The potential use of routine datasets in Health Technology Assessment

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Abstract

This paper reports preliminary findings from the above HTA methodology project including:

a) setting the context and defining the terms,
b) suggesting three different kinds of HTA: efficacy/effectiveness, equity/diffusion and cost related,
c) proposing 4 useful types of routine datasets with potential use in HTAs dealing with efficacy/effectiveness or equity/diffusion, with examples of each from the UK, (and noting that of the over 200 NHS routine datasets in each of the four countries of the UK , only a tiny number are of any possible value to any type of HTA)
d) proposing, on a similar basis, four potentially useful types of routine datasets for use in cost related HTA, again with UK examples,
e) some tentative conclusions.

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Introduction

One of the characteristics of healthcare has to do with technological developments. In the past fifty years, new health technologies have appeared and been implemented at an accelerating rate. These in turn opened new indications for treatment, both treatments for those who could not hitherto be treated and changes in types of treatments . The term 'Health technology assessment' has developed as covering a variety of more detailed assessments (clinical, medical, economic, etc) and has different audiences for various types of evaluation. Assessment of some kind is vital, but HTA itself has been characterised as a 'half –way technology' which itself needs to become routinised. If it is to do so, greater use of routine data will play a major part.

This project, funded by the NHS national R&D's HTA panel, will provide:

a) an annotated inventory of routine data sources in the UK which might be useful for HTA
b) reviews of the actual and potential use of routine data in HTA
c) a discussion of the 'validity' of routine data.

The present paper deals mainly with the annotated inventory. A background section reviews definitions, discusses the evolution of routine datasets and distinguishes three types of HTA: those dealing with efficacy/effectiveness, those dealing with equity/diffusion and those relating to costs.

Routine datasets potentially useful for efficacy/effectiveness and equity/diffusion are classified into 4 types linked to their scope in identifying outcomes, whether at patient or population levels. Cost related HTAs also have four types of routine datasets with potential use. Relevant UK databases are listed in Appendices. Finally some conclusions are offered.

This paper is in the HESG tradition of 'work in progress' This means that it should not be quoted. Comments on methods and in relation to missing datasets will be particularly welcome.

Background

Each of the key terms - routine data, health technology and HTA - requires clarification.

Routine data

The Shorter Oxford English Dictionary defines 'routine' [1] as follows:

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

1. b 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.]

Some indication of routine data in relation to health and healthcare can be gleaned by briefly reviewing what data are regularly collected and published. The decennial Census of Population since 1801 has provided the most basic data on population size and composition. Mortality data have long been collected. Morbidity data, particularly in relation to infectious diseases have also been required by law to be collected. The analysis of such data such as by Snow and Farr in 19th century London, has been seen as the golden age of epidemiology of infectious disease.

Some data on the use of healthcare have also been routinely collected for a long time. Mental hospital admissions data date from the 1840s under the 1845 Lunacy Act. This was necessary in part due to compulsory detention requiring such data for legal reasons, and covered patients in both public and privately funded hospitals[2].

Data on admissions to other hospitals came later, but have been collected and published from 1948. Data include demographic, administrative and clinical headings (including surgical but not medical interventions or technologies). Although these are not subject to legal statute they can be seen as part of administrative law.

Influence of law

Historically data has been collected on mortality for probate reasons (the term coroner derives from guardians of the crown - *custos placitorum coronae*). Mortality statistics have been regularly collected at national level in England since the Births and Deaths Registration Act 1836 and became compulsory since 1874. Natural and unnatural causes of death have been distinguished and classified, partly for legal reasons, partly for epidemiological reasons. For example stillbirths were added to notifiable causes of death in 1927 and changed in 1992 in line with changes in the legal definition of stillbirth.

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[1] Few definitions exist in the healthcare literature of 'routine data' One interpretation is 'data collected as by products of clinical care by the clinician and as an integral part of the process of care. This however seems to us to be too restrictive a definition. We note it offered to contrast with the suggested alternative of 'managerial data collected through processes outwith the clinicians control'[1] (William JG Making routine data adequate to support clinical audit, letter, BMJ 310, 665, 1995.).

Literature searches provide few references under this as a key word, but a very large number come up under 'administrative data'.

[2] Continuous data on inmates of both mental hospitals and mental handicap units exist from 1845 to 1985 for each country in the UK, with breakdowns by type of illness, age, sex, cause of death and cost- see unpublished PhD thesis 'Economics of psychiatric services in counties of the UK 1845-1985' J Raftery, Univ. of London, 1993.

Legal requirements have been most likely around issues of life and death. Besides deaths, terminations due to abortion have to be notified, as do *in vitro* fertilisations (IVF). As the data collected for IVF includes details of both mother to be and donor plus outcomes the result is a particularly rich (if largely inaccessible) database.

