data for clinical or evaluation purposes reduces clinician motivation. The poor clinical quality of much routine data results from its not being used by clinicians in their work. Other problems include variation in expertise, lack of training, time required to enter data, and coding by non-medical coders (who lack formal training in the UK – unlike in the USA where coders have to be qualified). Plausibly, a trade-off exists between the increased accuracy and cost from having clinicians code records compared with less highly trained staff.

Signs of progress

IT, in healthcare as elsewhere, offers the potential for major change. Computerisation of casenotes offers scope for their 'routinisation'. Some services, such as intensive care units (ICUs), are collecting routine data electronically‡§ with much greater levels of detail than hitherto. EPRs are a reality in some hospitals and their widespread use is an objective of the NHS Information and Communications Technology strategy,[18] which also acknowledged that, up to 1998, they had 'not been a success story'.[19]

Computerisation, unique patient identifiers and linkage between databases offer the prospect of improvement. They make it increasingly possible to chart patients' complex itineraries through healthcare systems, provided that the appropriate detail has been captured and coded. Linkage between databases on the basis of unique patient identifiers enables routine databases, including registers, to collate much more detail than has traditionally been the case.

As the level of detail increases, issues around the confidentiality of healthcare data, protected historically by data aggregation at local level and the inability to link different databases, will have to be confronted. Encryption offers scope for protection of both patient and doctor identities but will require clear rules about who can access what. The Department of Health in England, faced with a possible collapse of the Cancer Registers in 2001, clarified its ownership of NHS data and put in place arrangements for supervising the sharing of data with third parties.[20] The issues of confidentiality are discussed in more detail elsewhere.[21]

Despite the problems with routine data, disease and HT databases are already being used

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* For example, rather than acute and chronic renal failure being distinguished, the coding often places both in 'renal failure unspecified', reducing sensitivity and specificity.

† Only limited coding systems are available for diagnostic and imaging procedures.

‡ 'Almost routine' in that such systems are seldom linked to the larger data systems in the hospitals concerned, but these are likely to be linked in the future in ways that go far beyond traditional approaches to include patients' clinical characteristics and short-term outcomes. Standard terms such as Read codes enable data, such as those in casenotes, to be interpreted in standardised ways.

§ The Intensive Care National Audit and Research Centre (ICNARC) organises its data according to whether care was related to surgery or not, and then, within this category, whether it was emergency, urgent, scheduled or elective. Reason for admission and past medical history are also collected.[17]

occasionally in assessing the effectiveness of HTs. One example is an assessment[22] of *in vitro* fertilisation (IVF) based on data collected routinely by the UK Human Fertilisation and Embryology Authority (HFEA), which identified factors associated with successful conception, including age, number of previous children, if any, and duration of infertility. This in turn formed the basis of evidence-based guidelines on managing the infertile couple.[23]

Another example is the use of the National Transplant Database to show the benefits of human leucocyte antigen (HLA) matching[24,25] and to identify best methods of cadaveric organ retrieval.[26]

In England, the Hospital Episode Statistics (HES) have been used to explore variations in clinical outcomes. The NHS Clinical Indicators published in 1999, covering specific types of hospital mortality, readmission and discharge (but not specific interventions), are entirely based on HES.[27,28] Their extension to include 30-day mortality relies on linkage of hospital admission data to mortality records, following the example of Scotland, and will greatly extend their scope. Linked routine data in Scotland, when validated[29] as part of the West of Scotland Coronary Prevention Study Group (WOSCOPS) prospective trial of pravastatin, proved as effective as reporting based on direct patient contact for mortality, hospitalisations and cardiac surgical procedures, had better coverage of non-responders and dropouts, and was considerably less costly. Other examples of the use of HES include policy assessments of the impact in England of GP fundholding (arguably an HT) on waiting times,[30] prescribing[31,32] and day case rates.[33]

Routine data have been essential to analyses of inequity in healthcare and health, notably by the Black[6] and Acheson[34] reports. Needs indices, designed to distribute NHS capitation funding[35] more equitably, are based on routine databases, notably HES[36] and the General Practice Research Database (GPRD).[37] Routine data are clearly central to analyses of the diffusion of HTs.

The use of routine data in the different types of HT assessment varies by country. In the USA, the Patient Outcome Research Teams (PORT) studies[38] used administrative claims data to assess the effectiveness of a range of common treatments, but have been criticised[39] for potential bias. Sweden has over 40 'quality registers'[40] that include patient-specific data on diagnoses, medical interventions and outcomes.* Denmark has developed standards for use of its 'biobanks', defined as all health-related databases which include personal identifiers.[41]

Iceland provides an example of an attempt to develop a single computerised database linking medical records, family trees and assorted genetic information. Its small population size (270,000), the existence of detailed medical records and the involvement of deCode genetics (an indigenous commercial firm) are important factors. The Icelandic parliament approved the controversial project in 1999.[42] Countries such as Iceland, with national identification numbers (and ID cards), can link all national databases – population census data, disease-specific registries, mortality, emigration and hospital use for specific conditions. In the UK, the Department of Health and the Wellcome Trust have funded similar† DNA collection from 500,000 volunteers for epidemiological studies of the environmental and genetic causes of common diseases.[43,44]

Approach in this report

Although many routine databases have been developed in healthcare, the lack of any method for classifying them makes difficult an assessment of their potential use in HT assessment.

In this report we have eight objectives:

1. To develop criteria for classifying databases in relation to their potential use for HT assessment.
2. To list the databases of relevance in the UK.
3. To apply the criteria for classifying databases to this list and identify and investigate those with most scope for use in HT assessment.
4. To explore the extent to which they could pick up those HTs prioritised by the UK's NHS R&D HTA programme.
5. To investigate the extent to which routine databases have been used for HT assessment purposes.
6. For those databases with most potential, to explore the degree to which they have been validated.
7. To estimate the cost of the main databases.
8. To make recommendations as appropriate.

* Some UK registers have been influenced by the Swedish experience. For instance, the Scottish Hip Fracture Audit is modelled on and uses the coding/classification system developed by its Swedish equivalent.
† The proposed UK database notably differs from the Icelandic in being composed of volunteers who 'opt in' and formally consent.

Chapter 2
Background

This chapter summarises the history of routine data on health and healthcare in the UK.

Demographic and mortality data

The decennial Census of Population in the UK by country since 1801 has provided basic data on population size and composition. Public health concerns have long had an input to the Census, including pressure for inclusion of age (not included up to 1841) and on the prevalence of physical and mental disability (questions concerning the deaf, dumb and blind were included from 1851 to 1911). William Farr, the first chief medical statistician in the Board of Health, used these data to analyse the distribution of handicapped people by age and locality, the proportion of congenital origin and institutional requirements for their care.[45] In recent decades, questions have been included on ill-health and a 1% sample has been followed up and linked to vital events (births, deaths, marriages) to provide longitudinal data.[2] Overall, the Census of Population provides a unique source of data for use as the denominator in epidemiological studies and as the numerator in others.

Mortality data have long been collected for probate reasons (the term coroner derives from guardians of the crown – *custos placitorum coronae*). Mortality statistics have existed at national level in England since the Births and Deaths Registration Act 1836 and became compulsory in 1874. Natural and unnatural causes of death have been distinguished and classified, partly for legal reasons, partly for epidemiological reasons. Stillbirths, for instance, were added to notifiable causes of death in 1927 and changed in 1992 after changes in the legal definition of stillbirth.

Infectious diseases

Different diseases attracted attention at different times. Vaccination Acts from 1840, 1853 and 1867 led to special machinery for enforcing compulsory vaccination for cholera. Compulsory notification of smallpox dates from 1899.

The first notification of venereal diseases was under the Contagious Diseases Act 1866, which applied only to garrison towns and naval stations, but this requirement was deleted in 1886. "From 1886 until 1914, neither prostitution nor venereal disease existed officially in Britain so no action could be taken."[46]

Under the Public Health Act 1984, medical practitioners are statutorily obliged to report 29 notifiable diseases, including cholera, plague, relapsing fever, smallpox and typhus. AIDS/HIV became notifiable in 1988 and Creutzfeldt–Jacob disease in 1990.[47] Although notification is legally required in order to prevent the spread of diseases, treatment is not specifically authorised without consent.[48]

Healthcare use

Some data on the use of healthcare have also long been routinely collected, at first mainly for legal reasons. Mental hospital admissions data were collected from the 1840s under the 1845 Lunacy Act. Compulsory detention required such data and covered patients in both public and privately funded hospitals.[49] Annual data were published up to 1960 on the numbers admitted and discharged from each lunatic asylum, along with diagnoses. Payment arrangements for pauper lunatics by local Poor Law Boards required data at patient level. Other than this exceptional group, however, data were not collected on use of other health services until the advent of the NHS in 1948.

NHS and Central Returns from 1948

The establishment of the NHS in 1948 led to mandatory Central Returns.* For each UK country, and by region within England, a large set of Central Returns, including activity and finance data, were obligatory.[10,50] Most Central Returns were based around service providers, generally aggregated at the level of the hospital. They tended to focus on structure (number of hospitals, number of beds by specialty, staffing levels) rather than on number of patients treated. Since

providers were not funded on the basis of activity, data on numbers treated and costs generally remained separate, but with some exceptions, including drugs prescribed by GPs and GPs' lists.

Drugs prescribed by GPs and dispensed by pharmacists required payment linked to the number of items dispensed by particular pharmacies. The Prescription Pricing Authority (PPA), which is responsible for payments to pharmacists, processes some 500 million prescriptions each year. Although these data are limited to details of the drugs, who prescribed them, who dispensed them and to whom, their complete coverage of GP dispensing makes them an invaluable source, limited mainly by lack of any patient or disease information.

The NHS Central Register has been used since 1948 to pay GPs in relation to the number of patients registered. This register, originally used for the issue of identity cards for rationing food in the Second World War, not only helps estimate payments due to GPs, but can also be used to track people for research purposes. The Central Health Register Inquiry System (CHRIS) contains 'flags' relating to both cancer registration and membership of around 240 ongoing medical research studies, in which around 2 million people or some 4% of the UK population are included.[3]

Data on the use of NHS acute hospitals were collected and published as Hospital In Patient Enquiry (HIPE) on a sample basis from 1949 – first as a 100% sample of 87 hospitals, then from 1952 as a 10% sample of admissions, which expanded to complete coverage by 1977.[51] These data included demographic, administrative and some clinical headings (surgical interventions and ICD coding of conditions but not medical interventions or technologies). The Hospital Episode Statistics with around 10 million records per annum has since the early 1990s provided data on patients' use of NHS acute and psychiatric hospitals. Although not subject to legal statute, these datasets had the force of administrative law.[52]

The Korner review

The Korner review[10] in the mid-1980s led to fundamental changes in the organisation of Central Returns. For inpatient activity, 'finished consultant episodes' replaced 'deaths and discharges' as the unit of measurement in acute hospitals. Minimum datasets were implemented for acute hospital services but those proposed for community, maternity and mental health services suffered repeated delays. A mechanism for changing minimum dataset specifications, the Committee for Regulating Information Requirements (CRIR), was set up. Although aimed at bringing the NHS up to date, the Korner reorganisation was itself rendered out of date by the NHS reforms of 1991, which led to the separation of purchasers (or commissioners) and providers, and to GP fundholding. These changes required Central Returns to collect information on which patients were treated where. Both Trusts and Health Authorities have been subject to ongoing reconfigurations through to 2002 with the establishment of Primary Care Trusts, which have required further changes in the Central Returns.

NHS information technology policy

The NHS Central Register was computerised in 1991. The PPA, which is responsible for payments to pharmacists, operated a massive paper system with several hundred million items annually until computerisation in the 1990s.

NHS policy was outlined in the early 1990s[53] as having the following key elements:

- information being person based
- systems integrated so that the bulk of patient-based data need only be collected once
- management information being derived from operational systems
- information being secure and confidential
- information being shared across the NHS.

NHS IT policy was reviewed in a 1997 White Paper,[54] which reaffirmed these aims with commitments to lifelong electronic patient records

* The NHS from 1997 has produced an annual listing of over 200 Central Returns (*Health Service Circular 1999/070. Central Data Collections from the NHS*, and its predecessors in 1997 and 1998). These define Central Returns as structured collections of data from the NHS commissioned by the Department of Health including the regional offices of the NHS Executive (NHSE), including financial, workforce and activity information, short-term and one-off requests, voluntary and sample surveys, exception reporting, collections, commissioned from academic, commercial and other external agencies. However, the annual listing is confined to the first of these – financial, workforce and activity information, broken down into activity, estates, Family Health Services, Miscellaneous, Patient's Charter and workforce. Most of these returns relate to financial management.

for every person and on-line access for clinicians in order to allow 'seamless care'. Targets were set for roll-out of this strategy. A new NHS Information Authority was established as an executive agency, working to implement policy to be developed within the Department of Health by a new Information Policy Board.[55]*

Widespread dissatisfaction with the number of Central Returns and their lack of usefulness to managers led to an efficiency scrutiny of NHS information requirements in 1996,[56] which recommended discontinuation of a (small) number of Central Returns but judged the bulk of them to be necessary. This report endorsed the broad direction of NHS information policy outlined above, particularly the development of a single computer-readable NHS number for each person, and the development of electronic patient records.†

The development of National Service Frameworks [for mental health, coronary heart disease (CHD), diabetes and the elderly] in the late 1990s requires new sorts of routine information capable of monitoring progress towards the milestones which have been set. For example, GP practices will have to establish local registers of patients with established CHD and their treatments. These developments will require the electronic patient records envisaged in the NHS IT strategy and national disease and HT registers. The NHS Plan has earmarked investment to meet detailed IT targets.

Gaps in NHS Central Returns

Since NHS Central Returns are specific to particular services, their coverage of the full range of HTs and settings has left some major gaps. Although inpatients in NHS hospitals are recorded in the HES, outpatients, diagnostic tests and GP and community health service contacts tend not to be captured at all or only in simple counts of contacts by provider. A national Minimum Dataset for outpatients, introduced in 1996, is limited owing partly to the nature of outpatients (very many repeat visits, often for diagnosis or monitoring). Within HES, important service structures such as stroke units are not distinguished. Duration of follow-up without special record linkage is limited to the inpatient stay and readmission data are difficult to derive. The large number of contacts with GPs means that no routine patient-based data are collected centrally (other than for the payment of prescriptions) so that analysis of trends relies on periodic surveys such as the GP Morbidity Survey[60] or the ongoing GPRD[61,62] and other similar databases. The scale and complexity of diagnostic imaging pose similar problems‡ for defining Minimum Datasets.

Linkage

Linkage of data between different routine databases provides a powerful way of extending their use in addition to validating data items. Apart from the NHS Central Register, more detailed linkage including hospital records has been pioneered in the Oxford Region[63,64] and in Scotland.[65–67] Historically, the lack of a single computable NHS patient number has limited health record linkage. Use of a single computerised patient number (the Community Health Index) to link different datasets has allowed greater progress in Scotland, providing pointers for England. Annex 2 (p. 73) deals with the Scottish experience.

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* The Secretary of State for Health noted that, "For too long the NHS has thought of IT projects in isolation. Something to be left to the IT specialists. Something that is not a priority for patient care and health services. Let us set this right. The better capture, management and use of information – analysed, communicated and shared through modern systems and networks – is central to managing change and modernising the front-line delivery of care, treatment and services to patients. It is central to improving the day to day working and skills of staff. It is about improving the very nature of care itself – information, communication and understanding."[55]

† NHS IT policy has been the subject of critical reports by the National Audit Office (NAO). The disposal of regional information in the South West to a private company (EDS) was criticised for not achieving best value for money.[57] A review of the purchase of Read codes by the NHS[58] was criticised in relation to both the purchase of the codes and their subsequent management. The overall strategy outlined in 1992 and reaffirmed in 1998 was criticised by the NAO:[59] the design of the 1992 strategy was deemed unsatisfactory and "its impact undermined by certain shortcomings in implementation". The 1998 strategy was deemed an improvement in design with greater coherence and local implementation plans, but room for improvements in terms of specific and measurable targets was identified.

‡ The use of routine data to assess diagnostic/imaging tests would require considerable data, including which diagnostic/imaging tests were being used (which implies an appropriate coding scheme), patient characteristics and indications, subsequent tests, diagnosis made and follow-up for test negative cases for false negatives.

Hospital statistics

Increased scrutiny of hospital statistics in the 1990s resulted from GP involvement via fundholding, and later and more generally through clinical governance and clinical indicators. Fundholding, by having GPs purchase elective surgery on the basis of surgical codes, led to repeated arguments between GPs and hospitals over quality of data. The quality of data was the most frequent complaint in a survey of Health Authority contracting.[68]

The policy of GP Total Purchasing in almost half of English health authorities extended the scrutiny by GPs of HES to non-elective work. Primary Care Trusts (PCTs), which can be seen as the extension of Total Purchasing to the whole of the English NHS, means that the funding of hospital activity as recorded in HES is important to GPs. It seems inevitable that such increased scrutiny will lead to correction of the more obvious errors. While lack of standardisation of computing systems and codes will remain major barriers, the NHS Plan will fund a major roll-out of computing in primary care.

Equally important may be the development of NHS Clinical Indicators. Although the first set of Clinical Indicators were confined to in-hospital mortality and discharge destination, their extension to 30-day mortality (by linkage to mortality record using the NHS number, as in Scotland)[66] marks a major advance. To the extent that the planned development of electronic patient records is realised, much more detailed clinical data may become available. For some conditions HES as currently constituted will be able to provide data similar to clinical registries, whereas for other conditions, the greater detail of clinical registries will be essential.

The development of a Data Quality Indicator (DQI) for HES, developed to support the NHS Performance Assessment Framework,* marks an important development. It includes an assessment of data coverage and a series of component indicators for groups of related data items in the HES dataset, providing a summary measure of data quality for health authorities of residence and NHS Trusts. The quality indicator is to be supplemented with accreditation and audit of HES data.

Nonetheless, hospital data will inevitably have limited use in HT assessment, owing to the lack of detail on specific HTs, on health states (such as severity and co-morbidity) and on clinical outcomes.

Private sector

Although the NHS accounts for the bulk of health service provision in the UK, the private sector cannot be ignored. Some 12–14% of total healthcare expenditure is privately funded, as is over 20% of elective surgery.[69] The bulk of nursing home places are privately provided.

Data on privately provided services have generally been lacking, except for services whose legal regulation required such data (such as compulsory psychiatric admissions, terminations and IVF). However, many countries (e.g. USA, France) in the 1990s imposed legal obligations on private providers of acute hospital services to provide minimum datasets to the state. In the UK, no such requirement applies and only occasional survey data are available.[70] The remit of NICE and CHI does not apply to private hospitals except in relation to NHS patients treated there.

Moves to regulate the private healthcare sector, spurred by several tragedies in private hospitals and by the House of Commons,[71] prompted discussion[72] and the establishment of the National Care Standards Commission[73] in 2000. This did not include any requirement for that sector to provide information on levels of activity (such as the numbers treated by which treatments). No data comparable to the NHS Clinical Indicators exist for private hospitals.†

Some private companies have developed technology-specific register-type information. Genzyme, for example, collect data on all patients who receive a particular knee treatment that they helped pioneer (autologous chondrocyte implantation) with the aim of long-term follow-up of patient outcomes.

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* The DQI is made up of 13 component indicators. All indicators are weighted equally with the exception of the two maternity indicators (which have a combined weight = 1) in order to give an overall DQI which is expressed as a percentage. The values for DQI have been computed for 1997–98 and 1998–99 (although the latter year is incomplete). Taking the 12 available indicators gives a composite DQI for 1998 of 94%. The figures for each indicator were high – all >90% with the four indicators with lowest scores being administrative, diagnosis 2, practitioner and maternity (see www.doh.gov.uk/hes/).

† The reorganisation of the various regulatory bodies in 2002, which includes the private healthcare sector, may lead to improved data on that sector.

Disease and health technology registers

A wide variety of registers exist, some old and limited, some newer and much richer. Registers have often been developed by enthusiasts for various reasons and are funded from many sources.

Registers have been defined as containing "data concerning all cases of a particular disease or other health relevant condition in a defined population such that the cases can be related to a population base. With this information incidence rates can be calculated. If cases are regularly followed up, information on remission, exacerbation, prevalence and survival can also be obtained."[74] Registries have been defined as the place where registers are kept.[75]

The report 'Disease Registers in England' by Newton and Garner[21] (commissioned by the Department of Health and published after the present report was completed) reserved the terms 'disease register' and 'case register' for those databases that have a clearly defined denominator population.

The oldest registers go back to the collection of data on the deaf, blind and dumb, which were used to estimate requirements for care and later for social security benefits. These contained no data on treatments (which often did not exist).

Cancer registries were developed on a regional, voluntary basis in England from 1962[76–79] in the UK after follow-up studies of patients treated with radium in 1929. The aim was to collect a record of patient and tumour characteristics for every newly diagnosed primary malignancy in residents of England. The linking of cancer registrations with mortality data via the NHS Central Register enabled survival rates to be compiled. However, relatively few data were collected on treatments (other than broad categorisations of chemotherapy and radiotherapy) or on outcomes. The NHS Cancer Plan, 2000, required fundamental improvements in the data collected on treatments for cancer. A review of the cancer registries[80] identified informational weaknesses in relation to current policy needs and recommended changes which were accepted by the Government.* These included electronic transfer of data, measures to improve data quality, timeliness and completeness and integration of registry data to inform the emerging cancer networks.

Psychiatric case registers were developed in the 1960s but fell out of use in the 1980s,[82] mainly owing to lack of funding. Supervision registers aimed at identifying high-risk psychiatric patients have developed unevenly and with much criticism.[83,84] A new dataset, the Mental Health Minimum Dataset, was developed to improve information on mental health services usage and need. Due to become mandatory in 2003, this person-centred dataset describes the care received during each overall spell of care. Its purpose is to provide local clinicians and managers with better quality information for clinical audit, and service planning and management.

A more recent development has been that of HT registers, for example of patients who have had devices implanted, such as pacemakers. Since medical devices have to be commercially manufactured, the possibility of litigation due to malfunction has provided an impetus to the development of technology registers. Other examples include registers for those who have had IVF or have had organ transplants or artificial heart valves. Some registers focus on those who have had particular kinds of procedures (for example, coronary artery revascularisation, hip prostheses[80,82]). Occasionally the disease and the technology overlap, such as for haemophilia. Disease registers have long been proposed for diabetes and stroke[80] and will finally be implemented as part of the relevant national service frameworks. *Our Healthier Nation*[82] committed the Department of Health to disease registers for the first time to monitor trends towards the objectives set.†

* The Government "agreed with Prof. Gillis that current arrangements for cancer registration in England were no longer sufficient to support the National Cancer Programme and accepted the recommendation … that a network of regional cancer registries should remain the cornerstone of cancer registration with new arrangements for accountability being required. New resources will be allocated to drive up the quality, timeliness and completeness of cancer registration. Over time providers of cancer services (e.g. Trusts) will take on responsibility for local data collection. Electronic transfer of data to cancer registries will become the norm. This will enable all registries to concentrate their efforts on collation of data from multiple sources, quality assurance, analysis, dissemination of information and research."[81] A detailed plan for improving information in cancer has been announced.

† The report *Disease Registers in England*[21] arose directly from this commitment.

To survive, disease registries have required both enthusiasm and resources. A WHO review[87] of coronary heart registers stressed that success required the full cooperation of the majority of doctors and relevant lay people, the necessary epidemiological skills and adequate resources to organise a team large enough to cover the population. Some lessons have been learnt from previous initiatives, for example the European Dialysis and Transplant Association (EDTA) Register failed to survive in its format owing partly to the labour involved in completing the patient-specific forms manually and to the lack of useful comparative feedback to data providers to assist them in the evaluation of clinical practice.[88]

Adverse drug events and Confidential Enquiries

Safety (or risk) of HTs has historically taken precedence over the analysis of efficacy, effectiveness, equity or cost in the compilation of healthcare databases. Two factors have arguably contributed to this: the long-standing medico-ethical commitment to 'do no harm' (*no nocere*) and limitations on data collection. Scandals due to severe adverse events, notably with thalidomide, led in 1964 to a formal adverse event reporting system for drugs. Similar systems have been developed more recently for devices and procedures.

Although the PPA (and its Scottish, Welsh and Northern Irish equivalents) collects data on drugs dispensed on GPs' NHS prescriptions, it has no data on adverse events arising. Several systems of adverse event reporting of drugs exist. Doctors noting adverse reactions should complete an NHS yellow card, which is included in copies of the BNF, and send it to the Medicines Control Agency (MCA). The PPA can forward details of prescriptions of specific new drugs to the Drug Safety Research Unit (one in England, another in Scotland) for detailed follow-up. Pharmaceutical companies engage in adverse event reporting through post-marketing surveillance, sometimes via the Drug Safety Research Unit.

By contrast with the focus on individual adverse events, databases covering all patients treated have also been used. The GPRD and similar databases not only provide data on serious events but also allow the analysis of the factors associated with the effectiveness of different drugs to be explored. The acquisition of GPRD by the MCA may extend its role and make it more accessible to researchers.*

The roll-out of computerisation in general practice will, over time, make such data much more widely available.

Adverse events arising from medical devices have led to a parallel reporting system, run by the Medical Devices Agency (MDA). The MDA also funds four HT registers, covering heart valves, pacemakers, hydrocephalous shunts and silicone breast implants.

Confidential Enquiries

Four Confidential Enquiries existed in England in 2000:

- Confidential Enquiry into Peri-Operative Deaths (CEPOD) (from 1989)[89]
- Confidential Enquiries into Maternal Deaths (CEMD) (from 1952)
- Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) (from 1992)
- Confidential Enquiry into Suicides and Homicides associated with mental illness (from 1992).

Scotland has its own versions of each of these. The confidentiality component is designed to encourage reporting of the relevant adverse events. In 1999, responsibility for these enquiries in England was delegated to NICE,† which commissioned an independent review[90] and has continued to fund them.[91]

Confidential Enquiries share limitations with adverse event reporting. Both have hitherto been voluntary (although this may change with clinical

* The MCA is offering a range of levels of access to GPRD. The new 'Full Feature' GPRD and associated research services are accessed through a secure online mechanism and include advanced query tools to access the database. GPRD can be used to optimise decision-making across the health research spectrum including clinical epidemiology, drug safety, disease management and drug utilisation. It will be licensed to academics, regulators, pharmaceutical organisations and research service providers. Further information is available at www.gprd.com or via e-mail at admin@gprd.com. See the MCA website at http://www.open.gov.uk/mca/mcahome.htm

† The review of the Confidential Enquiries, chaired by Professor Grimley-Evans, queried the rationale of making NICE responsible for the enquiries and made various recommendations, including that management of the enquiries be brought together under a single agency (see http://www.nice.org.uk/catlist.asp?c=42).

governance). Each requires detailed data only on the relevant adverse incident(s), and thus lacks denominator information, without which rates cannot be estimated. The absence of a control group limits aetiological inference. The conventional focus on mortality as the main hazard restricts the scope for analysis of effectiveness and safety of the relevant technologies.

Termination of pregnancies and *in vitro* fertilisation

Legal requirements have been most common around issues of life and death. In addition to deaths, terminations due to abortion have to be notified under the 1967 Abortion Act, covering both public and private sectors. From 1986, IVFs have also to be recorded under statute. As the data collected for IVFs by the Human Fertilisation and Embryology Authority (HFEA) include details of mother-to-be, donor, technique and outcome, the result is a particularly rich (even if largely inaccessible) database. Although access is restricted to members of the HFEA board, one important assessment of the effectiveness of IVF has been carried out using these data.[22]

National audit 1990s

Clinical audit as introduced to the NHS in the early 1990s initially shared much of the safety emphasis of adverse event reporting. It tended to be local, *ad hoc* and highly confidential.[91–92] One important result of funding being made available was the introduction of personal computers. Clinical databases began to be developed and extended to include other hospitals for comparison, sometimes at regional or national levels. Effectiveness began to replace adverse event reporting, with increased interest in evaluating the range of patient outcomes, in the context of standard setting and benchmarking.[95]

Although much of the early clinical audit would fail to meet the definition of routine data outlined above (irregular collection, lack of standardised definitions, confined to one site), the emergence of regional and national audit databases would qualify. Examples discussed below include six cardiac registers, the ICNARC database, the trauma audit and research database plus a number of others in development. Several of these generate income by providing a comparative data analysis service which units can use for audit and benchmarking. The decision by the NHS Executive in 2000 to require "NHS Trusts to sign up to the national comparative clinical audit scheme, ICNARC"[96] marks an important development which may be applied to other such services.

National comparative audit can be seen as a form of effectiveness analysis as it has the potential to evaluate the delivery in routine practice of interventions which have been shown to be efficacious in clinical trials. Processes and outcomes can be audited against standards of practice suggested by research studies (or by consensus opinion).

Hospital statistics were repeatedly criticised as being deficient for audit.[97–99] Deficiencies in HES (or more specifically the NHS Hospital Minimum Dataset of which HES is a subset, compiled at national level) have often been seen as a reason for developing clinical audit databases. HES treatment fields are limited to diagnosis and surgical codes, thus lacking the detail necessary for audit for more than a few procedures. The NHS Clinical Indicators, which are based on HES, focus on a relatively small set of relatively well-defined conditions (such as myocardial infarctions, strokes and fractured neck of femur)[100] which are not directly linked to single specific health technologies.

Confidentiality and consent

The 1997 Caldicott report[101] laid down both principles and a framework including the appointment of local Caldicott 'guardians' in each NHS organisation to protect the confidentiality of data.

The 1998 Data Protection Act included a requirement that any use of identifiable data relating to the "physical or mental health or condition" of a living individual requires either his or her informed consent or that the "processing is necessary for medical purposes". While these 'medical purposes' include 'medical research', no definition of medical research was provided and no exceptions to the need for consent were given.

In response, several professional organisations issued guidance requiring informed consent before identifiable information could be used for research. This has posed major concerns for the future of audit[102] and the Cancer Registers.[103]

Lord Hunt, in introducing the 2001 Health and Social Care Bill, noted that 'the existing legal framework concerning the control of information relating to patients is complex and contains some uncertainties'.[104] The Bill proposed to deal with these issues by giving the Secretary of State for Health powers to determine what information should be disclosed in the public interest, whether anonymised or not. The resulting Health and Social Care Act, under pressure of the May 2001 general election, focused on the processing of patient information, leaving the issues around disclosure largely unchanged.*

Further legal complications seem likely as a result of the Human Rights Act of 1998 (which has become law in the UK) and the European Convention of Human Rights. More detailed discussion of these issues is available elsewhere.[21]

Key points

- Although some data have long been collected in healthcare for legal, financial and safety reasons, the data were usually aggregated at the level of local providers. Exceptions had to do with concerns over safety (drugs, confidential enquiries) and ethics (terminations, IVF).
- More recent policy, facilitated by information technology, has led to the collection of data on patients treated, with what technology and to what effect.
- As the cost of collecting and linking data falls, databases of extraordinary clinical richness can be assembled, which will help assessments of the effectiveness, equity and cost of HTs as used in practice.
- However, tensions have arisen over access to these databases, not least in relation to confidentiality.

* See critical review from R Anderson, specialist in information security and advisor to the BMA, at http://www.cl.cam.ac.uk/~rja14/#Med

Chapter 3

Terms and definitions

This chapter defines the key terms – routine data, health technology and health technology assessment.

Routine data

Literature searches were conducted using as keywords 'routine data' and 'administrative data'. The former yielded relatively few references (181 using MEDLINE 1966–2000), whereas the latter generated a large number (44,193 using the same source and period). 'Routine data'* appears to be a more recent term which is more common in the UK and Europe. 'Administrative data' is widely used in the USA, often referring to data collected as part of health insurance arrangements. None of the articles located using 'routine data' defined the term, except in passing.[105]

In the absence of an unequivocal definition in the literature, this chapter identifies the following important characteristics in routine databases:

- regular and continuous or periodic collection
- use of standard definitions for all the population group covered
- some (usually considerable) degree of obligation to collect the data completely and regularly
- collection at national or regional level, including more than one centre, depending on the representativeness of the sample.

Health technology

HT tends to be broadly defined. A UK definition:

"all methods used by health professionals to promote health, prevent and treat disease, and to improve rehabilitation and long term care";[106]

and from the USA:

"the set of techniques, drugs, equipment and procedures used by healthcare professionals in delivering medical care to individuals and the systems within which such care is delivered".[107]

These definitions are so broad as to include almost any aspect of healthcare. Further, different levels can be distinguished, from broad interventions (such as organisational structures) through to possibly numerous components (individual diagnostic tests, drugs, surgical procedures and other interventions).

Health technology assessment(s)

HT assessment is taken to include the assessment of efficacy, effectiveness, diffusion, equity, cost-effectiveness and cost impact. We distinguish three kinds† of HT assessment, each with distinct data requirements:

- **efficacy** and **effectiveness** (including safety)
- **equity and diffusion**
- **costing** HTs.

Efficacy and effectiveness

Efficacy studies usually assess patient benefit and harm in experimental and closely monitored research studies, normally RCTs. Although these trials have major advantages in minimising bias, their generalisability is questionable (restricted entry criteria, unrepresentative settings). Effectiveness, by contrast, is concerned with patient benefit and harm when the technology is actually applied in everyday practice. Effectiveness can be assessed to varying degrees using pragmatic clinical trials, adverse event reporting, clinical audit and comparative audit of performance.‡

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* The *Shorter Oxford English Dictionary* defines 'routine' as follows:

1a. Routine – a regular course of procedure, a more or less mechanical or unvarying performance of certain acts or duties.

1b. A set form of speech, a regular set or series (of phrases, etc.).

2. Regular, unvarying or mechanical procedure or discharge of duties.

[From French: routine, rotine, route.]

† These can, of course, be combined, as in cost-effectiveness analysis.

‡ The boundary between efficacy and effectiveness cannot be tightly drawn, and the various methods suggested here for assessing effectiveness differ from each other in important ways.

Efficacy-oriented HT assessment rightly emphasises the evidence from well-designed RCTs and systematic reviews of trials. Well-conducted trials provide the most scientifically robust information on efficacy and, when there are broad and pragmatic entry criteria for patient and centre selection, they can also provide data on effectiveness.

Assessment of diffusion and equity

Equity within healthcare can be defined in terms of the extent to which different groups use or receive particular HTs in relation to some measure of their clinical need or to perceived fairness. Relevant databases must enable groups of interest to be identified. Such groups can be defined in many ways (age, sex, ethnicity, socio-economic group, disease severity and geography). Diffusion has to do with the factors influencing the uptake of HTs by place and time and so requires broadly the same information as equity. The key requirements are data on the use of HTs, by time and relevant group for equity, and by time and place for diffusion.

Assessment of the costs of technologies

Cost-related HT assessments include the range of approaches in economics: cost efficacy, cost-effectiveness,* 'cost of illness', cost consequences and cost impact studies. Costing is complicated by several factors, including the wide definition of cost used by economists and the lack of prices or unit costs (used equivalently here) for many HTs. Economics defines costs in terms of societal opportunity costs, which require data on the range of knock-on effects of particular HTs (both in terms of the full range of personal costs and benefits and over the entire life of the patient). In practice, only some HTs are priced – such as pharmaceuticals and particular packages of healthcare, depending on the country. Costing often involves estimating unit costs for HTs. Prices vary, depending on patent, industrial processes and competition. Estimation of knock-on costs and lifetime costs requires separate studies.

To be useful in costing HTs, databases must at a minimum include the HT and its unit cost. Databases that specify resource use alone require the addition of unit costs to be used in costing.

* Although cost-effectiveness is often included as an aim in clinical trials, modelling is usually required to generalise from the results of the trial and to explore the sensitivity of the results to changes in parameters. Modelling employs data from various sources, including routine data, in addition to clinical trial data. No review of the types of data that might appropriately be used in modelling has been located.

Chapter 4
Methods

This chapter specifies the methods used for each of the aims outlined in Chapter 1.

Aim 1: to develop criteria for classifying databases which have potential for HT assessment

Several literature searches were undertaken:

- conventional, using keywords 'methodology/ method/classification/criteria/types/groups', combined with the descriptions of routine databases outlined in *Tables 1* and *2*
- use of MEDLINE 1966–2000 and HealthSTAR 1975–2000.

TABLE 1 *Literature search using keywords for 'routine data'*

routine data, ti, ab, hw, tn, mf
Observational data, ti, ab, hw, tn, mf
exp Data Base/administrative data, ti, ab, hw, tn. mf
Database, ti, ab, hw, tn, mf
data set, ti, ab, hw, tn, mf
dataset, ti, ab, hw, tn, mf
exp register/or registry, ti, ab, hw, tn, mf
exp information systems/or information systems, ti, ab, hw, tn, mf
Medical Record Linkage

TABLE 2 *Literature search using keywords for 'health technology assessments'*

*Medical Audit/Audit
*Drug Evaluation/or *Evaluation Studies
Economic evaluation, ti, ab, sh
Utilisation, ti, ab, sh
*Health care access/or Health Care Delivery/or equity, ti, ab, sh
health technology assessments, ti, ab, sh
medical technologies, ti, ab, sh
Technology assessments, ti, ab, sh
outcome assessment (health care)
cost effectiveness, ti, ab, sh
diffusion, ti, ab, sh
Cost of illness, ti, ab, sh
Burden of disease, ti, ab, sh
Modelling and Model, ti, ab, sh
Equity, ti, ab, sh
Diffusion/or diffusion of innovation and technology, ti, ab, sh

The criteria for classifying databases were derived partly from these articles* but mainly from a 'first principles' examination of the data necessary for each type of HT assessment.

The literature search for the 'use' and 'validity' (see pp. 18–19) of routine HT assessment was also used to identify articles dealing with methods of classifying or grouping routine databases. As these were extremely few, an approach from first principles was necessary.

Aim 2: to list databases of relevance in the UK

No comprehensive list of routine health and healthcare databases exists in the UK. The list in this report was developed through a combination of use of key literature sources, references from within those sources and a network of people with experience of routine databases. Key literature sources comprised mostly books, book chapters or health service circulars and official publications rather than journal articles. These were assembled, in the first place, from the prior knowledge of the principal investigators, and included:

- guides to official statistics, both official[108] and unofficial[47]
- the *Oxford Textbook of Public Health Medicine*[109,110]
- official reviews including the reports of the Korner Steering Group,[111,118] the Department of Health efficiency scrutiny[56] and a White Paper on NHS information[112]
- Health Service Circulars[50]
- the Department of Health's Annual Reports[113]
- an unpublished review made available by the Department of Health.[114]

These sources were scrutinised not just for the databases that they listed, but also for further potential references in the literature.

* As very few articles were identified, and only three dealing with classification, a subset of papers dealing with methodological questions were excerpted from the results of the literature searches described under aims 5 and 6 and read by all three authors.

Private sector databases were explored using the published literature and a survey of the major UK health insurers.

Aim 3: to apply the criteria for classifying databases to identify those with most scope for use in HT assessment

The databases identified were annotated to include information on each of the key criteria developed in aim 1: summary details, including title and brief descriptions, published data for each database (typically annual reports), augmented by iterative postal and telephone enquiries to their 'keepers'. Each 'keeper' was sent drafts of our account of their databases for comments, which were incorporated into successive versions.

Each identified database was reviewed by the principal investigators in relation to the criteria developed by methods outlined above. Databases were allocated to an appropriate category, with some iteration as new databases were explored and additional details became available.

The emphasis was databases which covered the UK or England rather than being comprehensive for each of the four UK countries. This was justified partly by the scale of the exercise and the likelihood that each country had essentially the same databases. However, the possibility that Scotland was different was explored, first with a group of experts and then with the Information and Statistics Division (ISD). The note that resulted is included as Annex 2.

The data headings were reviewed against the criteria for classifying databases described above. Although a liberal definition of HT could be used to justify inclusion of databases dealing with staffing or provider units, the lack of any data in these databases on patient or population health states tended to rule them out.

Aim 4: to explore the extent to which databases with potential could pick up the UK NHS R&D HTA programme HT priorities

The NHS R&D HTA programme had by February 2000 allocated funding for research on 161 HTs, which had been prioritised using national panels of expert clinical advisors. The aim was to explore the extent to which these 161 HTs could be picked up in routine datasets.

The list of topics on which research had been commissioned was downloaded from the National Coordinating Centre for Health Technology Assessment (NCCHTA) website in February 2000. An initial checklist of the relevant disease and HT was discussed by the three principal investigators to check the extent to which those topics might in principle be picked up in routine databases. The results of this exercise were then discussed, coding manuals checked and some minor amendments made.

Aim 5: to specify the uses of the identified routine databases in any of the three types of HT assessment

This was undertaken using several literature searches:

- conventional using keywords outlined in *Table 1*.
- using MEDLINE 1966–2000, HealthSTAR 1975–2000 and the Health Management Information Consortium (the main database containing 'grey' literature)1960–2002
- focused using titles of databases as keywords
- searching by author using the name of any clinician closely associated with the database, supplemented by
- annual reports of identified databases and
- direct enquiries to the holders of each database of interest.

The conventional literature search used the keywords outlined in *Tables 1* and *2*.

All keywords **within** *Tables 1* and *2* were combined with **or**. The keyword results from *Table 1* were combined with the keyword results from *Table 2* with the connector **and**. The same keywords were used for HealthSTAR and close variations of the keywords were used for EMBASE. Each of the searches was restricted to human and English.

The search strategy yielded over 2000 references. The abstracts of each of these were divided among the three authors, each of whom selected those likely to be of relevance either for methodological reasons (in which case they joined the literature review discussed above), or in relation to their use in some form of HT assessment. A short list of 165 articles prioritised in this way was obtained and distributed to each of the principal investigators, to identify those of relevance.

As the results of this strategy omitted some known references on particular databases which had been classified as potentially of most use in HT assessment, a second search was carried out using the title of each of the prioritised databases as the keyword and the same sources as described above. This generated a small number of references for most of the most promising databases. Each of these articles was obtained.

In order not to miss any potentially relevant reported uses of particular databases, the 'keepers' of each dataset were also asked to identify any published reports using that dataset. The annual reports of each dataset were also examined to identify any mention of published work using the dataset, including comparative audit. This identified a further small number of references, which were located.

Any reported use of the dataset was checked by the three principal investigators as to which if any type of HT assessment it might be classified.

Aim 6: to explore the degree to which the key routine databases have been validated

For those databases identified as having most potential for use in assessing HTs, the aim was to review their validity using criteria based on a literature search, and involvement by two of the authors (JR, PR) in a group chaired by Professor N Black.*

The search strategy for validity used the keywords outlined in *Tables 3* and *4*.

All keywords **within** *Tables 3* and *4* were combined with **or**. The keyword results from *Table 3* were combined with the keyword results from *Table 4* with the connector **and**. The same keywords were used for HealthSTAR and close variations of the keywords were used for EMBASE. Each of the searches was restricted to human and English and UK.

TABLE 3 *Literature search strategy on validation*

routine data, ti, ab, hw, tn, mf
Observational data, ti, ab, hw, tn mf
exp Data Base/administrative data, ti, ab, hw, tn, mf
Database, ti, ab, hw, tn, mf
data set, ti, ab, hw, tn, mf
dataset, ti, ab, hw, tn, mf
exp register/or registry, ti, ab, hw, tn, mf
exp information systems/or information systems, ti, ab, hw, tn, mf
Medical Record Linkage

TABLE 4 *Literature search strategy on validation*

consistency, ti, ab, sh
internal consistency, ti, ab, sh
external consistency, ti, ab, sh
internal validity, ti, ab, sh
external validity, ti, ab, sh
data collection methods, ti, ab, sh
capture recapture, ti, ab, sh
double entry, ti, ab, sh
completeness, ti, ab, sh
Incompleteness, ti, ab, sh
generalisability, ti, ab, sh
truthfulness, ti, ab, sh
validation techniques, ti, ab, sh
data reliability, ti, ab, sh
data quality, ti, ab, sh
database validation, ti, ab, sh

Titles and abstracts were reviewed to short list 381, which were obtained in full.

A separate literature review explored the extent to which databases which had been used had been the topic of any published discussions of validity. The literature search used the name of the dataset on the same bibliographic databases as above. A final check on validity involved putting questions to the keepers of databases by letter and by telephone based on the draft annotations, which were also circulated for comment.

Aim 7: to estimate the cost of dataset collection

The issue of the cost of the various databases was the subject of a separate piece of work in late 1999 which led to a report[115] on the costs of those datasets with most potential for HT assessment, which was circulated widely within the Department of Health. This report invited readers to identify any missing databases and correct any errors.

The costs of the key databases were established as far as possible from annual reports and funding agencies, supplemented with direct enquiries to

* This informal group was set up following a seminar on routine datasets organised by Professor R Lilford in autumn 1999 and met several times with the aim of classifying routine datasets in relation to their validity. The criteria employed in this report draw heavily on the discussions of that group but are not identical to those proposed by the group. For details of the group's work, see http://www.lshtm.ac.uk/docdat/

keepers of each dataset for databases with no available data. Information on costs was supplemented by the publication in early 2002 by the report Disease Registers in England,[21] which discussed the cost of maintaining a register.

Data were available for some databases on the total cost or on the cost per record. Where the total cost was not available, it was estimated using the best estimate of cost per record. It was recognised that the multiple purposes served by some databases limited the validity of this approach and also that this method could overestimate the costs of some of the larger databases. The results presented should be interpreted with these caveats in mind.

Aim 8: to make recommendations for how and where it is worthwhile to increase the use of routine data in HT assessment

This was based on the above and discussion among the authors.

Chapter 5

Results

Classifying routine databases by their potential use in HT assessment

The literature investigating the potential value of routine data in HT assessment is sparse. A number of authors have drawn attention to the potential value of elements of routine data,[1,116,117] but also to their limitations.[118]

Wray and colleagues[119] defined the following criteria for routine data (administrative databases) to be useful for evaluation: a well-defined, easily diagnosed disease, homogeneous ICD codes, relevant interventions, inclusion of plausible outcomes and an understanding of the limitations of the database. This approach could be used to classify routine databases on the basis of how many criteria each met.

Hansluwka and colleagues[120] explicitly sub-categorised databases but only at a crude level. They distinguished between type 'A' general data, useful for technology assessment but collected without this specific aim, and type 'B' data collected specifically for technology assessment. Registries of healthcare procedures or of diseases, and also clinical databases, were quoted as examples of type 'B' data. Examples of sources of type 'A' data included population census, vital statistics, health service statistics and health surveys, all of which were deemed valuable as baseline information and for monitoring the long-term effects of the application of medical technologies.

Kahn[121] distinguished three types of database: 'protocol-oriented research databases', 'practice-oriented medical record databases' and 'practice-oriented clinical databases'. 'Protocol-oriented research databases' contained data designed for research. 'Practice-oriented medical record databases' included *ad hoc* routine data, both administrative and clinical. The third combined type, 'practice-oriented clinical databases', Kahn suggested, combined features of the other two, including being multi-year, multi-institution, with longitudinal patient-specific data including key clinical parameters, similar to good-quality registry data. Such databases, which he suggested could help generate hypotheses and monitor treatments, were particularly suitable for chronic diseases.

At best these approaches offer a starting point for dealing with the complexity of both types of databases and types of HT assessment discussed above.

A new approach

To classify routine databases in relation to their potential use in each kind of HT assessment (effectiveness/efficacy, diffusion/equity and cost), we employed the following criteria:

- Any database to be useful in any type of HT assessment must include data on the HT of interest.
- To be useful for assessing the effectiveness, equity, diffusion or cost of a particular health technology, the database must include data on the relevant dimension, ideally with the relevant covariates.

These criteria are applied to each kind of HT assessment below.

Assessing effectiveness/efficacy

To assess efficacy or effectiveness, we take as the 'gold standard'* the information that would result from a clinical RCT: the health state of the patient before and after treatment with the HT in question, along with potential confounders.

For the database to have useful health state data, it must normally be organised at the level of individual patients. Historically, as discussed above, health service databases have been aggregated at the level of provider unit, or less often by disease. Aggregated data, by restricting

* Grimley Evans has commented on the equation of randomised trials and gold standards as follows: "The randomised trial, the gold standard (pyrites standard some would assert) of evidence based medicine …" (para 13.3.2).[90]

the analysis to pre-defined sub-headings, limit the scope of any further analysis. By contrast, databases with patient-level data allow analysis limited only by the range of headings included. Further, patient-level databases, as long as a unique identifier is attached to each patient, can be expanded by record linkage.

Although patient-level data are generally necessary to assess changes in health state, in some circumstances the relevant information at the level of the population may be sufficient. With immunisation/vaccination and screening programmes, the proportion of the population covered may be sufficient to assess effectiveness, provided that the intervention itself is effective. Single intervention programmes which are oriented to whole populations (or some age/sex segment) can be assessed at a macro level using population coverage data. These data may need to be supplemented by data on the incidence of diseases targeted for the full assessment of the effectiveness of such programmes.