Registries

Some disease specific registries have long been established, notably the cancer registries. Registries are defined as '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.'[3]. Cancer registries were developed on a voluntary basis from 1962 in the UK after registry type follow ups of patients treated with radium in the 1930s. The linking of cancer registrations with mortality data via the NHS Central Register enabled survival rates to be compiled. It is suggested below that developments in information technology are making registries increasingly feasible . Those datasets potentially most useful for HTA tend to be registries. Not all registries however identify, either implicitly or explicitly, a health technology.

The influence of the NHS

The establishment of the NHS in 1948, by including (almost) the entire population increased the scope for use of routine data for wider purposes. Of particular note is the NHS Central Register, which has been used since 1948 to pay GPs in relation to the number of patients registered with them. This register, which was based on a special 1939 Census of Population, subsequently used for rationing food in the 1939-44 War, was computerised in 1991. The Central Health Register Inquiry System (CHRIS) contains 'flags' relating to both cancer registration and membership of around 240 existing medical research studies, in which around 2 million people or some 4% of the population, are included[4]. This represents a major and relatively little known exercise in record linkage.

Linking of data between routine datasets provides a powerful way of greatly extending their use as well as validating data items. Besides the NHS Central Register, more detailed linkage including hospital records has been pioneered in the Oxford Region (Goldacre 1993). The advent of the single computable NHS number from 1995 greatly increases the scope for such linkage.

Influence of the private sector

The NHS may have also had some adverse effects on routine data, due to its emphasis on publicly funded services and its narrow definition of healthcare. Data on privately provided services has often been lacking except for services whose legal regulations required such data (compulsory mental health admissions, terminations, IVF) . However many countries (US, France etc) have recently imposed a legal obligation on private providers of acute hospital services to provide minimum data sets to the state.

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[3] A Dictionary of Epidemiology Ed JM Last OUP 1988 p112.

[4] The OPCS records in medical research and clinical audit Botting B, Reilly H Harris d, Health Trends 27, 1, 4-7, 1995.

(refs). In England, where no such requirement applies, as much as 20% of all elective surgery is carried out in the private sector and the figure is higher for some procedures and in some parts of the country. Only occasional data are available[5]. Although nursing home and residential care is increasingly provided privately (if often publicly funded) no routine data are required. Routine data on personal social services, which increasingly are seen as part of a wider definition of healthcare, are also largely absent in the UK.

Some private companies have developed register type information. Genzyme, for example, collect data on all patients who receive a particular knee treatment they have helped pioneer (autologous chondrocyte implantation). The aim is long term follow up of a sort which would be difficult to examine in a randomised clinical trial. Manufacturers of other relative expensive treatments with long term effects may well follow suit - a development with which patient groups may well be happy to co-operate.

Pharmaceutical companies, required by law to submit data on efficacy and increasingly on cost effectiveness, may well have an interest in exploring the use of routine data for such purposes. Customised data costs much more and those costs are imposed on society in the form of higher prices. Routine data however tends to be the preserve of the public sector, partly due to history but also perhaps due to concerns over confidentiality.

Influence of Information Technology

A considerable amount of patient specific data are recorded in the course of treatment, such as diagnostic and treatment data as well as some outcome data, which are usually held in casenotes. A useful distinction can be made between 'data' (given) and 'capta' (captured or taken). Health services capture enormous amounts of detail, often in casenotes but these seldom get translated into data. Casenotes in England still tend to be handwritten (Audit Commission, 1995), specific to the site of treatment and are difficult to interpret. However computerisation of casenotes offers scope for their 'routinisation' . Electronic Patient Records (EPOs) are a reality in some hospitals and their widespread use is an objective of the NHS Information and Communications Technology strategy (1998). Computerisation of some services, such as Intensive Care Units means that some services are collecting almost-routine data[6].

Coding systems

If the 'capta' are to be turned into data, standardised coding systems are essential. The International Classification of Diseases (ICD) was originally developed for classifying causes of death but from 1948 was extended to cover morbidity[7]. ICD has had to be regularly updated to keep up with new diseases (currently on ICD10).

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[5] specifically surveys of private sector hospital admissions by Nichol et al . (ref), which can be supplemented by data on prices from a number of sources, notably Laing & Buissons annual review

[6] 'Almost-routine' in that such systems are seldom linked to the larger datasystems in the hospitals concerned, but these are likely to be linked in the future that goes 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.

[7] Israel RA The history of the International Classification of Diseases Health Trends 1990, 22, 43-4.