Assessing diffusion/equity

To assess equity of use of a particular HT, databases must include the relevant HT, time and person characteristics (such as age, sex, ethnicity and capacity to benefit). A broader assessment of equity* in relation to need would require additional data on those not using the service (or at least a dataset with an overall denominator). Diffusion assessment requires identification of place through provider unit or geographical identifier.

Knowing the number of people in receipt of a particular HT at regional or international levels can have major policy implications.[122] For instance, demonstration of the relatively low uptake of end-stage renal failure therapy in the UK helped raise the level of provision.[88,123] The relatively poor survival rates from the major cancers were cited as one of the factors leading to the UK's Cancer Plan.[124]

Proposed classification system for assessing efficacy and effectiveness†

In order, then, to classify databases in relation to their potential usefulness in assessing efficacy/effectiveness of HTs, the two key requirements are identification of the HT and the health state,‡ at either patient or relevant population level. This implies the threefold classification in *Table 5*.

TABLE 5 *Preliminary classification of routine databases in relation to HT and health states*

Group	Health technology	Health states
I	Yes	Yes
II	Yes	No
III	No	Yes

Group I, by having both HT and health states, clearly offers most potential for assessing the effectiveness of HTs. Group II, by having data on HTs but not health states, may be of use for diffusion and, indirectly, for equity studies depending on the degree of patient-specific information held. Group III, although it contains data on health states, by lacking HTs has little to offer beyond the generation of hypotheses for further investigation. Thus group I has most potential for assessing HTs, followed by group II (HTs only),§ with much more limited potential for group III (health states only).

Databases in group I can be subdivided into the following three groups, which differ only in the degree to which they capture HTs and health states:

Ia. Clinical registries are 'clinically rich' databases which contain data on both HT and health states at patient level – these frequently have been designed for research purposes. Within registries there is a further sub-classification according to whether the information is arranged by disease/patient group, such as cancer, on the one hand, or by HT, such as hip prostheses, on the other.

* Narrow equity can be defined as between those using the service and broad equity as including all those who might use the service.

† The proposed classification system, although primarily for assessing efficacy and effectiveness, overlaps substantially with how databases might be classified for assessing diffusion and equity, in that both require substantially the same kinds of data, specifically on HTs and patients. Assessing the cost of HTs requires a different kind of data: unit costs linked to particular HTs. The same database may be classified under both systems.

‡ Health state is used here to include proxy clinical measures which vary by disease and which are often recorded in clinical registers.

§ Linkage between databases in groups I and II would also widen the scope for their use in HT assessment.

Ib. Clinical–administrative databases contain data on HTs and limited health state data at patient level. Typically they were designed to meet administrative functions – the key example is the English HES.

The differences between Ia and Ib are of degree, with the former typically containing more detail on both the HT and health states.

Ic. Population-oriented databases identify the HT and the health state at population rather than individual level, with examples being immunisation/vaccination programmes and screening programmes.

Group II databases (those which identify an HT but not health states) are potentially open-ended, depending on the definition of 'health technology'. Examples include databases of drugs prescribed but with no patient or health-state data. Most HT-only databases deal with single technologies and are aggregated at provider or regional level. The wider definitions of health technology (see Chapter 3) could include counts of the number of different types of personnel or provider units or settings under this heading. For convenience this report focuses on well-defined HTs such as drugs and devices in exploring group II databases.

A threefold distinction can also be applied to group III (health state only, no HT) as follows:

IIIa. Adverse event reporting and confidential enquiries. Adverse event reporting databases contain data on the (adverse) health state or outcome. Some adverse event systems link to particular types of HT (such as drugs); confidential enquiries look to identify deficiencies in care, including all relevant HTs. They differ from clinical registers (group I above) in not having complete data on all people treated with an HT, but only on that HT and patient with the adverse reaction.* Adverse event reports help identify the relevant HT, which in confidential enquiries may lead to further investigation (e.g. the time at which procedure was carried out, level of skill of the surgeon).

IIIb. Disease/disability-only registers show the number of persons with particular diseases or disabilities, often those which are legally notifiable (infectious diseases) or of people who are defined as handicapped (deaf, blind, physically handicapped). These traditional registers cannot be linked to particular HTs and can be described as 'clinically poor'.

IIIc. Health surveys generally contain data on health states which cannot easily be linked back to use of any particular HT. Exceptionally, a few surveys contain limited data on the use of HTs, specifically the Health Survey for England, which has some data on use of prescribed drugs. These data can be used for cross-sectional assessment of equity and diffusion.

What matters is the extent to which the classification identifies and prioritises a number of databases which deserve attention. These databases are listed in the next section and classified under the above criteria in the following section.

Assessing the cost of health technologies

Assessing the costs of HTs requires a similar set of distinctions between databases as discussed above. Cost-related databases can be classified by the extent to which they identify an HT and attribute a price or unit cost to it.

Different types of cost-related routine databases could be distinguished as follows:

- an HT directly and its unit cost (or price)
- a group of HTs with a single average unit cost
- an HT that can be linked to data on resource use and hence to unit costs
- regular surveys on HTs and their unit costs.

Although the first type is clearly the best, in practice the other types are commonly used.

Applying the classification system

The challenge is to test the extent to which the proposed classification systems will help sort and prioritise routine databases. To this effect, the next section assembles a long list of routine databases applicable to the NHS (the full list for England is given in Annex 3) and the subsequent section reports on the application of the above classification system to the long list.

* Both assess the effectiveness of HTs, with adverse event reporting focusing on safety and confidential enquiries on the potential misuse of HTs. Adverse event reporting is limited to a particular type of HT, whereas confidential enquiries enable a broad assessment of the contribution of HTs to types of fatal event.

Long list of databases

A 'long list' of databases which cover the UK, Britain or England with potential for HT assessment is provided in Annex 3. Of the 272 databases listed, around 240 were listed as NHS Central Returns for England. The rest include databases run by a variety of state agencies such as the MCA and the MDA. Some are run by clinical groups on either a voluntary or non-profit basis. None of these databases is run for profit.* While commercial agencies may help collate or analyse the data, no information has been obtained on routine databases held by commercial agencies, such as the pharmaceutical companies. Our survey of health insurers had a low response rate and identified no new databases.

Scotland, Wales and Northern Ireland, each of which has a comparable number of NHS Central Returns, have been excluded from the long list to avoid repetition. The NHS in each country collects essentially the same data. No full listing of Central Returns was located for UK countries other than England. Inclusion of these countries would put the total number of databases in excess of 1000, made up mainly of Central Returns. Owing to the large numbers and the similarity between the countries of the UK, at least in terms of the NHS, the focus in the remainder of this study is on databases covering the UK or England and Wales, or England. Attention is drawn to the other countries if and as necessary, and with a separate section on Scotland included as Annex 2.

Classifying routine databases for assessing the effectiveness/ diffusion/equity/cost of health technologies

The results of applying the classification system developed above to the set of databases listed in Annex 3 are outlined, first at the overall level of the number of databases falling into each category, and second by type.

Overall, a relatively small number (62) of databases are identified in *Table 6* as having any potential use in any of the three kinds of HT assessment (plus five clinical registers which were being developed).

Clinical registers (group Ia)

Eighteen clinical registers as defined in Ia (p. 22) existed in mid-2000, with a further five being developed (*Table 7*). The 18 exclude some duplicates/variants,† mainly in Scotland, which could boost the number to around 25.

These databases are routine in the sense of being regularly collected in more than one site. The

TABLE 6 *Overview of number of databases by type of health technology assessment*

Type of dataset	Number
A & B. Assessing effectiveness/equity/diffusion	
Ia. Clinical registers (whether disease or HT oriented)	18[a]
Ib. Clinical–administrative	3
Ic. Population-based single health technology databases	5
II. HT-specific databases	4
IIIa. Adverse event reports/confidential enquiries	6
IIIb. Disease registers	16
IIIc. Health surveys	10
Total	62
C. Assessing cost	
Cost and HT databases	2
Total	64

[a] Plus five which were being developed.
Newton and Garner[21] identify a number of other disease registers, for none of which were we able to obtain details.

* The only database run for profit seems to be IMS's Mediplus, which is broadly similar to GPRD. DIN-LINK and MEMO are not for profit, although they are widely used by the commercial sector.
† These include the Scottish and Welsh counterparts of the Health Survey for England, the Scottish equivalent of ICNARC, the Scottish Renal Register and Trauma Audit Research Network (TARN).

extent of clinical detail on the HT and/or disease distinguishes these databases from group Ib, clinical–administrative. The degree of clinical detail varies – in part related to the fact that most of these databases are 'clinician-led', mainly on a voluntary basis. Many have developed fairly recently, prompted partly by the limitations of traditional routine administrative databases. Comparative audit is emerging as a major purpose of these databases, partly owing to the NHS policy emphasis on benchmarking and the emergence of clinical governance. The cardiac intervention databases, which are broadly similar to those in existence in the USA, provide a good example of this. Not one database appears to have been initiated by the Department of Health, although a number have or continue to receive support from the Department or its agencies. Only two databases are statutory – those of the HFEA and the UK National Transplant Database.

Two different kinds of clinical registry exist: those that are oriented principally around the recipients of a technology, and those that cover a whole client or disease group. Technology-oriented databases include HFEA, ICNARC, UK Renal Registry and the various cardiac intervention registers. Such a focus may be entirely appropriate for complex and costly technologies, particularly when there are questions over the effects of variants of the technology, for example between types of cardiac procedure. However, these technology-oriented databases, as they do not capture all those patients with a particular disease or condition, cannot be used to compare the effectiveness of treatments (owing to lacking no-treatment or alternative treatment comparator); nor do they allow direct assessment of equity in the wide sense, by omitting those who do not receive treatment. However, if all provider units participate it becomes possible to investigate equity of use by geographical area using proxies for need.

In disease registers and in most HT registers, the underlying target condition(s) or disease(s) is sufficiently well defined and serious to allow capture of patients through their use of services such as haemophilia, thalassaemia and cystic fibrosis. In others, such as the Breast Implant Register, the associated condition is less well defined. This dataset, funded by the Medical Devices Agency, has put to tender bids to evaluate the feasibility of measuring local complications including rates of rupture and contractor:[125] it has been included here as a clinical register, even though the nosology for breast augmentation remains underdeveloped. Similar but less extreme examples of databases based on the use of HTs include those focused on ICU, trauma and infertility, and also the UK Renal Register and the various cardiac treatment registers.

All databases have problems with ensuring that numerator and denominator match. Emigrants and visitors can be a problem – for example the HFEA database has difficulty distinguishing non-UK residents who come to the UK for fertility treatment. The North of England leukaemia and lymphoma registers, while unusual in capturing data from laboratories on patients diagnosed with these diseases, cannot be sure that they have captured all the patients with the relevant diseases treated in the NHS outside the region, let alone those treated privately.

All these databases contain data on patients' health states. This varies by database, reflecting the disease/treatment and the purpose of the dataset. For outcomes, many use mortality after treatment, both in-hospital and later, although long-term follow-up can be a problem (such as in the cardiac treatment registers). For others, childbirth (HFEA, St Mary's Maternity Information System) is a measure of outcome. Some use technology failure [e.g. graft failure in the National Transplant Database or restenosis post-angioplasty in the British Cardiovascular Intervention Society (BCIS) Database]. Some employ clinical morbidity such as re-operations or intermediate biochemical markers (e.g. calcium or dialysis adequacy in the UK Renal Registry). None routinely includes quality of life assessment. Some implicitly assume normal health state unless complications are recorded (National Breast Implant Register).

The databases vary in the frequency and intensity of follow-up of patients over time. Those that are surgical tend to have limited follow-up, whereas those concerned with chronic diseases or with implants (pacemakers, breast implants) tend to be longitudinal, collecting data on each patient over long periods.*

An important problem for these databases used for comparative audit is risk adjustment. Examples include ICNARC and the UK Cardiac Surgery database. Risk adjustment requires data on well-defined prognostic factors (severity, co-morbidity)

* Patients discharged from specialist units can be difficult to follow up, as shown by the National Transplant Register and the various cardiac treatment registers.

that influence outcome and which can confound inter-unit comparisons or more sophisticated HT effectiveness analysis. The databases considered above are limited in the extent of their coverage of such potential confounders, but in the longer term, the drive to risk adjustment will require such data. The extent to which such data are captured will in turn depend on wide clinician support and involvement, not only for defining the relevant variables but also for the time and resources required to capture such rich clinical detail.

Clinician ownership and participation are important in securing collaboration and appropriate data collection. However, this often leads to access being largely restricted to the participating clinicians, usually in the form of comparative audit, sometimes by request. Many clinical registers do not produce a publicly available annual report. These databases are often fragile, in that the loss of a key clinician can imperil the future of the database. This problem is exacerbated by their often uncertain funding arrangements (see Chapter 7), with many receiving no formal funding from the NHS or its agencies whereas others receive intermittent or short-term funding.

Some of the databases listed in *Table 7* are 'quasi-patient specific' in that standard patient-level data are held in particular centres (usually participating hospitals) rather than centrally. The fact that these data are standardised does mean that national reports can be compiled in addition to occasional more detailed analyses. The four cardiac registers listed in *Table 7* fit this model, as does the haemophilia database. The cardiac databases (some of which contain patient-level data centrally) plan to move to centralised collection of patient-specific data in a single database but have been held back by logistical factors. The haemophilia database remains largely paper based at local level, mainly because it is unfunded.

Databases in development*

Databases that are being developed include:

- The Diabetes Register, which in 2000 had a coverage of around 25% of England, based on those Health Authorities with diabetic registers. The National Service Framework on Diabetes seems likely to provide an impetus to the development of a national diabetes register.
- The Central Cardiac Audit Database (CCAD), which completed its pilot phase in 1999, aimed to link six cardiac registers (National Pacemaker database, BCIS database, CSD databases, Heart Valve database, anaesthetists, European Congenital Heart Defects database) at patient-specific level. A decision was still awaited in late 2001 on whether the Department of Health would fund the roll-out of CCAD.[126]
- Functional Analysis of Care Environments (FACE) in mental health is being piloted with Department of Health support in around 50 sites. It collects data on patients with mental illness by type of care environment and on their costs.[127] The relationship between FACE and the new Mental Health Minimum Dataset was unclear at the time of writing (July 2001).†
- Trauma Audit Research Network (TARN) plans to collect data on trauma cases admitted to Accident and Emergency Units, including incident details, anatomical description of injuries, health state on discharge from emergency department and longer term outcomes.
- Cancer and Oncology Information Network (COIN),[128] supported by the Department of Health, which has been developed in one hospital for possible 'roll-out'. However, COIN was not mentioned in the Cancer Plan's information strategy.[81]
- Myocardial Infarction National Audit Project (MINAP), which arose from the National Service Framework in Coronary Heart Disease, produced a baseline report in 2001,[129] and plans to produce regular reports.
- The Clinical Incidents Reporting system which arose from the Chief Medical Officer's report, 'An organisation with a memory'[130] will include a national database. This may more appropriately be classified with other adverse reporting systems (group III), depending on the details.

* The publication of *Disease Registers in England* in early 2002 identified many other registers on the basis of a search of the NHS National Research Register and a survey of Directors of Public Health. Most of the registers identified there but not included in the present report appear to be local registers, with a focus on disease rather than, as in the present report, disease plus technology. A number of those databases identified were known to the authors of the present report but had been omitted owing to non-availability of details despite literature searches and letters to the last known 'keepers' of those databases.

† See http://www.facecode.com/

TABLE 7 *Clinical registries, UK, Britain or England, 2000, in alphabetical order, with brief description of contents (group Ia)*

Title	Health technology	Clinical characteristics/outcomes	Comment
1. British Cardiovascular Intervention Society (BCIS) Database	PTCA, with/out stent	Clinical factors, diagnostic catheter data, coronary anatomy Outcomes: in-hospital mortality and morbidity	Aggregated at hospital level. Central patient level data from 14–17 centres. Unfunded. Moving to Central Cardiac Audit Database (CCAD)
2. Cancer Oncology Information Network (COIN)	Oncology treatments	Cancers by site and stage, treatments and outcomes	Sponsored by Royal Colleges, DH funded to provide audit data based on operational data. Slow progress owing to complexity of oncology. No plans for national audit role. One site at present but serving as prototype
3. Clinical Incident Reporting System	As appropriate	All major clinical incidents	Arising from 'An organisation with a memory', Department of Health 2002
4. Coronary Care Audit Database	Range of cardiac interventions including those in cardiac registers above	Angina, myocardial infarction patients, arrhythmias	Pilot integration of 6 cardiac databases, including the 5 listed above, plus one in group Ib. Subject to DH approval and funding
5. Functional Analysis of Care Environments (FACE)	Mental health therapies (list)	Mentally ill treatment, diagnosis, severity, treatments, outcomes	Used as part of Care Programme Approach (CPA) in mental health services as pilot in around 40 sites. Supported by Central Outcomes Unit of Department of Health. Data collection had not begun in February 1999
6. Human Fertilisation and Embryology Authority (HFEA) Database	IVF by type	Obstetric history, cause of infertility Pregnancy outcome including successful conception	Statutory. Moving to self-financing. Data access limited to HFEA members
7. Intensive Care National Audit and Research Centre (ICNARC)	Intensive care units	Patients' history, range of clinical physiological measures Outcomes: including death and LOS	Self-financing comparative audit service. Membership increasingly required by NHSE
8. Myocardial Infarction National Audit Project (MINAP)	Treatment of myocardial infarcts: time to defibrillation and thrombolysis	Myocardial infarctions	Data collection linked to 23
9. National Breast Implant Register	Breast implant and explant by type	Minimal	MDA funded. Concerned with possible adverse events and possible litigation
10. National Pacemaker Database	Pacemaker fitted by type	Pre-procedure and procedure details, refit of device and death	Moving towards CCAD. MDA funded

continued

TABLE 7 *Clinical Registries, UK, Britain or England, 2000, in alphabetical order, with brief description of contents (group Ia) (cont'd)*

Title	Health technology	Clinical characteristics/outcomes	Comment
11. National Prospective Monitoring System (HIV)	Drug therapies	HIV-positive patients, self-reported risk factors, diagnosis and test details Outcomes: use of services, death	Has interventions by drug and disease markers (CD4) but partial coverage (mainly London) and uncertain funding
12. National Transplant Register (UK Transplant)	Heart, heart–lung, kidney and liver transplants, immuno-suppression	HLA matching, donor status, patient severity. Outcomes include: death, postoperation course, graft failure, rejection episodes	UK Transplant is a special health authority funded to facilitate organ transplantation. Register is used to match organs to recipients
13. Northern Region Haematology: Leukaemia Database	Treatments given, transplant status	Diagnosis, history, investigations pathology/cytology, staging Outcomes: death, remission	Unfunded. Used for research purposes. Receives data direct from laboratories
14. Scotland and Newcastle Lymphoma Databases	Treatments (radiotherapy, chemotherapy, surgery)	Diagnosis, history, investigations, pathology/cytology, staging Outcomes: death, relapse/remission	Run by same people as 8, using essentially the same methods. Some financial support from the Scottish Executive
15. Scottish Hip Fracture Audit (SHFA)	Operation for hip fracture	Patients' health state pre-fall and postoperation. Fracture details. Operation details. Complications. Re-operation. 4-month postoperative status	ISD support, linked to clinical indicators
16. St Mary's Maternity Information System (SMMIS)	Antenatal, perinatal and postnatal care	Previous pregnancy history, ultrasound and screening details, antenatal conditions/ complications, labour and delivery, postnatal maternal and infant health states	Former N. Thames system, continues in 10 hospitals, run by commercial firm
17. UK Cardiac Surgical Register	Cardiopulmonary procedure, CABG (8 types), other cardiac or non-cardiac procedure	Pre-procedure health indicators (used in risk adjustment). Operative detail. Post-procedure: in-hospital mortality, post-discharge date, cause of death	Aggregated at hospital level. Some individual patient-level data held centrally. Moving to CCAD. Unfunded
18. UK Cystic Fibrosis Database	Drugs and compliance by period	Cystic fibrosis patients, demography, diagnosis, antibiotics, complications, tests including microbiology, transplant status, fertility, social impact, survival	Covers most of UK except London. Funded by Cystic Fibrosis Trust
19. UK Haemophilia Centre Directors' Database	Blood factors (VIII, IX) by amount and frequency	Limited patient identity plus many clinical measures. Death, adverse events	Aggregated at hospital level. Unique source of data on patients and blood products used. Unfunded
20. UK Heart Valve Registry	Type of valve	Patients' pre-procedure health state. Deaths	Aggregated at hospital level by patient and valve type. Full patient-level data locally. Moving to CCAD. MDA funded

continued

TABLE 7 *Clinical Registries, UK, Britain or England, 2000, in alphabetical order, with brief description of contents (group Ia) (cont'd)*

Title	Health technology	Clinical characteristics/outcomes	Comment
21. UK Hydrocephalous Shunt Register	Shunt details	Clinical indication, including details of reasons for removal of shunts as part of long-term follow-up. Operation and device detail. No patient-specific outcomes	MDA funded. Collects details on ~3000 operations per year
22. UK Renal Register (with Scottish equivalent, SRR)	Dialysis type, transplant	Co-morbidity, cause of ESRF. Survival, intermediate outcomes including biochemistry, haemoglobin, dialysis adequacy	Contains treatment and outcome. Planning to be self-financing on basis of charges to participating units
23. UK Thalassaemia Register	Transfusion status, iron chelation therapy, bone marrow transplant	Thalassaemia type, when diagnosed, deaths	Over 1000 records, and thought to be 97% complete for Britain. Funding via charities and research
24. UK Diabetes Dataset	Therapies	Diabetes patients by diagnosis. Complications, survival	Based on 25% of health authorities with registers – planning to expand. Likely to expand with National Service Frameworks
25. UK Trauma Audit and Research Network (TARN, with Scottish equivalent, STAG)	Care in A&E, operation/procedure	Incident details, anatomical description of injuries, discharge from emergency department, outcomes	Funding from NHS R&D. Coverage? Plans?

For more detail on all databases, see Appendix 1.
CABG, coronary artery bypass graft; ESRF, end-stage renal failure; HLA, human leucocyte antigen; ISD, Information and Statistics Division; LOS, length of stay; PTCA, percutaneous transluminal coronary angioplasty.

Clinical–administrative databases (group Ib)

Some databases, unlike the clinical registers designed for assessing HTs, were originally developed for administrative purposes but contain patient-level data including identity, treatment and some health state or outcome data (such as death). Clinical–administrative databases have less depth but greater breadth of coverage than clinical registers.

The main database under this heading is the Hospital Episode Statistics (HES) and its Welsh and Scottish equivalents (COPPISH and PEDW). Two other types of dataset are included under this heading: the General Practice Research Database (along with its counterparts DIN-LINK, MEMO and Mediplus) and the various cancer registers, which exist in each region in England as well as in Scotland, Wales and Northern Ireland. The main databases in this section are listed in *Table 8*. Cancer Registers have been classified as clinical–administrative on the basis of their restricted inclusion of data on HTs. Although a case could be made for seeing them as disease-only registers (group III), their scheduled development under the Cancer Plan justifies their ranking as group Ib.

A number of general points can be made about this group of databases. They are essentially 'practice-oriented medical record' systems,[121] based on administrative records. The HES is the prototype. The GPRD and its variants DIN-LINK, MEMO and Mediplus are also based on administrative medical records but augmented by patient and disease details. The regional Cancer Registers include some medical record data augmented by disease staging data and survival.

Record linkage can enhance these administrative databases especially by linkage to mortality records.

TABLE 8 *Clinical–administrative databases, England, 2000 (group Ib)*

Dataset	Health technology	Disease/condition	Comment
Hospital Episode Statistics (with Scottish, Welsh and N. Irish equivalents)	Any surgical procedures as captured by OPCS4	ICD disease codes, OPCS4 surgical codes. Outcomes: in-hospital mortality	Increasingly being linked to longer term mortality via development of clinical indicators
General Practice Research Database (GPRD) (plus DIN-LINK, Mediplus and MEMO)	Drugs prescribed, by first, repeat, switch	Disease by ICD. Treatments including drugs and referrals. Outcomes: new conditions	GPRD is public sector, owing to donation by Reuters. DIN-LINK, Mediplus and MEMO are essentially similar but mainly used by the pharmaceutical industry
National Cancer Registry (with regional Cancer Registries)	Broad measures of radiotherapy and chemotherapy but no details of these or other treatments	Have details of stages of cancer. Outcomes: death and recurrence	Other registers are based on the cancer registries (Leukaemia Registers, National Registry of Childhood Tumours and UK Children's Cancer Study Group Registers). Can be used as a sample frame for research studies

Mortality records are increasingly linked to clinical–administrative databases, as planned in the clinical indicators based on HES. Although GPRD (along with DIN-LINK, MEMO and Mediplus) is unique in linking prescriptions by GPs to diseases, the planned NHS initiative 'Collection of health data from GPs' aims to provide this type of data for all GPs. Against this, it seems unlikely that clinical–administrative databases will ever achieve the level of clinician support enjoyed by those clinical registries that are 'owned' by clinicians and used by them in comparative audit.

The databases in *Table 8* tend to cover a wide range of diseases/HTs and thus differ from clinical registers which tend to focus on a single disease or HT. As a result, these clinical–administrative databases tend to have less detail on any one HT or disease.

Although these clinical–administrative databases cover a wider variety of services and HTs, their coverage of the full range of HTs used in the NHS is incomplete. For example, no data exist in any detail on HTs in community health services or in family health services (except for prescriptions). No data are routinely collected on who receives which hospital drugs, or which diagnostic and imaging tests.

These databases generally have poor information on clinical characteristics and outcomes other than the presenting disease and survival. This results partly from being based on one-off individual episodes of treatment, which are seldom linked (and historically could not be linked). By contrast, clinical registers tend to follow patients in time. As noted above, new minimum datasets for cancer and mental health will be designed to enable patients to be followed up and the take-up and effectiveness of treatments to be assessed.

In general, improved record linkage may improve the capture of both health service use and health states in clinical–administrative databases. Electronic patient records (EPRs) and electronic health records (EHRs) could bridge medical records with clinical registers, but progress has been very slow and requires standard terminologies and classifications.

These databases offer limited scope for assessing effectiveness except in some well-defined conditions/procedures, such as in the clinical indicators, and then to only a limited extent. The best use of existing clinical–administrative databases in relation to effectiveness may be for comparative mortality as in the conditions covered by the clinical indicators and the cancer registers. Some, such as GPRD, have been used mainly for

evaluating drug safety. These databases are also potentially useful in assessing the diffusion of HTs and for equity assessment.

The position varies by UK country. The titles in *Table 8* often include the country of origin or coverage and include the full range of possibilities: National, British, UK, English, Welsh and Scottish, with some British or English with Scottish or Welsh equivalents. While this reflects historical ambivalence and confusion within the UK over national identities,[131] the range seems likely to diverge with devolution, which would in turn make a full listing more difficult. Against this, the likely economies of scale of having a single, large database need to be set against the benefits of local ownership.

A discussion of the extent to which Scottish databases are superior to those in England (Annex 2) suggests they may have some advantages, particularly as Scotland has pioneered the linkage of clinical–administrative databases with mortality records and is exploring adding patient identifiers to prescribing data.

Aggregated population databases (group Ic)

Although patients are not identified at an individual level in these databases, as they relate to entire sub-populations (children, elderly, women of particular ages), the databases can be used to assess the effectiveness of specific population-oriented interventions.* These databases are central returns used to monitor programme coverage and, in some instances (cervical screening, immunisation and vaccinations), to pay GPs for ensuring the services are provided. The data are aggregated at the level of relevant providers (GPs, Trusts, Health Authorities) with records of individuals treated maintained at local Health Authority level.

Since the effectiveness of the national immunisation and vaccination technologies is well established, data on the coverage of these programmes enable their overall effectiveness to be assessed. Similarly, the coverage of the national breast and cervical cancer screening programmes, the critical target variable, can be assessed using these databases. The inclusion of additional data from the laboratories on test results allows the estimation of other quality indicators such as the level of 'false positives'.

While the above databases can be used for analysis of effectiveness at the level of the particular programme, they can also be used for equity/diffusion and costing.

Table 9 lists five types of database under this heading. The immunisation and vaccination programmes have Central Returns in each UK country for a range of diseases (mumps, measles, rubella in children, influenza for the elderly).[132,133] Reports are produced annually by the Department of Health[134] based on data held by Health Authorities on the number of children immunised.

The breast and cervical cancer screening programmes have similar data collection systems, each using aggregated test returns for laboratories (cervical) and local units (breast) and data from Health Authorities on the proportions of women in the appropriate age groups who have been screened. Annual reports are produced for each screening programme.[135,136] Similar systems apply to each UK country.

Although some follow-up data are required on false positives, no details of further treatment are included.

The programmes are based on assumed effectiveness of relevant HTs in preventing disease. Evaluation of effectiveness in practice would require additional work linking screening of cohorts of patients to eventual mortality of the same cohorts. Such an approach was employed in a recent evaluation of the effectiveness of breast cancer screening in England,[137] which was shown to be considerably less than was originally estimated.

Group II databases: those which identify HTs but not patients or health states ('HT-only' databases)

These databases contain data on the use of an HT by time and place but without any linkage to patients

* Two other programmes might be classified under this heading: influenza vaccination for the elderly, which became a national programme in 1997, and the Dental Screening Programme. The only central return located was for the Community Dental Health Survey (KC64), which provides aggregated data based on an annual survey which is discussed under surveys. As no routine data sources have been located for the influenza vaccination, it has been omitted from the discussion.

TABLE 9 *Population-based, single health technology databases, England, 2000 (group Ic)*

Dataset	Health technology	Target disease/condition	Comment
Immunisation programmes (by UK country)	Number of people immunised by type of immunisation	Target diseases	Several central returns. Show % covered by type of immunisation and/or vaccination
Cervical Cytology Screening Programme (by UK country)	Screening method	Cervical cancer	KC53 covers the Call and Recall Programme, KC61 data collected from laboratories
Breast Screening Programme (by UK country)	Screening method	Breast cancer	KC62 covers the Call and Recall Programme, KC63 the coverage rate by HA
Influenza vaccination for the elderly	Influenza vaccination, numbers vaccinated	Influenza	Introduced in 1998 for >75s, extended in 2000 to >65s
Dental Screening Programme, England (by UK country)	Dental examination plus interventions	Tooth decay, gum diseases	Applies to under 16s who get dental service free and who are screened at school
A new national haemoglobinopathies screening programme to detect thalassaemia and sickle cell disease in pregnant women and newborn babies is planned for the NHS from 2003.			

or their conditions. Such databases can be used to assess the diffusion by geographical area and hence equity (through linkage to geographical area but not by personal characteristics). The prime example is the PPA data, which specify the amount of each drug dispensed by community pharmacists under GP prescriptions in each UK country each year. These data, whose main use is to pay community pharmacists, are fed back to GPs and play a role in monitoring and controlling prescribing.

Other databases under this heading, shown in *Table 10*, include central returns of particular programmes. Family planning returns (NHS return KT31) specify the use of particular family planning technologies via the NHS, but are limited by lack of data on non-NHS family planning techniques. These data are aggregated at the level of GP practice and family planning clinics.

Abortion returns, which are statutory and cover all terminations, are more comprehensive, covering all terminations in public and private clinics. Limited data are provided on the methods of termination employed.

Central returns on radiology and nuclear medicine provide data on the total number of tests/procedures carried out, but lack any data on the patients or conditions.

The major limitation of these databases is that with the exception of the drugs identified by the PPA, the other HTs are not well defined. In particular, the central returns on radiology and nuclear medicine provide data that are much too crude to fill the major gap in data on use of these services by particular types of patients. No data are available on the number of scanners by type, a position complicated by the role of charitable organisations in donating such scanners to the NHS.

Group III 'health state-only' databases

Databases in this group specify health states but without reporting either the HT or the patient. Three sub-types can be identified: (a) adverse events and confidential enquiries, (b) disease-only databases and (c) health surveys. Although adverse event and confidential enquiries can be useful for assessing the performance of organisations (arguably a form of HT assessment), the last two types have little to offer HT assessment except where linkage to a particular technology can be established.

Group IIIa adverse events reporting/confidential enquiries

The six systems under this heading are shown in *Table 11* for England. The other UK countries have their own equivalents.

TABLE 10 *Health technology-only databases, England, 2000 (group II dataset)*

Dataset	Comment
PPA databases (PACT in England, with equivalents in Scotland, Wales and N. Ireland)	Has details of each drug dispensed by community pharmacists on GP prescriptions, along with cost
Family planning returns (for England, Scotland, Wales and N. Ireland)	Central NHS returns provide data on number of specific NHS services by age group and geography. Misses non-NHS services (non-NHS clinics, condoms)
Abortion returns	Arguably an HT. More comprehensive than family planning returns owing to including all terminations
Radiology/nuclear medicine returns	Central returns in each country. Limited to number of contacts/scans, with no data on patients or machines used

TABLE 11 *Adverse event/confidential enquiries databases, England, 2000 (group IIIa)*

Dataset	Comment
Adverse Drug Reactions Yellow Card Reporting Scheme (from 1964)	MCA-run voluntary 'Yellow Card' scheme
Adverse Events Relating to Medical Devices (from 1994)	MDA-run voluntary scheme for devices via its Adverse Incident Centre
Confidential Enquiry into Stillbirths and Deaths in Infancy (with Scottish equivalent) from 1992	Former DH voluntary scheme, under the aegis of NICE from 1999
Confidential Enquiry into Perioperative Deaths (with Scottish equivalent) from 1989	As above
Confidential Enquiry into Maternal Deaths (with Scottish equivalent) from 1952.	As above
Confidential Enquiry into Suicides among Psychiatric Inpatients (from 1992)	As above

Adverse events and confidential enquiries are essentially the same in that both focus on adverse outcomes. The difference is that adverse event reports on drugs and devices contain HT details, relying mainly on further inquiry to reveal the cause of the adverse event. Confidential enquiries start with the event and work back to the technology. As a result, both require further enquiries to establish causes. It should be noted, however, that Drug Safety Units in both England and Scotland play a role in exploring the factors associated with adverse events. Further, the increasing use of clinical registers and clinical–administrative databases by both the MCA and MDA points to greater sophistication in the exploration of adverse events.

Both adverse event reporting and confidential enquiries are voluntary in their reporting, with the result that they lack data on the denominator – the extent of the problem – which precludes estimation of rates. They also lack data on 'control' groups.

The limitations of existing adverse event databases have been recently acknowledged officially:

"Some of these systems (such as the Confidential Inquiries and the national reporting system for incidents involving medical devices) achieve good coverage of very specific categories of event, and produce high-quality recommendations based on analysis of the information collected. Overall though coverage is patchy and there are many gaps. Guidance on the reporting of adverse incidents in the NHS stretches back over 40 years, but there is still no standardised reporting system, nor indeed a standard definition of what should be reported."[130]

The transfer of responsibility for confidential enquiries to NICE in 1999 may signal changes in the extent to which reporting remains voluntary. It also provides scope for links to comparative audit.* Similarly, drug adverse event reporting seems set to become more comprehensive with the shift in responsibility for GPRD to the MCA. Use of GPRD for adverse event reporting will provide a means of estimating rates for adverse events. Similarly, the planned use of four databases classified under Clinical Registers above (UK Heart Valve Register, National Pacemaker Database, UK Hydrocephalous Shunt Register and the National Breast Implant Register) by the MDA marks a similar move towards more sophisticated data collection.

Disease-only registers (group IIIb)

As shown in *Table 12*, 16 databases were grouped under this heading. This group includes long-standing disease registers, such as notifiable diseases and lists of the handicapped (blind, deaf or physically handicapped). More recent additions include the congenital abnormalities database, the chromosome abnormality database and the cleft lip and palate database. All these databases differ from the registers classified in group Ia by lacking data on HTs. The one partial exception is the National Down Syndrome Register, which collects data from laboratories on the number of prenatal diagnoses and their outcome (termination, live birth).

TABLE 12 *Disease-specific registers without data on health technologies, England, 2000 (group IIIb)*

Dataset	Comment
Asbestosis Register	Register of deaths mentioning 'asbestosis' as cause
Chromosome Abnormality Register	Run by the UK Association of Clinical Cytogeneticists, holds >123,000 records on all chromosome abnormalities detected by NHS cytogenetics laboratories in the UK since 1991
Craniofacial Anomalies Register	Originally register of people born with cleft lip and palate. No treatments or outcomes included but are planned
Creutzfelt-Jakob Disease Surveillance	Recent UK database, no treatment of data possible
Drugs Misuse Databases	National and regional, with data on numbers treated by type
HIV/AIDS Newly Reported AIDS Cases and Deaths	Register of new cases and deaths
Mesothelioma Register	Register of deaths mentioning 'mesothelioma' as cause
National Amputee Statistical Database	Register of number of amputees fitted with prostheses by area. Minimal details on prostheses
National Congenital Anomaly System (Welsh equivalent)	Lists number of patients. No treatments
National Down Syndrome Cytogenic Register	Screening tests plus normal birth or termination, plus antenatal diagnosis of Down syndrome
Notification of Infectious Diseases Register	Notifiable disease register. Gross count of cases notified published
Register of Blind or Partially Sighted	No details of causes, treatments. Used to determine eligibility for specific services
Register of Deaf or Hard of Hearing	No details of causes, treatments. Used to determine eligibility for specific services
Register of Physically Handicapped	No details of causes, treatments. Used to determine eligibility for specific services
Sexually transmitted diseases: new cases	Anonymised data only of new cases of specified diseases
UK Subcutaneous Immunoglobin Register	Monitors the number of patients trained to self-infuse intravenous immunoglobulin at home

* The use of routine data to assess diagnostic/imaging tests would require considerable data, including which diagnostic/imaging tests were being used (which implies an appropriate coding scheme), patient characteristics and indications, subsequent tests, diagnosis made and follow-up for test negative cases for false negatives.

A further 25 disease registers are listed in the report by Newton and Garner,[21] which was published after we had completed this report. We were not able to clarify the contents of these but many appear to have originated in specific studies or trials. The degree to which they would meet our criteria of being representative by covering a geographical region could not be readily clarified. Since these registers have very limited potential for HT assessment, we did not explore them further here.

Registers of notifiable diseases, both infectious and chronic, share some of the characteristics of adverse event reporting. The whole purpose of the notifiable disease reporting system is to ensure that individual patients have been treated. However, the treatment (or HT) is of less interest for policy purposes than ensuring that outbreaks are minimised. The databases do not contain headings on action that was taken, even though the HTs used to treat some notifiable diseases (such as HIV/AIDS) may be of interest for policy purposes. Unlike adverse reporting systems, rates can be estimated.

Contrasts can be drawn between some of these databases and those classed as clinical registers. For HIV/AIDS, the central return 'Newly Reported HIV Infected Persons' provides data on new cases, but for details on drug treatments and clinical impact one has to turn to the National Prospective Monitoring System (classified as group Ia).

Registers of the number of people who are blind or deaf are of no obvious use for assessing current HTs and their outcomes. Such registries have traditionally played a mainly administrative role in entitling patients to particular services. Part of the reason for their lack of treatment or outcome data has to do with the lack of such treatments historically. When treatments are available, such as for HIV/AIDS, it becomes harder to see the rationale for two separate databases.

Health surveys (group IIIc)

Health surveys provide data on health states but generally without usually identifying relevant health technologies. The main health-related surveys are listed in *Table 13*. Without linkage to HTs these databases have little to offer HT assessment. Only one survey has some data on HTs: the Health Survey of England (and its equivalents in Scotland and Wales).

The Health Surveys are unique in this group in their detailed emphasis on health and healthcare. An annual survey in each UK country, they focus on particular diseases as well as general population health. On the basis of visits by nurses to participants' houses, details are provided on specific diagnosed diseases and a range of clinical measures including blood samples and details of

TABLE 13 *Health Surveys, England, 2000 (group IIIc)*

Dataset	
Adult Dental Health Survey (UK)	ONS, decennial
Children's Dental Health in the United Kingdom (UK)	ONS, decennial
General Household Survey	ONS, annual. Includes regular health questions. Has been used in reviews of hearing impairment, private insurance, contraception
Health Education Monitoring Survey	ONS, annual since 1995
Health Survey for England (1991–2001) [+Health Survey for Scotland (1995, 1998, 2001) and Health Survey for Wales (1995, 1998)]	ONS, annual
ONS Omnibus Survey (has health-related modules)	ONS, ongoing with occasional health-related uses: back pain, contraception, drinking, smoking (from Department of Health website)
Survey of Health and Well Being (1994 and 2000)	ONS, focus on mental health
Survey of Smoking, Drinking and Drug Use Among Secondary School Children	ONS, fourth annual survey in 1998

ONS, Office for National Statistics.
The Morbidity Survey of General Practice has been omitted as no plans for its repeat have been located.
The OPCS Surveys of Psychiatric Morbidity 1993–94 have been omitted as they were one-off. The Department of Health has a range of surveys relating to mental illness which includes the Survey of Health and Well Being (see above).

prescribed drugs and self-reported use of health services. However, even when the Health Survey for England focuses on particular diseases, the number of patients included tends to be relatively small, limiting the scope for analysis.

A number of surveys were excluded on the basis that they do not contain useful data relating to either HTs or health states. These included: the National Survey of NHS Patients, the National Child Development Survey, the Family Resources Survey, the National Survey of Ethnic Minorities, the National Food Survey, the National Diet and Nutrition Survey 1970, the British Cohort Study, the British Household Panel Study: BHPS (England and Wales), the Family Resources Survey: FRS, the Health Promotion Wales Lifestyle Surveys, Health in Wales Surveys, Smoking Among Secondary School Children in England and Young Teenagers and Alcohol (England and Scotland). The ONS Omnibus Surveys (England, Wales and Scotland), it was recognised, sometimes included questions relating to health and health services.

Assessing cost

This section is concerned with databases that contain cost rather than resource use data. Most of the databases discussed above include some data on resource use, but very few contain cost data.

Overall, remarkably few cost-related databases in the NHS specify HTs. Of the 127 NHS Financial Returns for England included in Annex 3, only two could be linked to HTs at any level – the English NHS Reference Cost database*[138] and the PPA data on costs of drugs dispensed by GPs.† Both of these, it should be noted, also qualify for assessing effectiveness, equity and diffusion, in addition to assessing cost. Many of the databases discussed under group I contain data on resource use which can be linked to cost.

Many cost evaluations of HTs (other than drugs and hospital stays) have had to improvise, often by combining customised data with routine data such as pay scales or by special surveys. Examples of the former include those evaluations which have combined data on number and duration of contacts with healthcare personnel and valued these using national payscales. The most usual source for pay scales has been the Annual Pay Review Body,[139,140] published annually, covering doctors, nurses and professions allied to medicine.

Many different approaches have been taken to using these pay scales. The reported 14 ways of costing a GP consultation[141] resulted from the lack of agreed routines in the use of such data. However, standardised estimates are now produced annually for these and a range of other personnel, such as district nurses and health visitors, through the annual report from the Personal Social Services Research Unit in the University of Canterbury. Funded by the Department of Health, this provides well-founded estimates of unit costs for community health services.[142]

Key points

- A classification system was developed to distinguish three groups of databases: those with both HT and patients' characteristics, and those with one or the other of these.
- Databases which include both HT and patients' characteristics (group I) can be used not only to assess effectiveness but also to assess diffusion and equity. By contrast, databases in group II (HT only) can only help assess diffusion and, indirectly, equity. Those in group III (patient health-related characteristics only) have restricted scope for assessing health technologies, except for analysis of adverse events.
- This classification was successfully applied to a long list of over 270 databases at the level of UK/England and Wales/England,‡ identifying some 60 databases in groups I–III. The rest of the databases, mainly Central Returns, fell outside these groups.

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* Healthcare Resource Group (HRG) unit costs refer to the average costs of treating particular groups of patients in acute NHS hospitals. Since HRGs are based on the HES data, their level of specificity is limited by the coding systems used there. HRGs can be divided into those which identify a single technology, such as total hip replacement, and those which comprise a group of technologies, such as HRGs that group miscellaneous procedures or which apply to medical admissions. Trust Financial Returns provide data on cost per day and per specialty both in general and by specialty for all NHS Acute Trust hospitals. Since these can contain a variety of more detailed HTs ranging from surgical procedures to drugs, they are more general than HRGs.

† The PPA data include prices, which apply when the NHS pays for drugs dispensed by community pharmacists under GP prescriptions. These data are published annually by the PPA and made available in electronic format to pharmaceutical advisors and to researchers.

‡ Over 1000 databases if Scotland, Wales and Northern Ireland are included.

- Within group I, clinical registers had most potential for assessing effectiveness, followed by clinical–administrative and by population-based single HT databases.
- Most of the clinical registers have developed out of voluntary initiatives, and are run by clinicians. Access is usually restricted to participating clinicians. Many have uncertain funding although some are funded by the Department of Health or its agencies such as the MDA or MCA.
- Even the most detailed clinical registers have limited data, particularly on patients' characteristics, which inhibit comparisons of effectiveness. The focus of around half the clinical registers on particular HTs prohibits comparisons between HTs, except for the narrow range included in the database.
- While comparative audit is driving some clinical registers towards risk adjustment models, these are limited to known confounders. Even the best registers are therefore open to bias due to unknown confounders.
- The key difference between clinical registers and clinical–administrative databases has to do with depth versus breadth. Clinical–administrative databases, such as the HES, cover a range of HTs but at a summary level.
- The boundaries between clinical registers and clinical–administrative databases are beginning to erode with record linkage and electronic patient records. These developments, however, are limited both by lack of universal detailed coding systems and increasingly by concerns over the confidentiality of patient data.
- Clinical–administrative databases provide the basis of a small number of clinical indicators, but have hitherto been mainly used for diffusion and equity studies.
- Clinical registers and clinical–administrative databases together cover only a small share of the total number of HTs that require assessment. Large gaps exist.
- Population-based single-HT databases, such as those on immunisation/vaccination and screening, provide useful data on the uptake of these effective technologies.
- For use in costing, databases need to include the different dimension of unit cost or price, which does not generally overlap with the dimensions needed for effectiveness.
- Only a few databases contain costs, particularly on drugs prescribed by GPs and more recently on hospital inpatients. Cost data are missing, however, for most HTs in the NHS.
- Clinical registers provide the only source of resource use data for some HTs (such as pacemakers, PTCA with or without stents).
- Other than for central returns, no overall strategy exists for healthcare databases.

Chapter 6

Potential capture of NHS prioritised health technologies in routine databases

Introduction

The first requirement in using routine data for HT assessment is to be able to identify the relevant HT using the database's coding system. This section explores the extent to which the HT topics prioritised by the NHS national HTA R&D programme could be identified in currently available routine databases. A list of the HTs on which assessments had been commissioned was downloaded in 2000 from the National Coordinating Centre for Health Technology Assessment (NCCHTA) website. These topics have been prioritised by the NCCHTA for research based on widespread consultation with clinical experts. Methodological topics were excluded from the list. The test was to explore the degree to which the technology in question could in principle be captured by any of the databases in groups I–III (Chapter 5). The results are shown in *Table 14*.

Results

Table 14 shows the limited potential of current routine databases for capturing the HTs that are being evaluated by the NHS national HTA R&D programme. Of over 160 HTs, only 22 could potentially be identified in routine databases. The bulk (16) of these were drugs prescribed in primary care, which are captured by the PPA (although not linked to any specific disorder) and the more detailed GP data systems (such as GPRD and its variants), which contain data on the underlying disorder. No routine databases exist on hospital prescriptions.

A few surgical procedures were identified, but limited by the surgical procedural coding system OPCS4, which, as noted earlier, is out of date and due for replacement. Many of the HTs of interest would probably in practice be entered as 'not otherwise classified', for example, endovascular procedures for aortic aneurysms or microablation of the prostate. Even when surgical procedures could be captured, no non-surgical comparator data are captured (for example, chiropractic as an alternative to surgery for low back pain).

Looked at from a registry perspective, surprisingly few topics prioritised by NCCHTA were concerned with HTs that might possibly be captured in group I datasets, the only ones being dialysis in the UK Renal Registry and ultrasound in the SMMIS. This partly reflects the limited range of HTs covered by such databases. Clinical registers generally did not reflect the topics selected by the HTA programme and the programme has not commissioned any research based in clinical registers.

Most types of prioritised HTs were poorly identified in routine databases, particularly diagnostic and imaging methods [magnetic resonance imaging (MRI)], screening (e.g. Down syndrome screening strategies), medical interventions (e.g. medical therapy for menorrhagia), but also interventions based on the type of professional/patient interaction (e.g. counselling, information provision, cognitive behaviour therapy), interventions by professions allied to medicine (e.g. paramedics, pharmacists, physiotherapy), new roles for non-doctors (midwife role in neonatal examination), care delivery in non-hospital settings (e.g. home nutrition, domiciliary visiting by health visitors) or processes of care (e.g. discharge arrangements).