Standard definitions have also been developed to classify surgical intervention, notably OPCS in the UK and CPT (Classification of Procedures and Treatments) in the US. Differences between these two systems have contributed to differences in casemix costing (DRGs in US, HRGs in UK). Standard definitions also apply to drugs, at least in Britain, via British National Formulary Chapter headings. These however do not readily map to International Classification of Disease headings. Other services lack routine coding systems. The development of Read codes, which would translate terms for diseases, condition and treatments, as used by doctors, into standard codes (such as ICD) by way of an electronic thesaurus, offers a way of enabling codes to be standardised.

Standard definitions however are limited, both in relation to sensitivity/specificity (poor recording of co-morbidities, interventions and particularly outcomes) and completeness (limited capture of diagnostics). Clinical trials usually go beyond standard classifications by using much more detailed clinical terms to remedy these limitations. Indeed, as argued below, clinical trials provide criteria against which the usefulness of routine data in HTA can be assessed.

New disease specific or health technology specific databases have been developing, partly due to the limitations of traditional routine datasets, and often led by clinicians. These are routine in the sense of being regularly collected but are similar to registries in reporting additional clinically relevant data and following up patients. Examples are discussed below. These developments, relying on computerised data capture and linkage, make registries increasingly feasible. As discussed below, such datasets offer greatest scope for assessing the effectiveness of health technologies.

Fully computerised datasets?

Iceland provides an example of where an attempt is being made to develop a single computerised database linking medical records, family trees and assorted genetic information. The small population size (270k), the existence of detailed medical records and the interest of deCode genetics (an indigenous commercial firm) are important factors. A decision is to be made shortly by the Icelandic parliament about the future of this project [8]. Several Nordic countries have large registry type databases linked to hospital and other health service records. Concerns over abuse of data seems to be the main limit to such extended and linked coverage.

Characteristics of routine data

An important characteristic of routine data, then, is that it is collected regularly and continuously using standard definitions for all of the population or group covered. The degree of obligation varies but is often considerable. The advantages of routine data include comprehensive coverage of the items included and relatively low costs for uses other than those for which it was intended. Disadvantages include limited coverage in terms of data items, and unknown levels of validity and reliability, which

[8] Norse code Economist p131. 5 December, 1998

may lead to bias. Routine data may also suffer from lack of timeliness and access may be restricted.

For our purposes we have defined routine data as that which is collected regularly, consistently and in more than one site (many local initiatives exist). Although the degree of compulsion involved can influence the coverage (more likely to be national) and quality (of at least some items such as patient identification), we have not confined our attention to such datasets. Routine data can be taken to cover not only administrative data (such as which patients were admitted to hospital or received prescriptions) but to also include data specific databases established for purposes including epidemiology and other research such as disease registers for cancer and renal disease.

Reliability of routine data can be expected to vary. To meet legal or administrative requirements, certain minimum data needs to be reliable (patient identification, date of entry and exit) but additional data may be less reliable due to factors such as lack of clear definition (health state, treatments etc), and lack of usefulness of such data for legal or administrative purposes.

Identification of routine datasets

The NHS annual returns are listed each year in a Health Service Circular [9]. These amount to just over 200 datasets, of which around 60% are Finance Returns. Around the same number exist for each NHS in each constituent country in the UK making a total of just under 1000 routine datasets. To this can be added a number of non-NHS datasets. Most but not all of those that are publicly provided are listed in the ONS (formerly CSO) Guide to Official Statistics. The Oxford Textbook of Public Health Medicine has published useful discussions of routine data sources. To these we have added datasets noted in journal articles as part of a systematic review of the use of routine data in HTA. In addition, we have relied on personal knowledge and reports in newspapers and magazines. We decided to exclude from consideration those datasets which were confined to one site, as otherwise we would have to include a very large number of systems particular to individual clinicians. While we believe we have captured the bulk of the relevant datasets at national or regional level, we have no doubt that there are some that we have missed. We would welcome any help the reader can give in identifying those.

Health technologies

The NHS Standing Group on Health Technologies has defined health technologies as: "all methods used by health professionals to promote health, prevent and treat disease, and to improve rehabilitation and long term care[10]"

The US congress' Office of Technology Assessment defined HTs as:
"the set of techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered[11]".

[9] Central Data Collections from the NHS. HSC 1998/054 is the most recent.
[10] Department of Health. Assessing the Effects of Health Technologies: Principles, Practice, Proposals. 1992

HTs are thus defined widely to include not only drugs and surgical procedures, but also medical and diagnostic techniques, settings and organisations, as well as professionals. While this has the advantage of inclusiveness, it leaves the boundaries fuzzy.