Paradoxically, although some clinical registers are moving to become more specific (such as types of hip prosthesis), many of the HTs prioritised by NCCHTA were non-specific (such as social and environmental approaches to stroke prevention).

This analysis has focused only on the simplest question of whether these HTs could in principle be identified and not whether routine data would be sufficient for assessing that technology.

Linkage to a specific clinical disorder is problematic for databases. For HES this relies on ICD coding, which, as discussed above, has limitations. For the primary care drugs the PPA database has no linkage to patients' conditions but the GP-based systems such as GPRD have such data based on Read codes. However, even these have limited information on disease severity (e.g. categories include 'mild' hepatitis C, and

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified*

HTA topic titles	HTs identifiable in a routine database?
Social–environmental, psychological and physical approaches to stroke rehabilitation	No
A controlled comparison of alternative strategies in stroke rehabilitation	No
Early prediction of rehabilitation needs following acute stroke	No
What is the place of surgery in the management of patients with low back and radicular pain?	Partly (HES as OPCS4 codes H51.1. Lumbar radiopathy but not the specific type of operation)
Controlled trial of microdiscectomy for lumbar disc herniation	No
A systematic review of the effectiveness and cost-effectiveness of total hip replacement prostheses	No (in HES, OPCS4 distinguishes total hip replacement by primary/revision and with/out cement. Nothing on the type of prosthesis)
Systematic review of factors influencing outcomes and costs of hip replacement surgery	No
A multi-centre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia	No
Comparison of medical and surgical treatments of menorrhagia	No
The costs and benefits of paramedic skills in pre-hospital trauma care	No
An RCT of infusion protocols in adult pre-hospital care	No
Effectiveness and costs of paramedic pre-hospital management	No
Systematic review of outpatient services for chronic pain control	No
Effectiveness of methods of dialysis therapy for end-stage renal disease	Yes (UK Renal Registry)
Prostate trials office (PROTO): coordinating trials of new technologies in the treatment of BPH	No
A randomised controlled trial comparing the efficacy, safety and cost-effectiveness of transurethral resection (TURP), laser vaporisation (LVAP), transurethral needle ablation (TUNA) and microwave thermoablation (MTA) of the prostate	No
Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with BPH	No
Systematic review of bone marrow transplantation and peripheral blood stem cell treatment for malignancy	Partial (in HES, OPCS4: W30 is allogeneic BMT)
A randomised trial to assess the effectiveness, costs and cost-effectiveness of laparoscopic, vaginal and abdominal hysterectomy	Partial (HES OPCS4 Q07. Q08 = hysterectomy vaginal, abdominal. No laparoscopic coded)
Cost and quality implications of the organisation of vascular services	Limited [volume but not organisation or quality in HES (OPCS4)]
Scottish trial of arthroplasty or reduction for subcapital fractures	Partial (HES: OPCS4 S42/S72. Arthroplasty WS5 S6)
Economic evaluation of different service models for the management of minor injuries	No
Extending midwife/nurse roles in the routine examination of the newborn: randomised controlled evaluation and cost-effectiveness (EMREN trial)	No
A randomised cross over trial of nurse versus doctor-led outpatient care in a bronchiectasis clinic	No

continued

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified (cont'd)*

HTA topic titles	HTs identifiable in a routine database?
Multi-centre randomised controlled trial of nurse practitioners and pre-registration house officers in pre-operative work-up	No
Endovascular aortic aneurysm repair (EVAR) trials	No
D&I ear patient or laboratory testing – an evaluation	No
Near patient testing in diabetic clinics: appraising the costs and outcomes	No
A systematic review of studies relating to the efficiency and effectiveness of near patient testing in primary care	No
Routine referral for radiography of patients presenting with low back pain. Is patients' outcome influenced by GPs' referral for plain radiography?	No
A randomised controlled trial to assess the effectiveness, cost-effectiveness and cost benefit of routine referral for lumbar spine radiography in patients with low back pain	No
Lumbar spine radiology in primary health care: clinical outcomes and cost-effectiveness	No
Does early imaging influence management and improve outcome in patients with low back pain?	No
The reassurance value to general practitioners and patients of lumbar spine radiography for low back pain	No
Systematic review of detection, management and screening for prostatic carcinoma	No
A review of evidence on the cost-effectiveness of different strategies for detecting and managing prostatic carcinoma	No (no specific diagnostic or treatment data in Cancer Registers)
The cost-effectiveness of MRI for investigation of the knee joint	No
Cost-effectiveness of MRI in the DGH setting	No
The value of routine pre-operative testing: a review of the evidence	No
The value of digital imaging in diabetic retinopathy	No
A systematic literature review of spiral and ultrafast CT	No
Systematic review of the use of biochemical markers of myocardial injury	No
Randomised trial comparing the efficacy and costs of endoscopy with *H. pylori* testing versus non-invasive *H. pylori* testing alone in the management of dyspepsia	No
Evaluation of molecular prenatal diagnosis for Down's syndrome	No
Systematic review of endoscopic ultrasound and gastrointestinal cancer	No
Central line insertion project (CLIP)	No
Diagnosis of endometrial abnormality: comparison of outpatient procedures within cohorts defined by age and menopausal status	No
The effectiveness of the Heidelberg Retinal Tomograph and the Laser Diagnostics Glaucoma Scanning System in detecting and monitoring glaucoma	No
Virtual outreach: a randomised controlled trial and economic appraisal	No
Randomised controlled trial of asynchronous and synchronous telemedicine in dermatology – RCT-ASTID	No
A randomised trial comparing four methods of investigating patients with suspected pulmonary thrombo-embolism	No
What is the best imaging strategy for acute stroke?	No
Evaluation of molecular techniques in prediction and diagnosis of CMV disease in immunocompromised individuals	No
Monitoring blood glucose control in diabetes mellitus: a systematic review-based protocol	No

continued

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified (cont'd)*

HTA topic titles	HTs identifiable in a routine database?
Systematic review on urine albumin testing for early detection of diabetic complications	No
A systematic literature review, with decision analytic modelling, on the use of intravascular ultrasound imaging in coronary artery disease	No
A structured review of the role of PET in the NHS	No
A systematic review of the urgent assessment of chest pain in general practice and of the most cost-effective method of investigation of recurrent chest pain	No
The cost-effectiveness of magnetic resonance angiography: carotid artery stenosis and peripheral vascular disease	No
Systematic review and evaluation of the use of tumour markers in paediatric oncology	No
Does algorithm-guided diagnosis improve the clinical management of acute abdominal pain? A systematic review	No
Developing evidence-based guidelines for the prevention of venous thromboembolism in surgical patients	No
Assessment of long-term efficacy of early introduction of inhaled steroids in asthma	Partial (inhaled steroid use is linked to disease group in GPRD)
Early asthma prophylaxis, natural history, skeletal development and economy (EASE)	Partial (drug use by disease group in GPRD, but no data on skeletal development)
Assessment of long-term efficacy of early introduction of inhaled steroids in asthma	Partial (drug use by disease group in GPRD)
Clinical medication review by a pharmacist of patients on repeat prescriptions in general practice	No
A systematic review of wound care	No
A systematic review of the risks, benefits and costs of home parenteral nutrition	No
UK home parenteral nutrition register	No
Antimicrobial prophylaxis in surgery: review and dissemination of its use in dirty surgery	No
Systematic review of alternative analgesics following day case surgery	No
Antimicrobial prophylaxis in total hip replacement: comparative efficacy and cost-effectiveness	No
The British Rheumatoid Outcome Study Group (BROSG) trial of symptomatic versus aggressive therapy in established rheumatoid arthritis	No
Identification of the most cost-effective, microbiologically safe antimicrobial treatments for acne	No
A cost–utility analysis of beta interferon for multiple sclerosis	No (requires hospital prescription data)
Improving the evaluation of therapeutic interventions in multiple sclerosis: development of a patient-based measure of outcome	No
Development of the protocol for the proposed trial of beta interferon in multiple sclerosis	No
A comparative study of hypertonic saline, daily and alternate day rhDNase in cystic fibrosis	Partial (no data on hospital prescriptions. GPs' prescriptions in PPA and GPRD)
Treatment of established osteoporosis	No
An RCT of longer-term clinical outcomes and cost-effectiveness of standard and new antiepileptic drugs	Partial (GPs' prescriptions in PPA and GPRD)

continued

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified (cont'd)*

HTA topic titles	HTs identifiable in a routine database?
Health benefits from anti-viral therapy for mild chronic hepatitis C	Partial (GPs' prescriptions in PPA and GPRD)
Intrathecal pump systems for giving opioids in chronic pain	No
Systematic reviews of (i) comparative studies of depot neuroleptic drugs, and (ii) studies of oral vs depot neuroleptic agents for patients with schizophrenia: clinical, social and economic outcomes	Partial (GPs' prescriptions in PPA and GPRD)
The efficacy, cost-effectiveness and long-term tolerability of implantable contraceptives	Partial (GPs' prescriptions in PPA and GPRD)
Cost-effectiveness of the 'statins'	Partial (GPs' prescriptions in PPA and GPRD)
Which anaesthetic agents and techniques are most cost-effective in day surgery?	Partial (GPs' prescriptions in PPA and GPRD)
Treatments for severe psoriasis: a systematic overview	Partial (GPs' prescriptions in PPA and GPRD)
Systematic reviews into treatments for atopic eczema	Partial (GPs' prescriptions in PPA and GPRD)
Cost utility of the latest antipsychotics in severe schizophrenia (CUtLASS): a multi-centre, randomised, controlled trial	Partial (GPs' prescriptions in PPA and GPRD)
Managing the dyspeptic patient: a systematic review and modelling exercise	No
A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin reuptake inhibitors and lofepramine	Yes (GPs' prescriptions in PPA and GPRD)
Cost benefit evaluation of routine influenza immunisation in subjects 65–74 years of age	No
The clinical and cost-effectiveness of inhaler devices in asthma and COPD: four systematic reviews of the research findings	Yes (GPs' prescriptions in PPA and GPRD)
The cost-effectiveness of thromboprophylaxis in medical patients	No
A systematic review of the effectiveness, cost effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischaemic stroke in the NHS	No
A large randomised assessment of the relative cost-effectiveness of new and old drugs for Parkinson's disease	Yes
Population screening policy for the drug treatment of high blood pressure	No
Screening for stroke	No
A randomised controlled trial of different approaches to universal antenatal HIV testing: acceptability, costs and benefits	No
SURUSS (serum, urine and ultrasound screening study)	No
Establishing appropriate screening practice for Down's syndrome	No
Critical review of the role of neonatal screening in the detection of congenital hearing impairment	No
Systematic review of ultrasound screening during pregnancy	Yes (St Mary's Maternity Information System)
Information needs for health planners: screening for cystic fibrosis	No
Screening for haemoglobinopathies in the UK: review and economic analysis	No
Haemoglobinopathy – a systematic review	No
Information needed for health planners: screening for fragile X syndrome	No
An assessment of screening for the fragile X syndrome	No

continued

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified (cont'd)*

HTA topic titles	HTs identifiable in a routine database?
Neonatal metabolic screening: cost, yield and effects on outcome	No
Systematic review of neonatal screening for inborn errors of metabolism	No
Pre-school vision screening	No
Child health surveillance: an evaluation of screening for language delay	No
Cost analysis of child health surveillance	No
Screening for ovarian cancer	No
Informed decision making in healthcare	No
Acceptability, benefit and costs of early screening for hearing disability	No
The determinants of screening uptake and effective interventions for increasing uptake	No
Cost-effectiveness of screening for hypercholesterolaemia versus case finding for familial hypercholesterolaemia	No
Cross-cutting issues: the implications of false negatives	No
Systematic review and modelling of the cost-effectiveness of screening for *Helicobacter pylori* to reduce mortality and morbidity from gastric cancer and peptic ulcer disease	No
The feasibility of conducting a multicentre randomised trial of treatment for localised prostate cancer: early detection, recruitment strategies and a pilot study	No
Randomised controlled trial and cost-effectiveness study of targeted screening versus systematic population screening for atrial fibrillation in the over 65s: the SAFE Study	No
Interventions based on stage theories to promote individual behaviour change in healthcare settings	No
Systematic review of the role of HPV testing in the cervical screening programme	No
Primary and community care: can the effectiveness of interdisciplinary team care for stroke be improved?	No
Effectiveness of counselling, cognitive behaviour therapy (CBT) and GP care for depression in general practice	No
A randomised controlled trial to evaluate the efficacy and cost-effectiveness of counselling with patients with chronic depression and anxiety	No
Primary care emergency centres: organisation and impact	No
The community provision of hearing aids: a systematic review of the evidence	No
Improving the referral process for familial breast cancer genetic counselling: an evaluation of complementary interventions	No
A systematic literature review of technologies for the diagnosis and monitoring of osteoporosis	No
The costs and benefits of post-natal midwifery support – a randomised controlled trial	No
Redesigning postnatal care: a randomised controlled trial of protocol-based, midwifery-led care	No
The use of laxatives in the elderly	No
The effectiveness of health visitor domiciliary visiting: a systematic review of the literature	No
Economic evaluation of a primary care-based patient education programme for osteoarthritis of the knee	No
A randomised controlled trial of intensive physiotherapy vs a home-based exercise treatment programme in knee osteoarthritis	No
Efficacy and cost-effectiveness of physiotherapy for children less than three years old with cerebral palsy	No

continued

TABLE 14 *HTA topic titles and extent to which the health technology(ies) are identified (cont'd)*

HTA topic titles	HTs identifiable in a routine database?
Promoting physical activity in south Asian Muslim women through 'exercise on prescription'	No
Randomised controlled trial and economic evaluation of two alternative strategies of providing support for socially disadvantaged inner city families with infants	No
A systematic review of discharge arrangements for older people	No
A systematic review of randomised and non-randomised intervention studies to examine which of the brief psychological treatments used in primary care lead to improved outcomes	No
A prospective randomised comparison of minor surgery in primary and secondary care	No
Psychological treatment in the regulation of long-term hypnotic drug use	No
EXERT (exercise evaluation randomised trial) – randomised trial comparing leisure centre-based exercise on prescription, home-based walking and usual advice in primary care	No
Systematic overview of health promotion in schools	No
RCT to assess the impact of a package comprising a patient orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease	No
A randomised controlled trial of two bandages for treating venous leg ulcers	No
Cognitive behavioural therapy versus antispasmodic therapy for irritable bowel syndrome in primary care	Partial (GPs' prescriptions only in PPA and GPRD)
Long-term outcome of cognitive behaviour therapy (CBT) clinical trials in central Scotland	No
Longer term clinical and economic benefits of offering acupuncture to patients with chronic low back pain	No
Acupuncture for migraine and headache in primary care: a pragmatic, randomised trial	No
Systematic review of the effectiveness of day care for people with severe mental disorders	No
Best place care for elderly people after acute and during sub-acute illness	No
Effectiveness of diabetes education interventions for adolescents	No
Systematic review to evaluate the effectiveness of interventions to promote the uptake of breast feeding	No
A systematic review of home treatment compared with admission for mental health problems evaluated in terms of clinical, social, and cost outcomes, user and carer acceptability and sustainability of programmes	No
Randomised trial of fluoxetine and cognitive-behavioural therapy versus fluoxetine alone in adolescents with persistent major depression	No
A randomised controlled multi-centre treatment trial of adolescent anorexia nervosa, including assessment of cost-effectiveness and patient acceptability	No
Trial of problem-solving by community psychiatric nurses (CPNs) for anxiety, depression and life difficulties among general practice patients	No
A systematic review of the costs and effectiveness of different models of paediatric home care	No

GPRD refers not only to the General Practice Research Database but also to its various 'sisters' including DIN-LINK, Mediplus and MEMO.
BPH, benign prostate hyperplasia; CMV, cytomegalovirus; COPD, chronic obstructive pulmonary disease; D&I, diagnostic imaging; DGH, District General Hospital; PET, positron emission tomography.

'severe' psoriasis) or on co-morbidities (which are required for case mix adjustment).

GPRD (and similar databases such as DIN-LINK, Mediplus and MEMO) can be used to assess non-fatal events, and its main use (see Chapter 7) has been in monitoring adverse events of drugs. Clinical register databases such as the Renal Registry and SMMIS collect details of patients' characteristics and outcomes, both fatal and non-fatal, but no information is available on generic quality of life or disease-specific measures.

Furthermore, few of the databases that capture HTs include any data on outcomes. The HES is limited to in-hospital events, although it has been linked to 30-day mortality for some treatments in the NHS Clinical Indicators.

Discussion

The ability of routine datasets to capture HTs depends on how well defined the latter are, how accurately standard coding systems classify them and the reasons for which the database was established. Those technologies that are regulated by law tend to have fuller, more precise definitions. Pharmaceuticals constitute a specific class of HTs, having been subject to licensing in most countries for many years. The regulation of pharmaceuticals, which tend to be manufactured and marketed by private enterprises, reflects a history of harm and subsequent litigation. Different regulations apply, however, depending on whether drugs are available only on prescription, over-the-counter in pharmacies only or in all shops.

Medical and surgical devices tend to be less regulated, but since they are often privately manufactured, they are also potentially subject to litigation, the extent of which varies internationally. Litigation concerns have contributed to the establishment of registers of patients who have had certain devices implanted (such as cardiac pacemakers or silicone breast implants).

Other HTs are subject to less regulation and tend to be less well defined. Surgical procedures are recorded in routine databases for inpatient and day cases (but not for outpatients or when carried out in GP surgeries) and are not regulated other than by clinical audit of outcomes of adverse events and confidential enquiries. The Safety and Efficacy Register of New Interventional Procedures (SERNIP) marks an innovation in registering new surgical interventions, partly in response to their proliferation, but is a voluntary system with no formal regulatory role.*

Many other health services are less regulated, including changes in the settings of care (e.g. from hospital to domiciliary care), the organisation of healthcare delivery (e.g. stroke units), the roles of different health professionals (e.g. nurse practitioners) and inter-personal interventions such as counselling. The recent history of community care for the mentally ill may have led to auditing of adverse events (spurred in part by media reports), but the collection of routine data for these services remains weak. More generally, the fuzzy boundaries between health and social care mean that some HTs will always have a degree of imprecision.†

The main regulation of technologies such as diagnostic tests has to do with quality control, such as the national external quality scheme for pathology and other laboratories. Data are absent on diagnosis and imaging except radiology overall activity levels only. The lack of any information on the types of patients scanned or the diagnosis made limits any assessment of these technologies. Collection of routine data on the use of such HTs would, however, require appropriate coding systems.

Overall, then, the extent to which data are collected routinely on HTs depends on the health system, including not only how services are funded but also how HTs are regulated. Regulation has historically been driven by safety concerns, linked to adverse reporting and licensing systems, both of which can be seen as generating routine data, although neither requires routine data on all persons using particular HTs. The requirement for data on the use and outcomes of HTs has been driven mainly by the 'effectiveness revolution' and by comparative audit.

This analysis suggests that routine databases have a very limited role in informing policy makers and the NHS about the effectiveness, diffusion or equity of delivery of those HTs that have been prioritised by the NHS HTA programme.

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* See http://www.aomrc.org.uk/sernip.htm

† The move in many countries to increased reliance on primary care may have the effect of reducing the extent to which existing routine data systems capture treatment data (such as minor surgery). Against that, primary care organisations may over time come to collect more detailed relevant data than at present, especially on those HTs provided.

Key points

- Of over 160 HTs identified as priorities by the NHS HTA programme, only 22 could be identified in routine databases.
- The bulk (16) of these were drugs prescribed in primary care, which are captured by the PPA. These can only be linked to specific disorders by special enquiries using one of the more detailed GP data systems (such as GPRD, DIN and Mediplus)
- A few surgical procedures were identified, but were limited by the procedural coding system.
- Few prioritised HTs were captured in the relevant HT-based clinical registers.
- Even when technologies could be identified in any routine database, data were generally lacking on the relevant characteristics to assess effectiveness or equity.
- Major gaps identified included hospital prescribing, diagnostics and imaging, screening, medical non-drug interventions, interventions based on the type of professional–patient interaction, interventions by professions allied to medicine, new roles for non-doctors, delivery in non-hospital settings and processes of care.
- Routine databases in England have a very limited role in assessing those HTs that have been prioritised by the NHS HTA programme.

Chapter 7

The uses of databases in health technology assessment

Introduction

This section summarises the extent to which the databases identified in Chapter 5 with most potential have actually been used in HT assessment. To answer this question, each of the three different types of HT assessment have been included: effectiveness, equity and cost. Within these, effectiveness has been distinguished from comparative audit, and diffusion from equity. By comparative audit is meant inter-provider comparisons of performance.

The criterion for use has been any published report or article, including 'grey literature', using the database for any of the three kinds of HT assessment. Contrary to expectations, neither the conventional nor the 'grey' literature yielded the important references. Searching by the title of the database was the best search strategy. 'Published reports' has been taken to include analyses in annual reports and reported use for comparative audit.

The focus was on databases in existence in 2000. All databases in group I (HT plus patients) have been included along with selected databases of particular interest from group II (PPA database) and group III (the Health Survey for England). Other databases from groups II and III have been omitted on the grounds of their very restricted potential, but any reported use is discussed in the relevant inventory. Thus adverse event/confidential enquiry reporting systems have been excluded along with simple disease registers and most health surveys.

Databases that were still being developed in late 2000 were excluded. Although several have very considerable scope for being used in HT assessments, particularly those to do with national comparative audit, their potential remains to be realised. The focus here is on databases covering the UK or England/Wales. Although some differences exist with Scotland, they are largely to do with pace of change and detail (see Annex 2).

Results

Summary results are provided in *Table 15* for 25 databases, indicating the extent of their use in any form of HT assessment.

TABLE 15 *Selected routine databases, UK/England, with summary indication of use in any kind of HT assessment up to December 2000*

Group	Title	HT assessment: effectiveness comparative audit	HT assessment: diffusion, equity	HT assessment: resource use, costing
Ia	British Cardiovascular Intervention Society (BCIS) Database	Effectiveness – no Comparative audit – yes[143]	Diffusion – yes[143] Equity – no	No
	Human Fertilisation and Embryology Authority (HFEA) Database	Effectiveness – yes (20) Comparative audit – no	Diffusion – yes[144] Equity – no	No
	Intensive Care National Audit and Research Centre (ICNARC)	Effectiveness – no Comparative audit – yes[145]	Diffusion –no Equity – no	No
	National Breast Implant Register	Effectiveness – no Comparative audit – no	Diffusion –no Equity – no	No
	National Pacemaker Database	Effectiveness – no Comparative audit – yes[146]	Diffusion – yes[147] Equity – no	Yes[148]

continued

TABLE 15 *Selected routine databases, UK/England, with summary indication of use in any kind of HT assessment up to December 2000 (cont'd)*

Group	Title	HT assessment: effectiveness comparative audit	HT assessment: diffusion, equity	HT assessment: resource use, costing
	National Prospective Monitoring System (HIV)	Effectiveness – yes[149] Comparative audit – no	Diffusion – no Equity – no	Yes[150]
	National Transplant Register	Effectiveness – yes[24–26] Comparative audit – no	Diffusion – no Equity – no	No
	Northern Region Haematology Leukaemia Database	Effectiveness – no Comparative audit – no	Diffusion – no Equity – no	No
	Scotland and Newcastle Lymphoma Database	Effectiveness – yes[151,152] Comparative audit – no	Diffusion – no Equity – no	No
	Scottish Hip Fracture Audit/Trent Hip Fracture	Effectiveness – no Comparative audit – yes[153]	Diffusion – no Equity – no	No
	St Mary's Maternity Information System	Effectiveness – no Comparative audit – yes[154]	Diffusion – no Equity – no	No
	UK Cardiac Surgical Register	Effectiveness – no Comparative audit – yes[155]	Diffusion – yes[155] Equity – no	No
	UK Cystic Fibrosis Database	Effectiveness – no Comparative audit – no	Diffusion – no Equity – no	No
	UK Haemophilia Centre Directors' Database	Effectiveness – no Comparative audit – no	Diffusion –yes[156] Equity – no	No
	UK Heart Valve Register	Effectiveness – no Comparative audit – yes[157,158]	Diffusion –yes[159] Equity – no	No
	UK Hydrocephalous Shunt Register	Effectiveness – no Comparative audit – no	No	No
	UK Renal Register	Effectiveness – yes[160] Comparative audit – yes	Diffusion – yes[161] Equity – no	No
	UK Thalassaemia Register	Effectiveness –yes[162] Comparative audit – yes[163]	Diffusion – yes[163] Equity – yes	No
Ib	Hospital Episode Statistics (HES)	Effectiveness – yes[164] Comparative audit – yes[27,165]	Diffusion – no Equity – yes[36,166–170]	Yes[138]
	General Practice Research Database (GPRD) (+ similar databases)	Effectiveness – yes[171] Comparative audit – no	Diffusion – no Equity – yes[37]	No
	National Cancer Registry	Effectiveness – no Comparative audit – yes[172]	Diffusion – no Equity – yes[173]	No
Ic	Immunisation programmes	Effectiveness (take-up) – yes[134] Comparative audit – yes[134]	Diffusion – yes[134] Equity – no	No
	Cervical Cytology Screening Programme	Effectiveness (take-up) – yes[135] Comparative audit – yes[135]	Diffusion – yes[135] Equity – no	No
	Breast Screening Programme	Effectiveness (take-up) – yes[136] Comparative audit – yes[136]	Diffusion – yes[136] Equity – no	No
II	Prescription Cost Analysis (PPA)	Effectiveness – yes[174,175] Comparative audit – yes[176,177]	Diffusion – yes[178] Equity – yes[178]	Yes[179–192]
	Health surveys: Health Survey for England (HSE)	Effectiveness – no Comparative audit – no	Diffusion – yes[193] Equity – no	No
	Costing databases: NHS Reference Costs	Effectiveness – no Comparative audit – no	Diffusion – no Equity – no	Yes[138]

Use in HT assessment

Overall, few databases have been used to assess effectiveness in the sense of linking HTs to final outcomes. Notable exceptions include the HFEA database, which has been used to show factors associated with successful birth,[22] and the National Transplant Database, which has been used to show the benefits of HL assessment matching[24,25] and to identify best methods of cadaveric organ retrieval.[26] Although the degree to which the statutory nature of each of the databases facilitated there for such analyses is unclear, this may have helped make the databases accessible to bona fide researchers. Access to these databases is restricted to those who are involved in running them, a characteristic shared by most clinical registers. Growing concerns about patient confidentiality may in future further restrict access to all databases.

The Scotland and Newcastle Lymphoma Database was used to evaluate treatment and outcome for all newly diagnosed patients with Hodgkin's disease[151] and to explore the long-term effects of autologous bone marrow and peripheral blood stem cell on loss of fertility.[152] The National Prospective Monitoring survey has been used to assess intermediate outcomes such as viral load in HIV patients.[149] The UK Thalassaemia Register has been used to assess the outcomes of screening for affected couples.[162]

Comparative audit was the most common role for clinical registers with around half being used for this purpose. Comparative audit of performance can be by hospital, unit or consultant, and tends to be highly confidential. Notables among this list are ICNARC[145] (which finances itself through a clinical audit service), the Scottish Hip Fracture Audit database,[153] the St Mary's Maternity Information System,[154] the four cardiac databases[143,146,155,157,158] and the UK Thalassaemia Register.[163] The UK Renal Register plans to be self-financing based largely on a comparative audit service of renal unit outcomes and processes against national standards.[194] The widely recognised desirability of risk adjustment in comparing performance seems likely to lead to more detailed clinical data being collected by these databases. Several databases already include clinical detail which could act as proxies for health states. Few databases, however, were used for both effectiveness assessment and comparative audit.

Several confidential enquiries have been based on clinical registers, particularly on the General Practice Research Database,[61] but also on the UK Cystic Fibrosis Register[195] and the UK Thalassaemia Register.[163]

Several registers have been used to explore the scope for clinical trials, notably the Northern Region Leukaemia Database,[196] or to provide patients for a clinical trial.[197]

Three clinical registers were used for neither effectiveness nor comparative audit: the UK Haemophilia Centre Directors' database,[156] the National Breast Implant Register[125,198] and the UK Hydrocephalous Shunt Register.[199] Plans exist to use the last two databases, funded by the MDA, for technology assessment. The Haemophilia Centre Directors' Database, despite its considerable potential, is only made public in annual reports, which are difficult to obtain.*

Overall, clinical registers have not generally been used in assessing the effectiveness of one technology against another, largely because they tend to be confined to single technologies. The scope for inter-technology comparisons is growing, partly in relation to detailed comparisons within the intervention (such as between PTCA with and without stents) but also owing to planned mergers between databases (such as the planned merger of the BCIS and the UK Cardiac Surgical Register in the Central Cardiac Audit Database, which would permit comparison of PTCA and CABG).

Much greater use was made of clinical–administrative databases for HT assessment, particularly for analyses of equity, owing in part to their wider scope and coverage.

The HES† has been used to compare in-hospital mortality by hospital through the clinical indicators in England[200] and Scotland.[153] Scotland pioneered the extension of these indicators to include 30-day mortality for specific interventions, an example which has been followed in England. HES was also used in the Bristol Inquiry, into the

* Charges of £200 have been imposed for the annual report, which is a short photocopied document. The latest report available in early 2001 related to 1998, and was made available to the authors free of charge.
† The HES CD-ROM contains statistical information including length of stay, waiting times and number of episodes occurring for ranges of diagnoses and operating procedures. Information is presented at national, regional and Health Authority levels. The CD-ROM consists of a large number of tables, fronted by an easy-to-use Windows-based system. HES CD-ROMs are currently available for the 1994–95 and 1995–96 data years.

management of care of children receiving complex heart surgery at the Bristol Royal Infirmary, in which it was shown to have captured the raised mortality better than the Cardiac Surgery Database.* HES has been widely used in analyses of equity,[36,166–170] providing the basis of a needs indicator used to take equity into account in funding health authorities. HES has also been used in relation to specific diseases, including access to cardiac revascularisation by sex.[153,166,167] HES provides the basic data for HRG costing (see next column).

GPRD has been used mainly to explore the risk of adverse events. Of the 104 articles published between 1984 and January 1999,[61] the bulk (63) were to do with adverse events/risk. GPRD has been used to devise an equity index for prescribing and for developing performance indicators.[37]

Cancer Registry data have been used to assess the influence of caseload and specialisation on cancer outcome,[172] the cost-effectiveness of treatments for oesophageal cancers[201] and survival by place.[173]

Among the HT-only (group II) databases, the PPA database has been widely used, including an assessment of the impact of on-site counsellors,[175] the quality of prescribing for asthma,[174] and for audits of benzodiazepine[177] and antibiotic[176] prescribing. It has also been used to assess the diffusion of antipsychotic drugs in schizophrenia,[178] and for costing ulcer-healing drugs,[179] non-steroidal anti-inflammatory drugs (NSAIDs),[189] asthma,[190] heart failure,[180] benzodiazepines,[191] antibiotics[192] and wound care.[183,184] Evaluations of the impact of fundholding on prescribing have also used PPA data.[185–188]

The Health Survey for England (HSE) differs from other databases discussed here in being a regular survey of some 20,000 individuals by household. It has been used to show the proportions of people with raised cholesterol who are taking lipid-lowering medication.[203]

The National Reference Cost database, which provides cost per HRG for every NHS hospital in England, has yet to be used in costing, partly owing to its relative newness. The PPA database has been used in costing. Despite the wealth of resource use data in the clinical registers, only one instance has been located of their use in costing.[148]

Key points

- The use of those databases with potential for assessing HTs has been limited and probably sub-optimal.
- The scope for use of clinical registers is probably greatest for comparative audit, but depends on these databases having credibility with clinicians, which in turn requires risk adjustment and reliable data.
- Effectiveness assessment is more possible when relevant outcomes can be readily included (whether simple, intermediate or proxy). Most databases contain insufficient data on health states to be of use in assessing effectiveness and lack the detail required for risk adjustment, an issue which some are planning to deal with.
- Accessibility is a major barrier to using clinical registers, with reported use largely limited to those who 'own' them. Central returns have also been largely inaccessible, but details and aggregated data are increasingly available via the Department of Health web pages.
- Concerns over confidentiality and consent may in future reduce access and restrict the scope of clinical databases.

* See the evidence for Day 70, 3 November 1999, available at http://www.bristol-inquiry.org.uk/bristol.htm

Chapter 8

Validation of databases in health technology assessment

This chapter proposes criteria for assessing the validity of databases and applies them to those routine databases deemed of most potential for HT assessment, with a focus on those databases used in some form of HT assessment (as discussed in Chapter 7). It omits databases that are still being developed.

Criteria for assessing validity

The literature searches yielded little on the overall issue of approaches to validation but some helpful discussions of attempts to validate the data in particular databases were located (which are noted below in relation to the relevant database).

Two broad dimensions are distinguished in *Table 16*, coverage and accuracy, each with a number of different levels.

Coverage can be thought of at four* levels:

- The extent of the dataset, specifically whether it includes all the important variables about the patient, the HT and the outcomes. Patient variables include socio-demographic factors, underlying disease including severity, and potential confounders such as co-morbidity.
- The completeness of data collection by variable. Missing data limit the usefulness and validity of the dataset. Data may be absent owing to random or selective factors, the balance of which can be hard to judge, but if selective, bias is likely. To use a variable with missing data means either excluding patients without it, or making assumptions about what the value should be, both of which prejudice internal validity. The effect of missing data is multiplied if many variables are needed in an analysis.
- The completeness of coverage of the relevant units (e.g. hospitals) or geographical areas, and how representative they are of the relevant population. Unrepresentativeness is more likely if units volunteer to join a registry (there is usually a higher response from specialist centres).† The characteristics of the patients or the delivery of the HT may differ in selected units, giving different results, which could reduce the external validity of the findings on effectiveness, equity and diffusion.
- Completeness of recruitment of patients or technologies in each setting. Are some patients excluded who were intended to be included? Again, if this is selective rather than random, the data will be biased.

TABLE 16 *Proposed criteria for discussion of validation of routine databases with potential use in HTA*

Coverage
1. Extent of dataset – completeness of variables or content validity
2. Completeness of data collection by variable – missing data
3. Completeness of recruitment of units and their representativeness
4. Completeness of recruitment of patients
Accuracy
1. Use of explicit definitions of variables, including coding system used
2. Any studies of reproducibility of coding
3. Extent to which data are audited, both internally (internal consistency) and externally (by an external agency or by comparison with another database)

Accuracy can also be distinguished at a number of levels:

- Use of explicit definitions of variables, including the coding system used. Lack of an explicit coding system can lead to unreliable data. Most databases use explicit coding systems but, as noted above, coding systems inevitably lag technological developments. Limitations of coding systems and definitions may also lead to misclassification, for example, of co-morbid disease states or disease severity (e.g. diabetes type 1 and 2 can be misclassified without clear

* A related issue is the completeness of the patients who might receive the technology being assessed, that is, does the dataset deliberately exclude key groups? If so there may be a problem with external validity.
† This may be less of a problem in regional databases or in databases with complete national coverage.

rules). Routine databases are subject not only to these random (non-differential misclassification) processes but also to biases in measurement (information bias). This can arise when those responsible for the measurements are not 'blinded' to how patients were treated.
- Reproducibility of coding provides a stronger check on the consistency with which codes are used. Some databases have had their reproducibility checked, but few are likely to have this carried out routinely.
- The extent to which data are audited, both internally (internal consistency) and externally (by an external agency or against another database), provides a further check. Internal checking of the consistency of data provides a useful indication of accuracy which many databases use to identify impossible or improbable records (such as people aged over 100 years, men having babies, lengths of stay of 999 days). External audit scrutinises the entire process of data collection and entry* and may involve comparing the extent of agreement between databases covering the same topics.

How valid are UK routine databases?

Those routine databases with most potential for HT assessment and which have been used in HT assessment (as described in Chapter 7), have been assessed by the criteria outlined in *Table 15*, using published reports and articles. The details for each database are listed in the Appendices 1–3, with some general observations discussed below.

The completeness of the variables varies by database with greater detail in the clinical registers than the others. The clinical registers, however, tended to have a narrow focus, often on a single HT, whereas the clinical–administrative databases tended to cover a range of diseases and HT.

The extent of missing data by variable is poorly reported. Those central returns with individual level data (e.g. HES) tend to be weakest in providing complete clinical details[99] but there are signs of improvement (the Data Quality Indicator in HES). Even those clinical registers which have feedback mechanisms to ensure completeness nonetheless have incomplete items, including key variables such as co-morbidity (as in the UK Renal Registry), and stage of cancer (as in Cancer Registries).[204] This may reflect poor recording in the medical notes or lack of agreement about definitions. Outcome data are particularly likely to be incomplete.[205] The impact of missing data where several variables are required for analysis is illustrated by the incompleteness of case mix scores in the British Cardiac Surgery database.[155]

The completeness of recruitment of units varies, being more complete for central returns (e.g. HES, although this excludes private hospital patients) but only partial for many clinical registers which tend to be voluntary but often include the private sector. Those which are statutory (HFEA and National Transplant database) cover all units, both public and private.

The extent of recruitment of individuals within participating units is difficult to assess as often no denominator is given. The degree of ascertainment has been studied for some databases. Cancer registration[78,206] has been shown to be low for certain cancers (e.g. non-Hodgkin lymphoma, non-melanotic skin cancer). Databases which draw off a patient administration system such as the St Mary's Maternity Information System[207,208] have high patient coverage. The Cancer Registries employ the ratio of mortality to incidence as a guide to completeness.[80]

Standard coding systems (ICD-10, OPCS4) tend to be widely applied, but with some clinical registers going beyond these to record more detail in specially designed coding systems, particularly on co-morbidity and disease severity.

Internal checks, a form of audit, are common, usually via computerised systems, and more likely for databases that are used directly to assist service provision or for comparative audit. The Cancer Registries provide comparative data on several indicators (the proportion of records with Death Certificate Only and proportions which have been

* As with any study, there are issues of the reliability of measures taken (i.e. how close would repeated measures be?). This may arise from different observers, different methods of measurement and, particularly for physiological variables, from within-individual variability. Another aspect of a database which may affect the confidence in the results is the size of the data source, in terms of absolute numbers of patients included. The number of patients affects the statistical analysis (in large databases, small associations will give statistically significant results, small databases may be underpowered). Although high coverage of units and detailed records are generally desirable, these impose problems of coordination to ensure that each unit collects data according to agreed protocols.

TABLE 17 *Selected databases, UK/England, 2000, summarised by extent of validation*

Group	Title	Coverage	Accuracy
Ia	British Cardiovascular Intervention Society (BCIS) Database	Extent of dataset: procedures distinguished in detail. Recruitment: 22% of NHS and 39% of private centres returned no data. Individuals: unclear. Completeness: 'fundamentally poor but improving' Outcomes are reported by hospital/procedure[143]	Coding: acknowledged weaknesses in definitions for risk adjustment to be remedied within CCAD Reproducibility: no checks reported Audit: some internal audit done. No external audit reported[212]
	Human Fertilisation and Embryology Authority (HFEA) Database	Extent of dataset: patient socio-demographic and clinical characteristics and outcomes (conception, pregnancy and details of birth). Recruitment: statutory basis implies high coverage of centres, individuals and mandatory fields. Some clinical pregnancies lost to follow-up (2.3% reported 1997/98)[144]	Coding: customised, in-house, unclear Reproducibility: no reports Audit: transcription errors estimated at 3–3.5%[144] HFEA visits to clinics act as a form of external audit
	Intensive Care National Audit and Research Centre (ICNARC)	Extent of dataset: high as specifically designed for ICU. Recruitment: 50% of Trusts. Individuals: 100% Completeness: 95–100% for admission variables, 90–100% for outcome variables and 40–50% for physiological variables	Coding: ICNARC Coding Method (ICM) used Reproducibility: no reports Audit: validity checks plus 6-monthly random sample of 20 records. External: ICNARC compare data with the large, validated UK APACHE II study dataset[145]
	National Breast Implant Register	Extent of dataset: limited. Recruitment: denominator of units and individuals unknown 60–90% compliance at individual level from 60 to 90%	Coding: no formal coding Reproducibility: no reports Audit: internal validation checks. No external audit[198]
	National Transplant Register (UK Transplant)	Extent of dataset: rich. Recruitment: statutory role in allocating organs requires high coverage re organ 'harvesting'. Individuals: high Completeness: 90–100% registration, 60–70% for follow-up	Coding: uses range of coding schemes Reproducibility: no reports Audit: internal – yes External audit: UK Cardiothoracic Transplant Audit[205]
	National Pacemaker Database	Extent of dataset: rich Recruitment: high re centres. Individuals: high, due to biannual survey of centres and use of manufacturers' estimates for non-responding centres. Completeness varies with mode of pacing: high for ECG and less for symptoms	Coding: to be specified as part of CCAD Reproducibility: no reports Audit: regular 'sanity' checks by BPEG, with return of invalid data to centres. External: reports are sent to each participating centre annually as well as to MDA[147]
	National Prospective Monitoring System (HIV)	Extent of dataset: specifically designed Recruitment: units limited to London. Individuals: unknown. Fields: unknown	Coding: range of clinical coding systems Reproducibility: no reports Audit: internal but no external validation. (E Beck, personal communication, 2000)

continued

TABLE 17 *Selected databases, UK/England, 2000, summarised by extent of validation (cont'd)*

Group	Title	Coverage	Accuracy
	Northern Region Leukaemia Database/Scottish and Newcastle Lymphoma Database	Extent of dataset: rich Recruitment: high coverage of units and individuals via laboratories but may miss patients treated outside region	Coding: unknown Completeness of variables: unknown Reproducibility: no reports Audit: internal via laboratory audit. External: one study (S Proctor, personal communication, 2000)
	Scottish Hip Fracture Audit/Trent Hip Fracture	Extent of dataset: rich Recruitment: central return with high coverage of NHS units. Captures 80% of hip fractures admitted in Scotland	Coding: standardised Reproducibility: no reports Audit: internal checks. External: patient follow-up[153]
	St Mary's Maternity Information System	Extent of dataset: rich Recruitment: limited to 10 units in former North Thames region. High coverage of individuals in these units because part of patient administration	Coding: mix of standard and customised coding Reproducibility: no reports Audit: used for comparative audit but no external validation[208]
	UK Cardiac Surgical Register	Extent of dataset: rich Recruitment: 71% of all Trusts undertaking adult cardiac surgery contribute. Individuals: data available for only 45% of individuals for the simplest risk score (Euroscore)	Coding: CCAD protocol to improve coding system Reproducibility: no studies Audit: computerised consistency checks External validation: none[213]
	UK Cystic Fibrosis Database	Extent of dataset: rich Recruitment: covers 95% of units but weak re London High coverage of individuals	Coding: The Cystic Fibrosis International Data Standard Reproducibility: no reports Audit: internal checks only (A Mehta, personal communication, 2000)
	UK Haemophilia Centre Directors' Database	Extent of dataset: limited Recruitment: coverage high but missing some major London units. Limited coverage of individuals owing to aggregated data submission	Coding: mix standard and customised Reproducibility: no reports Audit: limited internal cross-checking due to aggregate data. No external audit[156]
	UK Heart Valve Registry	Recruitment: similar to UK Cardiac Surgical Register Extent of dataset: limited (major revisions proposed as part of CCAD)	Coding: mix standard and customised Reproducibility: no reports Audit: internal validation checks only[159]
	UK Hydrocephalous Shunt Register	Extent of dataset: rich, specifically designed Recruitment: covers all UK neurosurgery centres and most paediatric centres. 75–80% completeness for individuals	Coding: ICD-10, OPCS4 plus additional shunt specifics Reproducibility: no reports Audit: internal cross-checks. No external audit[199]

continued

TABLE 17 *Selected databases, UK/England, 2000, summarised by extent of validation (cont'd)*

Group	Title	Coverage	Accuracy
	UK Thalassaemia Register	Extent of dataset: limited Recruitment: 97% of NHS patients treated	Coding: mix of standard and customised Reproducibility: no reports Audit: internal validation checks. External: cross-checks with UK Register of Prenatal Diagnosis of Haemoglobin Disorders[163] (B Modell, personal communication, 2000)
	Hospital Episode Statistics (HES)	Extent of dataset: limited to ICD and OPCS surgical coding Recruitment: all NHS units 5% of HES records lack a usable diagnosis code. Secondary diagnoses in 1% (94). Underestimation of private patient activity. The HES Data Quality Indicator assesses data coverage and component indicators[200]	Coding: ICD-10 and OPCS4 Reproducibility: fairly high levels of 'approximate' agreement (over the first three characters of the ICD-9 and OPCS4 codes)[209] Audit: verification error reports to Trusts plus feedback External audit – several studies, showing problems[9,64,209,214–216]
	General Practice Research Database (GPRD)	Extent of dataset: rich Recruitment: number of participating practices varies. Representativeness: likely to be high owing to size and dispersion. Completeness of capture of individuals high owing to computerised practices Completeness of fields: unknown	Coding schemes: Read 2, Multilex drug dictionary, mappable to BNF Reproducibility of coding: no studies Audit: internal quality checks. External: close agreement with Morbidity Survey of General Practice[211]
	National Cancer Registry	Extent of dataset: limited re treatments. Recruitment: sites: very high, but varies by region Completeness: varies by Registry and particularly by cancer site. Incomplete and inaccurate of recording especially of stage, nodal status and treatments[80,204,217]	Coding: range of standard systems (ICD-8, -9 and -10, country of birth) occupation Audit: internal computer assisted. External: various studies[78–80,204,217–219]
Ic	Immunisation programmes	Extent of dataset: focus on take-up Recruitment: high[134] Completeness: high[134]	Coding: standard Audit: unknown
	Cervical Cytology Screening Programme	Extent of dataset: take-up and false positives Recruitment: yes[135] Completeness: high[135]	Coding: standard Audit: some external audits
	Breast Screening Programme	Extent of dataset: take-up and false positives Recruitment (take-up): high[136] Completeness: high[136]	Coding: standard Audit: some external audits[220]

continued

TABLE 17 *Selected databases, UK/England, 2000, summarised by extent of validation (cont'd)*

Group	Title	Coverage	Accuracy
II	PPA	Extent: limited (drug, GP, pharmacist) Recruitment: high, used to pay community pharmacists for prescriptions dispensed. Completeness: high re details required for payment, but fraud has been shown regarding patients' payment status	Coding: BNF Reproducibility: unknown Audit: internal computerised. External: varies by disease. Comparisons with local disease registers show good fit for diabetes, less so for other chronic diseases[221–223]
	Health Survey for England	Extent of database: limited re treatments (prescribed medications) Recruitment: interviews 74% of sampled households, with 92% of adults and 96% of sampled children Individual response rate: 69% for adults and 75% among (sampled) children. Completeness: response rates around one-third for blood samples. 59% of adults and 64% of children saw nurse interviewer	Coding: drugs classified using six-digit BNF code Reproducibility: no studies located Audit: internal audit: yes.[202] No external audit[211]

The material in this table is based on the references cited. Where a single reference is cited, all the information is from that source.

'Microscopically Verified'), which help identify units with poor data.[80] UK Transplant, for example, owing to using the National Transplant Register to allocate organs, is subject to quality assurance both centrally and locally. Mistakes in those data fields used for organ retrieval and matching are likely to be identified and acted on.

Similarly, databases that are used in comparative national audit may be expected to have local participating units scrutinise their data (e.g. ICNARC, UK Renal Register). The HFEA also conducts site visits to validate local information.

The national breast and cervical screening programmes have been the subject of a number of independent audits, some of which have revealed major problems.

Validation of the accuracy of coding is rare but not unknown, for example, with the HES diagnostic coding,[209] in relation to treatment details in some Cancer Registries[210] and to clinical diagnoses in GPRD compared with the Morbidity Survey of General Practice.[211]

Summary of validation of key databases

Table 17 summarises the extent of validation of key English databases which have been used in HT assessment.

Key points

- The extent to which variables are completed is poorly reported and varies between databases.
- The completeness of recruitment of units varies, being more complete for compulsory central returns but only partial for many voluntary clinical registers. The latter, however, sometimes include private sector units.
- The extent of recruitment of individuals within participating units is often difficult to assess as denominator data were generally lacking,
- Standard coding systems (i.e. ICD-10, OPCS4) tend to be widely used, but some clinical registers record additional detail in *ad hoc* coding systems, especially co-morbidity and disease severity.
- Validation of the accuracy of coding is uncommon.
- Internal checks are common, usually via computerised systems.
- Formal external validation is uncommon, whether by comparison with other databases or by external audit.
- Databases used in comparative audit have their data scrutinised by local participating units.

Chapter 9

Cost of key routine databases

No established methods exist for costing databases and only one previous attempt to cost NHS databases has been located. The report *Disease registers in England* by Newton and Garner,[21] which was published as the present report was being finalised, suggests that the minimum cost of maintaining a disease register is likely to be of the order of £30,000 per annum, based on employment of one whole-time worker. The aim of this chapter is to estimate the costs of those databases with greatest potential use in HT assessment, which means a focus on those discussed in Chapters 7 and 8.

Some, but by no means all, databases publish annual reports (such as ICNARC), which sometimes include data on the expenditure of the central organisation running the database (see notes on *Table 18*). Those few databases that are self-financing through providing a comparative audit service tend to have published expenditure data. The grants to those databases that are funded externally are sometimes reported by the funding organisation.

Even when an annual budget is reported, this may differ from the cost of the database for several reasons. Budgets usually refer to the central cost: more local costs are borne by participating units, which may be formally or informally funded. Particularly where compliance is mandatory, some of the costs of the database shift to local level. Costs at local level can be difficult to distinguish unless specified staff are dedicated to the tasks. Additional costs are likely to be incurred by analysis of the database, and may be considerable if non-standard analyses are required. Against this, considerable savings may be realised if databases are used to ensure that the appropriate patients are treated cost-effectively.

Some databases exist to meet multiple purposes. Separate identification of the costs of the database by function may not be possible. For example, the HFEA database is used to regulate clinics and meet possible future requests for information from children conceived with the aid of assisted reproduction, with research playing a minor role. Similarly, the National Transplant Register is used mainly to support transplantation by matching organs and donors, with assessment of HTs a subsidiary role. The HES database, which draws off the Patient Admission Systems in all NHS acute and psychiatric hospitals, fulfils a variety of roles which cannot be readily separated. The PPA database exists primarily to pay pharmacists for dispensing medicines, with monitoring and evaluation as by-products.

The annual running costs of databases must be separated from the initial costs associated with setting them up, including gaining collaboration, defining minimum datasets and purchasing equipment. Once installed and working, the annual costs of recording and storing data may be relatively small, depending on the extent of automatic data capture. Validation and follow-up of records may, however, require considerable resourcing. All these set-up costs would have to be taken into account in planning and resourcing new databases.*

Over time, technology can be expected to reduce dramatically the cost per record. Should the NHS information policy goals of person-based data, entered once, with ready electronic transfer, come to fruition, then the unit costs of records could fall sharply. However, few of the databases discussed here were, by 2000, anywhere near electronic transfer of data.

Although costs were often not available even for single-purpose databases, broad estimates can be made on the basis of the cost per record. This unit cost might be expected to vary between databases, being low for those with relatively sparse records (entered once, no or limited updating) and higher for those with more detail (follow-up, updating and validation). Cost per new record is appropriate for the former and average cost for all records for the latter.

Of at least equal interest to researchers is the cost of accessing these databases. Available data are reported below.

* The extent to which the few existing databases that are self-financing on the basis of charges take these capital costs into account is unclear.

Reported unit costs

Just over £20 per registration has been reported as the unit cost in the Cancer Registers[224] with regional variations reflecting degree of electronic data transfer and size.[80] The Renal Registry has proposed a unit cost of £10 per record.[194] The National Pacemaker Database has an estimated central cost of £6 per record.[147] The Scottish Hip Fracture Audit has estimated a cost of £60 per record, which includes detailed follow-up and validation by a nurse at each centre (Scottish Hip Fracture Audit Coordinator, personal communication, 2001). The Health Survey for England has an average cost per record of around £100,* based on household interviews which include some physical measurements by a nurse.

An upper limit can often be derived from the total cost of the organisation running the database. When the database is used for payment, the cost per record is unlikely to exceed the average level of payment. Thus the upper limit of the cost per record in the PPA database is set by its annual budget of just over £50 million and its average payment per prescription, which is less than £10.[225] With 500 million prescriptions processed each year, the average cost to the PPA must be less than £0.10 per record (£50 million divided by 500 million records per annum). A cost per record of £0.05 seems reasonable, given the sparseness of the PPA records, which are confined to drug, pharmacist and GP. This probably represents the extreme low end of the range. Relatively low cost per record might be expected to apply to other mainly administrative databases such as the HES. Since its cost is met by the Department of Health but not separately identified, no upper limit is available. With 10 million records per year, each of which is considerably more detailed than those of the PPA, its central cost per record might be around £1. A similar unit cost of £1 per record might apply to the immunisation and screening programmes.

For clinical registers, a unit cost of around £20 seems reasonable, with higher levels depending on the extent that central staff visit units and validate data. An upper limit might be around £60, based on the Scottish Hip Fracture Audit. Key factors affecting the unit cost plausibly include the complexity of the database, the extent of validation and the method of data collection.

A two-pronged approach has been adopted to costing those databases of interest. First, any available data on the total cost of each database are reported. Second, in the absence of such estimates, a best estimate unit cost per record has been used, depending on what is known about the purpose of the database, its relative richness or sparseness and the total budget of its host organisation. A default unit cost of £20 per record has been used for the clinical registers.

Results

Available information on the size and estimated cost of each of the prioritised databases is summarised in *Table 18*.

The total cost of databases in *Table 18* is estimated to be around £53 million. Within this the differences are very marked, with the PPA accounting for half of the total at around £25 million, due mainly to its very large size, even when costed at £0.05 per record. This is followed by the HES, which costed at £1.00 per record comes to around £10 million or 20% of the total. The other bigger cost items included Cancer Registers (£6 million or 11% of total) and GPRD (£3 million or 6%). Together these four databases accounted for 80% of the total estimated central cost of the databases in *Table 17*.†

The pattern of spending, concentrated on those clinical–administrative databases with relatively little potential for HT assessment, suggests a lack of any strategic focus for the development of databases for any purposes beyond their original role.

These estimates are both approximate and tentative but are provided to give some estimate of NHS spending on those databases with greatest potential for assessing HTs. Even if out by several orders of magnitude, the total of around £50 million is only one-thousandth part or 0.1% of the NHS annual total spend of around £50 billion.

* A personal communication from the Department of Health put the total cost of the HSE at around £2 million each year, depending on the level of detail. With around 20,000 people surveyed, this comes to around £100 per person.

† The cost of the four confidential enquiries has been estimated as follows: CEPOD £2.0 million, CESDI £1.84 million, CISH £0.74 million and CEMD £0.15 million, making a total of £4.73 million.

TABLE 18 *Routine databases in England: size and annual cost (actual or estimated), 2000*

Group	Database	Annual report	Size (centres, records or staffing)	Budget or estimated cost per annum
Ia	British Cardiovascular Intervention Society (BCIS) Database	No	61 centres, 25,000 procedures p.a.	Estimated £0.5 million (25,000 procedures at £20). No formal funding
	Human Fertilisation and Embryology Authority (HFEA) Database	Yes	117 licensed clinics, 36,000 IVF cycles, 26,000 patients p.a.	Estimated £0.52 million (26,000 at £20/record). HFEA budget £1.3 million
	Intensive Care National Audit and Research Centre (ICNARC)	Yes	60,000 records from 132 units. 40,000 records validated. 10,000 records p.a.	Budget of £0.32 million actual (implies £30/record)
	National Breast Implant Register	No	36,000 records in total. Approx. 3000 p.a.	Budget of £0.03 million from MDA (implies £10/new record)
	National Prospective Monitoring System (HIV)	No	5000 records ongoing	Estimated £0.1 million (5000 records at £20). *Ad hoc* funding
	National Pacemaker Database	Yes	25,000 implants p.a.	Budget £0.17 million from MDA (implies £6/record)
	National Transplant Database (UKTSSA)	Yes	5000 transplants p.a.	Estimate £0.1 million (5000 at £20/record). Total UKTSSA budget £3.9 million
	Northern Region Leukaemia Database	No	No data in inventory	Estimate £0.12 million (Guesstimate same as SNLG). Funding: unknown
	Scotland and Newcastle Lymphoma Register	No	13,000 records	Budget £0.13 million. Estimated £10/record. Funding: partly Scottish Executive
	Scottish Hip Fracture Audit	No	10,000 records total. £60/record	Estimate £0.6 million (10,000 at £60/record). Funding: Scottish Executive
	St Mary's Maternity Information System	No	10 units with ~3000 births p.a.	Estimate £0.06 million (3000 at £20/record). Funded by participating units
	UK Cardiac Surgical Register	Yes	25 out of 35 relevant units, 30,000 records p.a.	Estimate £0.3 million (30,000 at £10/record). No formal funding
	UK Cystic Fibrosis Database	No	6000–7000 records	Estimate £0.14 million (7000 at £20/record). No formal funding
	UK Haemophilia Centre Directors' database	Yes	11,000 patients from 92 out of 102 centres	Estimate £0.11 million (11,000 at £10/record). No formal funding
	UK Heart Valve Registry	No	5000–6000 p.a.	Budget £0.15 million from MDA (implies £25/record)
	UK Hydrocephalous Shunt Register	Yes	3000 p.a.	Budget £0.05 million from MDA (implies £17/record)

continued

TABLE 18 *Routine databases in England: size and annual cost (actual or estimated), 2000 (cont'd)*

Group	Database	Annual report	Size (centres, records or staffing)	Budget or estimated cost
	UK Thalassaemia Register	No	1000 records	Estimate £0.02 million (1000 at £20/record. Funded by Department of Health to 2000, when discontinued
Ib	Hospital Episode Statistics (HES)	Yes	10 million records p.a.	Estimate £10 million (10 million at £1/record). Funding: Department of Health
	General Practice Research Database (GPRD) (+ similar)	Yes	3 million patients	Estimate £3 million (3 million at £1/record). Funding: MCA
	National/Regional Cancer Registries (including Leukaemia Registers)	No	280,000 new cases p.a.	Official estimate £6.5 million (or £23 per record). Funding: NHS
Ic	Breast Screening Programme	Yes	1.6 million invited, 1.3 tested (75%) p.a.	Estimate £1.6 million based on £1/record
	Cervical Screening Programme	Yes	3.9 million invited, 3.8 million tested p.a.	Estimate £3.9 million based on £1/record
	Immunisation/vaccination	Yes	1.2 million (0.6 million aged 2 and 0.6 million aged 5) p.a.	Estimate £1.2 million at £1/record
	Influenza vaccination	No	10 million aged >65 annually	Estimate cost £10 million at £1/record
II	Prescription Cost Analysis (PPA)	Yes	500 million records p.a.	Estimate £25 million (500 million at £0.05 per record). PPA budget ~£50 million
	Health surveys: Health Survey for England (HSE)	Yes	Annual national household survey, ~20,000 people p.a.	Budget £2 million (implies £100/record). Funding: Department of Health
	Total			Over £60 million

Even fewer data were available on the costs to researchers of accessing the databases, linked in part to the lack of clarity over who had rights of access. Most clinical registers when questioned suggested that researchers should write to the 'keepers' of the database requesting access and that the costs would be related to the costs incurred. The rules were clearer for clinical–administrative databases, for which a GPRD was the most explicit and expensive with different levels of access starting at around £25,000 per annum. Access to HES and Cancer Registers was by special request, with no prices quoted. At the other extreme, the HSE makes an anonymised but otherwise complete database of its person-specific records available to bone fide researchers for £200.

Key points

- The cost of a database depends on the detail, the level of follow-up and validation of records, in addition to size.
- Many databases have multiple functions, which cannot be readily separated for costing.
- The total central cost of databases in *Table 18* has been estimated at just over £50 million or around 0.1% of the NHS annual spend.
- Large variations exist in the annual estimated cost of each database, with the top four, made up of clinical–administrative databases, accounting for over 80% of total cost (PPA, HES, Cancer Registers, GPRD).
- The bulk of the estimated costs attributed to the large administrative central returns, particularly

the PPA (50%) and HES (20%), applied despite the use of very low cost per record estimates (£0.05 and £1.00, respectively).
- Most clinical registers claim very low cost per record, which may be due partly to uncosted inputs, particularly at local level.
- Many clinical registers receive no formal funding from the Department of Health or the NHS.
- The cost per record is higher when clinical registers are used for comparative audit, particularly when data receive some form of follow-up and validation.
- The pattern of spending on databases seems more driven by history than any strategy or policy of the NHS.
- Few databases produce annual reports, and those which are provided tend to be inaccessible, although web publication is improving matters.
- The cost to researchers of accessing most of these databases is not clear.

Chapter 10

Discussion and conclusions

Healthcare systems, despite requiring information on whether they provide the right interventions well and fairly to the right people, tend to have poor information systems. HT assessment is a central component of such healthcare evaluation but, without substantial investment in information systems, HT assessment will remain the preserve of research rather than policy.

HT assessment has a voracious appetite for high-quality, detailed and responsive routine data. This report takes HT assessment to include the investigation of (i) effectiveness, (ii) diffusion and equity and (iii) cost – all as applied to the range of HTs including pharmaceuticals, devices, procedures and settings. It identifies the key characteristics of routine data as regular collection, standard definitions and collection at least at a regional level, and often some mandatory element.

Routine databases have great potential in HT assessment. Routine data are already used extensively in RCTs (and in non-randomised trials), providing outcome data (such as mortality and hospitalisations) and cost estimates, and for characterising the representativeness of trial patients. For rare and/or delayed events, especially adverse events, RCTs cannot provide the answer. Finally, whereas trials measure efficacy, effectiveness requires monitoring HTs as they are actually used in practice.

For diffusion and equity assessments, routine data are essential both in tracking the introduction and withdrawal of HTs and in ensuring that efficacious HTs are provided appropriately, based on clinical need. Costing relies heavily on routine data, both for unit costs and often for resource use.

However, major problems exist. Strategic development and investment in routine databases for HT assessment are lacking. Coding systems are neither responsive to new HTs nor sufficiently specific for many existing technologies. Translating the mass of clinical data recorded in everyday clinical consultations into robust, valid data for HT assessment is a formidable task. A key element in ensuring that routine databases become robust has to do with their forming the basis of clinical practice. The degree to which routine data will realise its potential role in HT assessment depends on the extent to which these problems are solved.

Classifying routine data

This report has identified the characteristics that routine databases require if they are to be of value in assessing HTs. At a minimum the database must identify a specific, well-defined HT. For the purpose of assessing effectiveness, routine data need to produce much the same information as RCTs. This includes specification of the HT and of patients' health states before and after the intervention, in addition to confounding factors. The assessment of equity and diffusion requires information on the HT by time, age, sex, ethnicity, socio-economic group, disease severity and geography for those treated. Equity assessment may also require data on those not treated. For the assessment of costs, data need to identify the HTs and their unit costs or prices.

For HT assessment of effectiveness, diffusion and equity, we have classified routine data into three broad groups:

- group I datasets, which identify both HTs and health states
- group II datasets, which identify the HT, but not a health state
- group III datasets, which identify health states, but not an HT.

Clearly, datasets in group I are the most promising, although there are occasional potential uses for groups II and III at population level enquiries, and in adjunctive roles. Group I datasets can be further disaggregated into (a) clinical registries, (b) clinical–administrative datasets and (c) population-oriented datasets. Group III can be disaggregated into (a) adverse event reporting and confidential enquiries, (b) disease-only registers and (c) health surveys. Group I datasets can be used not only to assess effectiveness but also to assess diffusion and equity. By contrast, databases in group II (HT only) can only help assess diffusion. Those in group III (patient health-

related characteristics only) have restricted scope for assessing HTs, except for analysis of adverse events. For use in costing, databases need to include unit costs or prices,* a dimension which does not usually overlap with those needed for assessing effectiveness, equity or diffusion.

Identification of an HT is a prerequisite for any database to play a role in any kind of HT assessment, including costing.

The nature of existing databases

About 270 databases were identified at the level of UK, England and Wales or England (over 1000 if including Scotland, Wales and Northern Ireland specific databases).

Of these, just over 60 databases might be considered to have some potential for HT assessment. About half of these contain some data on both HT and patient characteristics (group I). The other half contain data on either HT (group II) or patient health (group III), but not both. Within group I, 18 clinical registers (group Ia) were identified as having the greatest potential, although the clinical–administrative datasets (group Ib) had some potential across a wide range of technologies.

Most group I databases are limited to narrowly defined, well-established technologies. Excluded are all diagnostic and imaging, many medical interventions (other than GP prescribing and hospital surgical interventions) and area-wide interventions, and nearly all interventions by non-medical staff. New HTs are poorly represented. Relevant clinical outcomes (let alone patients' quality of life) are seldom captured in these databases.†

The most promising databases, the clinical registers (group Ia), have usually been developed voluntarily by individual clinician 'champions' and/or by the relevant clinical organisations. However, these datasets are often limited in time and space. The focus of around half of all clinical registers on particular HTs prohibits comparisons between HTs, except for those included in the database. Even the most detailed clinical registers have limited data on patients' characteristics, which inhibits comparisons of effectiveness. Although comparative audit is driving some clinical registers towards risk adjustment models, these are necessarily limited to known confounders. Even the best registers are therefore open to bias. Furthermore, access is usually restricted to participating clinicians. Many registries have uncertain funding, although some are funded by the Department of Health or its agencies such as the Medical Devices Agency or Medicines Control Agency.

The large (group Ib) clinical–administrative datasets such as the HES differ from clinical registers in having a broader coverage (of technologies, settings and patients treated), but at the expense of detail. The HES and the PPA Prescription Cost Analysis cover a wide range of HTs in hospital and community, respectively. More detailed data on the patients' conditions, already available in GPRD and similar datasets, seem likely to become more widely available as general practices become computerised.

Usability, use and validity of existing data

A review of the potential capture of some 160 HTs identified as priority topics by the UK's NHS R&D HTA programme (itself based on a major consultation exercise of priorities) showed that only around 10% of these technologies would be captured in any existing routine database. The bulk of these were drugs prescribed in primary care, which are captured by the PPA. These can only be linked to specific disorders by special enquiries using one of the more detailed GP data systems (such as GPRD, DIN-LINK, MEMO and Mediplus). A few surgical procedures were identified, but limited by the procedural coding system, which would generally code them as 'not otherwise classified'. Surprisingly few prioritised HTs were captured in the relevant HT-based clinical registers. Even when they could be identified in any routine database, data were generally lacking on the relevant characteristics to assess effectiveness or equity. Some technology types – hospital prescribing, diagnostic and

* Databases may be useful in costing to the extent that they contain resource use data, which can be multiplied by unit costs or prices from elsewhere. However, as most databases contain some, often incomplete, data on resource use, inclusion of this criterion would not differentiate between databases. An indication of the extent to which each database contains relevant resource use data can be assessed from the list of variables included for each in the inventory.

† The few databases that have been used for HTA have had the relevant outcomes such as normal births (HFEA) or graft survival (UKTSSA), but these are the exceptions.

imaging, screening, medical procedures, interventions based on the type of professional/patient interaction, interventions by professions allied to medicine, new roles for non-doctors and delivery in non-hospital settings and processes of care – were not captured in any database. In short, routine databases in England have a very limited role in assessing those HTs that have been prioritised by the NHS HTA programme.

The literature on the use of routine data in HT assessment does, however, show some haphazard examples of practical use. Clinical registers are being used for national comparative audit. Some databases have only been used in annual reports (by the data collection team) for the purpose of informing relevant professional organisations of their existence. A small number of published papers have assessed the effectiveness of a technology using a clinical register. Most of these assessments concerned HTs with relatively simple outcomes (IVF and conceptions or graft failure in organ transplants). The authorship of such studies suggests that accessibility is limited to those who 'own' them. Clinical administrative databases have played very little part in assessing effectiveness except as adjuncts to trial evaluations. The HES data have, however, been used to build population needs indices and performance indicators. But even well-defined HTs which are hospital based have required surveys to establish levels of provision (ICU and stroke units, CT and MRI scanners).

A review of the validity of databases that have been used in some form of HT assessment showed that although internal consistency checks were common, relatively few databases had any form of external audit. Some databases used in comparative audit have their data scrutinised by local participating units and some service-oriented databases have assurance programmes that incorporate internal and external checks. Issues around coverage and coding have, in general, received little attention. Although NHS coverage is complete for compulsory central returns, it tends to be only partial for voluntary clinical registers, which, however, sometimes include some private sector units. The extent of recruitment of individuals within participating units in clinical registries is often difficult to assess as denominator data are generally lacking. Standard coding systems (i.e. ICD-10, OPCS4) are widely used, but some clinical registries record additional detail in *ad hoc* coding systems, especially co-morbidity and disease severity. Validation of the accuracy of coding is uncommon.

Costs of the databases

Many databases have multiple functions, which cannot be readily separated for costing, but a review of the cost of those databases with greatest potential in HT assessment provides cost estimates. The cost of a database depends on the detail, the level of follow-up and validation of records, in addition to size. There was no evidence of any strategy for funding databases for use in assessing HTs. NHS policy for funding databases has focused mainly on central returns, narrowly defined as those that are mandatory for management purposes. Most databases with greatest potential for HT assessment fall outside this brief. They receive funding from a variety of sources, including the MCA and the MDA, but some are unfunded, relying instead on clinicians' interest and goodwill. A few routine databases which have limited potential for HT assessment account for the bulk of the spending. The estimated total cost of databases in group I plus selected databases from groups II and III has been estimated at £50 million or around 0.1% of the annual NHS spend.

Discussion

To optimise its performance, any healthcare system requires valid and reliable routine data. Routine data have a crucial role given the large and growing number of HTs whose effectiveness and costs require to be monitored. Moreover, routine data can assess the diffusion and equity of delivery of efficacious technologies in addition to the withdrawal of less efficacious ones.

The findings of this report warn against any naïve optimism that routine data systems will in the foreseeable future be capable of meeting these requirements for HT assessment. These barriers apply particularly to assessing effectiveness, with few databases matching the required criteria. Institutional arrangements for progress are generally lacking. No overall strategy exists for healthcare databases. NHS policy has been concerned almost exclusively with administrative returns, narrowly defined. Concerns over confidentiality and consent are working to reduce access and perhaps to restrict the scope of clinical databases. Coding systems are too non-specific and slow to respond to the introduction of new technologies.

Against this, the continuing advances in IT and the policy requirements for improved data will

lead to fundamental changes. The demands of new initiatives such as Clinical Indicators and National Service Frameworks require data of the sort that only the clinical registers currently hold. Over time, more routine databases will meet the standards of the clinical registers.

On the basis of our work on this report, we offer proposals aimed at facilitating the use of routine data for HT assessment.

Proposals

We offer two sets of proposals, one to policy makers, the other to those concerned with research and development.

Proposals for policy makers

The evidence we have compiled suggests that the following issues could usefully be addressed:

- Clarification of responsibility for the strategic development of routine databases, especially clinical registers. The NHS Information Board may play an important role in this, but had not done so by 2001. All routine databases supported in any way by the NHS should be obliged to produce an annual report.
- The resourcing of all databases needs to be reviewed in relation to their potential value and use. Those responsible for strategic development should identify priorities and invite bids to meet those priorities, along the lines of NCCHTA-funded research.
- Facilitating the optimal use of IT. IT can enable different databases to be linked to provide patient profiles. It can also help validate data. Differential access to data can be established for clinicians, patients, researchers and policy makers.
- Priorities for strategic development should include developing databases which identify new important HTs as they begin to diffuse. The emerging databases on hip prostheses and coronary artery stents are examples.
- Coding systems require development and continuous updating. Existing coding systems such as ICD, OPCS and BNF are always somewhat out of date, and often too non-specific. Coding systems need to classify the range of new technologies when they are launched (or earlier when first 'horizon scanned'). Having different organisations responsible for different coding systems risks lack of coordination. The NHS Information Authority (NHSIA) should be responsible for maintaining and updating all relevant coding systems.
- Fears over the confidentiality of healthcare data must be allayed. The balance between the benefits of using such data for research and the risks of abuse needs to be continually assessed. The degree to which this role will be met by the new Patient Information Advisory Group, established under the 2001 Health and Social Care Act, remains to be established.
- Ownership of and access to databases require clarification. The proposed National Confidentiality and Security Advisory Body may have an important role to play.
- Clinical support in the development of routine databases is necessary. Increased use of databases in comparative audit offers a way forward, provided that the data are validated. The optimal use of clinical registers in comparative audit requires research and monitoring.
- The systematic gaps in routine data collection need to be addressed, notably ambulatory care, hospital prescribing and diagnostics and imaging. Regular inventories of structural interventions are needed.
- The major deficiencies (linkage, extension, access) of the most important clinical–administrative datasets, particularly HES, GPRD and PPA, require remedial action.

Proposals for development and research recommendations

The evidence we have compiled suggests that the following research issues could usefully be addressed:

- Widening the brief of those commissioning R&D to include routine data and information more generally. The R&D strategy needs to have an information strategy, not least to assess its own effectiveness. A closer alignment between R&D and the NHS Information Policy Board and the NHSIA is required.
- Research is required on how best to code and capture types of HT which have received little attention, including equipment, area-wide and diffuse technologies. Links between those responsible for HT assessment and the NHS Information Policy Board and the NHSIA should be established.
- Research is also required on international comparisons of the role, funding and use of routine data in healthcare systems.
- Information strategies such as those being developed around the National Service Frameworks and various collaborations should be coordinated and independently evaluated and monitored.

- The use of clinical registers in comparative audit should be evaluated.
- EPRs and EHRs require not only research but also development if they are to realise their great scope. The barriers to their wider use require attention, including clinician support, resourcing and training of coding clerks, in addition to templates for data entry, storage and retrieval.
- NHS R&D, when commissioning trials, should require comparison between any relevant routine data and customised data, along the lines of the West of Scotland Coronary Prevention Study Group (WOSCOPS) example.[29,226,227] Trials might be funded to undertake parallel research using routine data with a view to defining both deficiencies and the potential of the latter in specific case studies.
- The methods used in HTA require research. Modelling of effectiveness and costs, which is becoming widespread, notably in submissions to NICE but also in NHS-commissioned research, requires methodological research. Extension of the HTA brief, as suggested here to include diffusion and equity, prompts questions about the most appropriate research methods.
- Selective investment by NHS R&D in particular databases should be considered, linked to their potential use in assessing effectiveness (particularly comparative audit), diffusion and equity.

Many of these issues relate to improved coordination between the various NHS R&D programmes. Some of the topics might be more appropriately part of the brief of other programmes such as Service Delivery and Organisation. The priority for the HTA programme, we suggest, should be that of requiring randomised trials to include comparison between any relevant routine data and customised data.

Annex 1

Brief guide to the HFEA database and its use

This annex provides a brief guide to the content of one of the databases which not only has most potential for assessing HTs, but has been so used. The HFEA database, as discussed on p. 97, was established by the 1990 Human Fertilisation and Embryology Act, and is concerned with the regulation of infertility treatments involving donor insemination and IVF and human embryo research. The data collected include both donors and patients, the uses to which all embryos are put and personal details of donors in case babies born of successful treatment wish to trace their biological origins. Details of consent and storage are also specified in considerable detail. Given the importance of the topic and the statutory basis of the data collection, this database has been designed to particularly high standards.

Eight forms are required to be completed in all of the licensed clinics:

1. Patient and Partner Registration Form, which has personal and medical data on both patient and partner and also the donor. Personal details include names, ages and places of birth. Medical fields cover previous obstetric history by type of treatment [IVF or donor insemination (DI)], previous pregnancies and live births. Causes of infertility are classified.
2. The Treatment and Embryo Creation and Use Form has data for each centre on the source of both sperm and eggs, when collected and intended use. Details of the treatments include the number of eggs and embryos (fresh and frozen) used and those donated. For frozen embryos, the number found viable is recorded in addition to transfers of embryos to other centres.
3. Donor Insemination/Donor Gamete Treatment Form. This contains data on these particular forms of treatment, including by centre, the person provisioned sperm, the type of ovulation stimulation and the outcome by the relevant types of pregnancy, if any.
4. Pregnancy Outcome Form. This more general form covers outcomes from both IVF and DI, with data recorded for each fetal heart (gestation weeks, miscarriage, termination, still or live birth, neonatal death). For each baby born, method of delivery, weight, sex and any congenital abnormalities are recorded, along with place and date.
5. The Donor Information Form collects detailed personal data on donors in case children born due to treatment may wish to trace their biological sources. In addition to name, age, address and history, details include ethnic group, eye and hair colour and a self-completed 'description of yourself as a person'.
6. The Embryo Storage or Research Form has administrative data on fertilisation (clinic, date and number of eggs mixed with sperm), along with the number of embryos used in either research or treatment, including those discarded.
7. Form for Consent to Storage and Use of Sperm and Embryos. This form collects data on the consent given by sperm donors in relation to the use of both sperm and resultant embryos, including duration of storage and use should the consentee die, along with any other conditions.
8. Form for Consent to Use Eggs and Storage of Embryos. This form is almost identical to that in 7 but applies only to eggs and embryos.

Use of HFEA data in assessment of IVF

Although the above data were designed and collected for the HFEA to meet its statutory obligations, the details collected on each patient's treatment(s) including outcomes (gestation, birth) are such that the factors associated with successful outcomes could be researched. Although access to the HFEA data is highly restricted, with only those on the Board of the HFEA having access, an obstetrician on the Board, Professor Templeton, was able to carry out such an analysis.[22] The main outcome measure was livebirth rate per cycle of IVF treatment started. Cycles that involved gamete or embryo donation, frozen embryo transfer or micromanipulation were excluded. The time period was August 1991 to April 1994. The results showed the overall live birthrate per cycle of treatment was 13.9%. The factors associated with successful outcomes were identified as age, use of donor rather than own eggs, duration of infertility, previous pregnancy and livebirth.

The results of this analysis were used to help draw up guidelines for IVF by the Royal College of Obstetricians and Gynaecologists.[23]

Annex 2

Scotland: description of routine data sources in healthcare with particular attention to differences from England

NHS data sources

NHS Scotland collects largely the same data as elsewhere in the UK, but its processing of those data differs in several respects. The following are some examples of these differences:

- The Community Health Index (CHI) is a computerised patient number used mainly for GP registration from the late 1980s.[67] The CHI number is now unique for all Scottish residents registered with a GP or receiving screening services and is being rolled out as the national unique patient reference number.
- Continuous Morbidity Recording (CMR) is a data collection scheme from GPASS software (which is used in ~80% of all Scottish practices). Over 80 practices (7% of all practices) participate in CMR data collection to return a sample that is representative nationally in terms of age, sex and deprivation. These data form part of the national dataset and are quality assured.[228]
- The Scottish Record Linkage (SRL) system links together all records belonging to the same individual. There are currently two linked datasets maintained by the Information and Statistics Division (ISD): the first holds 20 years (1981–2000) of acute hospital discharge records together with psychiatric admissions and discharges, Scottish Cancer Registry records and Registrar General's death records. The second dataset holds linked maternity, neonatal, stillbirth and infant death records for 1980–99, with all records pertaining to a mother and relevant births held together.

The ISD of the Common Services Agency (part of NHS Scotland) is responsible for the majority of Scottish health statistics. This responsibility extends over a bigger list of datasets than in England, with specific examples including Scottish Cardiac Surgery (SMR20), Continuous Morbidity Recording in General Practice (CMR), Nurse Data collection which together with CMR is known as Practice Team Information (PTI), Scottish Care Resource Utilisation Groups (SCRUGS), Scottish Health Resource Utilisation Groups (SHRUGS) and New Referrals to the Prosthetic Services in Scotland (SMR44). Although equivalents of most of these exist in England, few are part of the Department of Health/NHS, and they tend to be much less developed.

National comparative audits have a longer history in Scotland, with four currently managed by the ISD in 2002: the Scottish Renal Registry, the Scottish Audit of Surgical Mortality, the Scottish Hip Fracture Audit and the Scottish Trauma Audit Group (STAG). Close links with the Scottish Morbidity Records datasets (SMRs, the Scottish equivalent of England's HES) have led to validation and integration of these data with those from the audits.

The ISD publishes more cost data for NHS Scotland than are available in England.*

An example of the Scottish approach is provided by the Coronary Heart Disease/Stroke Task Force Report, the recommendations of which are planned to lead to a single database via integration of the following: new primary care-based database with electronic links to secondary (and tertiary) care; Scottish Cardiac Surgery Database; Scottish Coronary Angioplasty Database; Scottish Coronary Angiography Database; hospital SMR1 dataset and elements of the SMR20 dataset plus the proposed database for cardiac rehabilitation.

As the effects of devolution and the role of the Scottish Executive grow, healthcare statistics for Scotland can be expected to diverge further from those in England; at the same time, it is recognised that there may also be increasing requirements for the harmonisation of statistics that will allow the production of UK-level (and

* See http://www.show.scot.nhs.uk/isd/Scottish_Health_Statistics/SHS2000/home.htm

UK-comparable) figures. For instance, the ISD is exploring the scope for clinically enhanced SMRs to include data on case mix, disease severity and process indicators for stroke, myocardial infarction and vascular surgery.

Validation

The following initiatives are of note:

- The CHI has been shown[229] to be 85% sensitive regarding population estimates, compared with 90% for electoral registers, and used to construct diabetes registers (better coverage than using hospital records).
- CMR data quality is 91% for both completeness and accuracy of Read coding.
- SRL has been validated[29] as part of the WOSCOPS trial, a large prospective trial of pravastatin. This showed that SRL was as effective as reporting based on direct patient contact, including mortality, hospitalisations and cardiac surgical procedures. Use of routine data was judged superior in some ways (coverage of non-responders and dropouts) and considerably less costly. A number of other validations have been carried out (more accurate cancer registrations, etc.).

Uses of Scottish data for health technology assessment

- Clinical indicators (including 30-day mortality and 28-day hospital readmission rates) have been routinely provided since the early 1990s.
- A diabetes register (DARTS)[230] created in Tayside based on record linkage (CHI, prescriptions, hospitalisations) is seen as the 'gold standard' for such registers.
- Coronary heart disease: SMR1,[231] Scotland's equivalent of HES, has been used to explore variations in investigation and treatment of patients with coronary heart disease. A study using record linkage showed that variations in investigation and management were demonstrated by age, sex, geography and socio-economic deprivation.
- Cancer: the Scottish Cancer Register[232] has been used to explore the impact of specialist surgeons on survival outcome in breast cancer,[233,234] ovarian cancer,[235] and malignant teratoma.[236]
- Service use and costs by proximity to death are the topic of a project supported by the ISD and the Chief Scientist Office of the Scottish Executive's Health Department.

Scotland and clinically rich databases

Partly owing to the above developments, Scotland has tended to develop its own clinically rich databases, independently and often before those in England. Apart from having its own clinical registers in renal disease, trauma audit, surgery and hip fractures, it is also part of a number of UK-wide registers, including the six cardiac registries.

Summary

Although Scotland has historically collected data on healthcare that are largely similar to those recorded in the rest of the UK, it has led in facilitating linkage between datasets, in validation, in widening the range of datasets included under official national statistics and in promoting their use in clinical audit.

Annex 3

Long list of NHS routine databases/Central Returns, England, 2000

Table 19 provides a long list of NHS and other routine databases, based on the annual NHS Report on Central Returns, supplemented by those other databases identified by the authors.

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999*[a]

Title	Department of Health code
Abortion Statistics England and Wales	
Acute Hospital Patient Centred and Clinical Information Systems Survey	
Adult Dental Health Survey	
Adult Screening Programme: Breast Cancer (Health Authority)	KC63
Adult Screening Programme: Breast Screening (Screening Unit)	KC62
Adult Screening Programmes: Cervical Cytology	KC53
Adverse Drug Events: Medicines Control Agency	
Adverse Event Reporting: Medical Devices Agency	
Ambulance Response Times: ERO Return	
Ambulance Services	TFR6
Ambulance Services: Quality of Service Return	KA34
Ambulance Services: Quality of Service Return	KA34 (New)
Analysis of Cash Limited Expenditure	FIS(FHS)4CI
Analysis of Creditors	CTF14
Analysis of Debtors	CTF13
Analysis of Expenditure by Type	HFR 25
Analysis of Expenditure by Type	TFR3
Analysis of Fixed Asset Investment	CTF12
Analysis of GP Fundholding and PFMA	FIS(FHS)4DI
Analysis of Losses and Special Payments	HAA 30
Analysis of Overall Income and Expenditure Position	H05
Analysis of Total Resource Expended	CTFO8
Annual HCHS Medical and Dental Workforce Census	SBH 50-56
Anticipated Borrowing Requirements	TF1
Appropriation Account Chargings	HRP OI
Assessment of Consultants' Performance	MCP5OO
Assessment of Contractors' Performance GOS Losses and Recoveries	MCP6OO
Assistants in Post with the HAs	CEN2
Availability of Dentistry: Quarterly Monitoring Report	A6

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
Average Cleared Balances	FIS(HA)9
Balance Sheet (3 different entries)	CTFO3, T2, TAC02
Bed Availability and Occupancy: Intensive Care and High	KHO3A
Birth and Death Database	
Blind or Partially Sighted Register	
Breast Screening Programme	
British Cardiovascular Intervention Society Database	
British Household Panel Study	
Care Group Analysis of Health Services Purchased	HFR 24
Cash Flow Statement	TAC 03
Cash Limit Reconciliation (end year reckoning)	FIS(HA)1 1
Census of Population	
Census Samples of Anonymised Records	
Central Cardiac Audit Database	
Cervical Screening Programme	KC53
Changes and Resources Available for Charity Use	CTF09
Childhood Cancer Research Group	
Chromosome Abnormality Register	
Cleft Lip and Palate Registry	
Clinical Negligence – Existing Liabilities Scheme (ELS) Actual/Expected	
Collection of Health Data from GP (Nottingham)	
Communicable Diseases Register	
Community and Continuing Care	CIC – Table 9
Community Dental Health Services	KC64
Confidential Enquiry into Maternal Deaths	
Confidential Enquiry into Post-Operative Deaths (CEPOD)	
Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI)	
Confidential Enquiry into Suicides and Homicides Associated with Mental Illness	
Congenital Malformation Registries: by region	
Consultant Outpatient Clinic Activity and Accident and Emergency Services Activity	KHO9
Consultant Outpatient First Attendances (Provider Based)	QMO8
Consultant Outpatient First Attendances (Relevant Population Based)	QMO8R
Contingencies and Commitments	CTF18
Contract Monitoring Following Tender	MCP3OO
Contract Tender Reporting	MCP2OO A and B
Cost Improvement Programmes	T5
Cystic Fibrosis Database	
Deaf or Hard of Hearing Register	
Demand for Elective Admission: Events Occurring During the Quarter (Provider Based)	KH06

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
Demand for Elective Admission: Events Occurring During the Quarter (Relevant Population Based)	KHO6R
Demand for Elective Admission: Number of People Who Have Deferred Admission Waiting at the End of the Quarter (Provider Based)	KHO7A
Demand for Elective Admission: Number of People Who Have Deferred Admission Waiting at the End of the Year (Relevant Population Based)	KH07AR
Demand for Elective Admission: Position at the End of the Quarter	
Dental Screening Programme	
Department of Health Initiative Schemes	HFR 17
Dependency Provision Summary of Ward Attenders	KHO5
Details of Resources Expended – Grants Payable	CT06
Details of Resources Expended – Other	CTFO7
Diagnostic Departments: Radiology, Nuclear Medicine and Medical Physics	KH12
Drugs Misuse Databases (national and regional)	
Earnings Survey	
East Anglia Cancer Register	
East Anglian Congenital Malformation Register	
EFL Statement	T3
EHS Complaints	K04I(B)
Emergency Dental	EDS1
Emergency Dental Services	EDS1
English Hip Fracture Prosthesis	
Estate Quality Estate Energy Estate Stock Forms Notifying Capital Scheme Approval	FB1–FB4
EU Requirement for Information on Public Purchasing	
European Congenital Heart Defect Database	
Family Resource Survey	
Finance Staffing Database	FDUO1
Financial and Workforce Information Return	FWIR
Fourth National Survey of Ethnic Minorities 1993–94	
Fundholding Residual	
General Dental Services	FIS(FHS)2
General Household Survey (GHS)	
General Ophthalmic Services	FIS(FHS)3
General Ophthalmic Services – Sight Tests Vouchers and Repairs and Replacements	SBE515
General Ophthalmic Services: Annual Return of Practitioners and Scottish Nominal Premises Roll	HA 48(1)
General Practice Research Database (GPRD)	
Genito-urinary Medicine Clinic Returns	
Glasgow Register of Congenital Anomalies	
GMP Calculation of Superannuable Remuneration	SUR 1
GMS – Cash Limited Expenditure	HFR 11–11a

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
GMS – Monthly Summary of Non-cash Limited Expenditure	FIS(FHS)4A
GMS – Quarterly	
GMS Non-cash Limited Expenditure	HFR 12A–C
GP Fundholders: Budget and Expenditure, Underspend and Overspend, Expenditure from Savings	PC1 01–06
GP Fundholder Savings Analysis of Expenditure on 'Other Items'	HFR 18
GP Morbidity Database	
GP Registrars in Post with the HAs	CEN1
HCHS Complaints	K041(A)
HCHS Expenditure by Activity Category	H08 – Table 10
HCHS Non-Medical Workforce Census	
Health Authority Refunds	FIS(HA)5
Health Survey for England	
Hospital Episode Statistics	HES
HSC Report: Activity (Hospital and Community) Returns	
HSC Report: Estates Returns	
HSC Report: Finance (2 separate returns)	
HSC Report: Miscellaneous Returns	
HSC Report: Patient's Charter Returns	
HSC Report: Workforce Returns	
Human Fertilisation and Embryology Authority Database	
I & E Account 3 Year Plans	TIB
I & E Account Memorandum Items	T1A
Immunisation Programmes: Health Authority Activity	KC5O
Income and Expenditure Account	T1
Infant Feeding Survey	
Influenza vaccination returns	
Informed Patients and Patients Detained Under the Mental Health Act: the Number of Uses of the Act	KP90
Intensive Care National Audit and Research Centre (ICNARC)	
Joint Finance	HFR 20
Junior Doctors' Hours	
Learning Disabilities	CIC – Table 3
Leukaemia Register Mersey & Clwyd	
Leukaemia Register Oxford	
Loan Repayment Notification	TF3
Longitudinal study (ONS)	
Losses and Special Payments (2 separate returns)	TAC 28, TAC 29
Losses and Special Payments	TAC 29
Maternity	CIC – Table 4

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
Medical Devices Agency Adverse Event Reporting	
Memorandum Items	H06
Mental Health	CIC – Table 5
Mersey & Cheshire Cancer Register	
Mersey & Clwyd Leukaemia	
Mersey Congenital Malformation Register	
Miscellaneous and Reserves	H07
Monitoring of Delayed Discharges	CCMON
Monthly Comparison of Outturn with Cash Limits	FIS(HA)I
Monthly Waiting Times and Activity	
Morbidity Survey of General Practice	
National Breast Implant Register	
National Cancer Register	
National Child Development Survey (NCDS)	
National Congenital Abnormality System	
National Congenital Malformation Register	
National Database of Reference Costs	
National Diet and Nutrition Surveys	
National Down Syndrome Database	
National Pacemaker Database	
National Prospective Monitoring System for HIV	
National Reference Costs (England)	
National Registry for Childhood Tumours	
National Survey of NHS Patients	
National Transplant Register (UKTSSA)	
National Vascular Surgical Audit Database	
Newly Reported HIV Infected Persons (in Year)	A(C)A2
Newly Reported HW Infected Persons (Cumulative)	A(C)A3
NHS Contraception Returns	KT31
NHS Day Care: Availability and Use of Facilities	KHI4
NHS Debtors and Creditors – Reconciliation (5 separate entries)	TAC 21, 22, 23, 24, 25
NHS Pharmaceutical Services – PHS1	PHS1
NHSCR/Births & Deaths Database	
North & Yorkshire Cancer Register	
North West Cancer Register	
Northern Region Congenital Malformation Register	
Northern Region Leukaemia Database	
Northern Region Young Persons Malignant Disease Register	

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
Northern Region Young Persons Register	
Notes to Accounts (2 separate entries)	HAA 22–29, TAC 05-20
Overall Income and Expenditure (I & E)	HoI
Overall Income and Expenditure (Alternate)	H 11
Oxford Cancer Register	
Oxford Congenital Malformation Register	
Oxford Leukaemia	
Pathology Laboratories: Cervical Cytology and Biopsies	KC61
Patient Care in the Community: Community Learning Disability Nursing	KC58
Patient Care in the Community: Community Psychiatric Nursing	KC57
Patient Care in the Community: District Nursing	KC56
Patient Care in the Community: Specialist Care Nursing	KC59
Patient's Charter Key Standards Covering – Emergency Admissions through A&E; Waiting in Outpatient Clinics; Cancelled Operations and Transfer of Medical Records	QMPC
Patient's Charter Standard – Single Sex Hospital Accommodation	SSA1
PCG Income and Expenditure Analyses	H02
PDC Application	TF2
Pharmaceutical Services	FIS(FHS)1
Physically Handicapped Register	
Prescription Pricing Authority Prescription Cost Analysis	
Private Hospitals, Homes & Clinics	KO36
Private Hospitals, Homes and Clinics Registered Under Section 23 of the Registered Homes Act 1984	RH(N)
Professional Advice and Support Programmes: Maternity Services	KC54
Professional Advice and Support Programmes: Other than Maternity	
Promoting Independence	CIC – Table 8
Provisional Resident Based Monthly Fast-Track Return: NYRO Return	MFO1
Psychiatric Morbidity Survey	
Public Health Common Dataset	
Public Health Mortality File	
Public Sector Payment Policy Performance	T6
Quarterly Manpower Return	QMX6
Questionnaire on Practice Staff	ANC4
Radiology and Nuclear Medicine Returns	
Regional Drug Misuse	
Regional Drug Misuse Return	
Registration and Inspection of Private Nursing Homes	HFR 29
Relevant Population Based Waiting List Return	QFO1
Reported AIDS Cases and Deaths	A(C)A1

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
Requisition for PGO Funding	FIS(HA)3
Return on Severance Payments	
Salaried Doctors Employed Under Salaried Doctors Scheme	CEN4
Scheme Monitoring Following Approval	MCPIOO
Scottish Hip Fracture Audit	
Scottish & Newcastle Lymphoma Database	
Scottish Renal Register	
Source of Funds	H03
South & West Cancer Register	
Speciality and Programme Costs Return	HFR 22
Speciality and Programme Costs Returns	TFR2
St Mary's Maternity Information System	
Statement of Financial Activities	CTFO1
Statement of Gains and Losses	TAC 04
Summary of Bed Availability and Bed Occupancy	KHO3
Summary of Chiropody Services	KT23
Summary of Clinical Psychology Services	KT24
Summary of Did Not Attends (DNAs) in Consultant-led Outpatient Clinics	
Summary of Family Planning Activities	KT31
Summary of Non-cash Limited Expenditure	FIS(FHS)4BI
Summary of Occupational Therapy Services	KT26
Summary of Physiotherapy Services	KT27
Summary of Speech Therapy Services	KT29
Summary Return of Patient Activity	KP70
Supplementary Funding of PGO Accounts	FIS(HA)4
Survey of Lower Limb Amputee Referrals – Limb Fitting Service	
Survey of Registration & Inspection of Local Authority & Health Authority Units	
Thames Cancer Register	
The North West Thames Congenital Malformation Register	
Three Year Financial Plans (1999/2000 to 2001/2002)	Holler
Total Tangible Fixed Assets	CTF1O
Trent Cancer Register	
Trent Congenital Malformations Register	
Trent Thyroid Follow-up Scheme	
Trust Finance Signatories	TFS
TSCAP(CL) (2 separate entries)	
TSCAP(NCL)	
UK Cardiothoracic Surgery Register	
UK Diabetics Dataset	

continued

TABLE 19 *List of identified databases of potential relevance in alphabetical order: UK and English NHS only (excludes NHS Central Returns for Scotland, Wales and Northern Ireland, plus other near duplicate databases), 1999[a] (cont'd)*

Title	Department of Health code
UK Haemophilia Centres Directors' Dataset	
UK Heart Valve Register	
UK Hydrocephalous Shunt Register	
UK Renal Register	
UK Thalassaemia Register	
UK Trauma and Research Network (TARN)	
Unit Costs of Community Care (PSSRU)	
Waiting List and Times	CIC – Table 7
Wessex Congenital Malformation Register	
Wessex/S. West Cancer Register	
West Midlands Cancer Register	
West Midlands Congenital Malformation Register	
West Midlands Leukaemia	
West Midlands Regional Children's Tumour Research Group	
Working Balances	H04

Sources: *Health Service Circular 1999/070. Central Data Collections from the NHS*, and its predecessors in 1997 and 1998. Supplemented by authors' searches.
[a] Excludes databases that were being developed in early 2001.
GMP, General Medical Practitioners; GMS, General Medical Services; HCHS, Hospital Community Health Services; HSC, Health Service Circulars; I & E, income and expenditure; PCG, Primary Care Group.

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Professor Nick Black of the London School of Hygiene and Tropical Medicine organised several meetings of interested experts which attempted to classify what are termed in this report 'clinical registers' in relation to their completeness and accuracy. Some of those discussions are reflected in the present report.

Barbara Graham, of ISD, provided helpful comments on the differences between Scotland and England, which have been included in Annex 2.

Finally, acknowledgement must be made of the many people associated with the various databases who responded to our requests for information with courtesy and promptness.

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