The above definitions share an emphasis on interventions to promote health or prevent or treat disease The relationship between health technologies and healthcare interventions can be complex in that the latter often comprise a bundle of specific technologies. Relatively small changes in one HT can lead to major changes in the package (such as an improvement in anaesthetics leading to many more patients being capable of being treated, or changes in methods of drug delivery which alter the drugs effectiveness).

A different approach to HTs looks at how regulation of HTs varies by type. Drugs are clearly different in that they have long been licensed in most countries both to ensure quality and to prevent damage. They are also generally supplied by private enterprises. The regulation of pharmaceuticals reflects a history of damage and subsequent litigation, particularly the thalidomide scandal in the 1960s which led to revised Medicines Acts in many industrialised countries. Within drugs, different regulations apply depending on whether drugs are prescribed or allowed to be bought over the counter (OTC) in pharmacies only or in all shops.

Medical devices tend to be less regulated and are often privately provided (manufactured) and, as such, subject to litigation (the extent of which varies internationally). Litigation has led to the establishment of registers of patients who have had cardiac pacemakers or silicone breast implants and a register has been recently suggested for hip joint prostheses[12].

Other health technologies are much less subject to regulation. Surgical procedures, except the most minor, tend to be recorded in routine data for hospitals but are not otherwise formally regulated other than by audit of adverse events. Routine data bases of adverse events can provide useful information on the inappropriate or non-use of a particular health technology. Changes in the settings or organisation of healthcare tend to be more free of legal regulation, but the recent history of community care for the mentally ill may be indicate a move towards auditing of adverse events (spurred in part by media reports).

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11 Office of Technology Assessment, U.S. Congress. *Development of medical technology: Opportunities for assessment.* Washington DC: U.S. Government Printing Office, 1976. *Quoted in* Klawansky S, Antczak-Bouckoms A, Burdick E, Roberts MS, Wyshak G, Mosteller F. Using Medical Registries and data sets for Technology Assessment: an overview of seven case studies. *International Journal of Technology Assessment in Health Care* 1991;7:194-199.

[12] Sochart DH et al, Joint responsibility: the need for a national arthroplasty register, BMJ 1996, 313, 66-7 see also Need for a national arthroplasty register Fender D et al. BMJ letter, 313, 1007.

Health Technology Assessments

There is danger in implying that HTA is itself a well defined technology. In contrast, it has recently been characterised a 'half way technology' (Hutton, 1994) on the basis of great differences in methods and consequently in types of data collected. *Half-way* technologies resemble crafts, where the skills are often specific to certain craftsmen and different projects have to re-invent the technology each time. Increased use of routine data could contribute, along with more standardised methodologies, to making HTA a more fully developed technology The scope for use of RD depends plausibly on the type of HTA being carried out.

This study distinguishes three broad types of HTA:

i) those to do with efficacy (demonstration of patient benefit) or effectiveness (demonstration of patient benefit in practice as opposed to in trials),
ii) those to do with equity (which groups) and diffusion (place and time).
iii) those to do with costs

The conventional use of the term HTA often focuses the first of these (efficacy, effectiveness). Such HTAs place particular emphasis on peer reviewed, scientific publications, reporting on RCTs. These tend to be restricted to a relatively narrow range of outcomes on a narrow range of patients. Limitations apply to the use of trials in assessing efficacy/ effectiveness. RCTs may be unnecessary, inappropriate, impossible or inadequate[13]. In these contexts observational methods (non-randomised trails, cohort studies and case control methods) may be more appropriate.

The dispute between experimental and observational approaches is almost certainly artificial. Experimental methods depends on observational ones to generate clinical uncertainty, generate hypotheses, identify the structure, process and outcome that should be measured in a trial and help establish the appropriate sample size for a randomised trial (ibid).

Efficacy tends, where possible, to be best assessed by RCTs, collecting customised data. Effectiveness can be assessed in RCT-based pragmatic trials, but some effectiveness considerations are beyond the scope of even pragmatic trials. Effectiveness studies require data on the degree to which a particular intervention retains its efficacy in everyday practice, which in turn demands data on the patients on whom it is carried out, and the degree to which the same outcomes are achieved. Existing RD can indicate *which* patients *are* treated with a particular *intervention*. Assessment of effectiveness as opposed to efficacy requires data not only *on* the number of persons treated in different locations but also on the characteristics of the patients treated. Clinical evaluations usually exclude certain types of patient (due to

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[13] Black has suggested the following reasons:

a) unnecessary because the effect of the intervention is dramatic

b) inappropriate due to infrequent outcomes, prevention of rare events, effects take a long time, or because randomisation may reduce the effect of the intervention

c) impossible due to lack of individual equipoise, ethical objections to randomisation, political or legal obstacles, geographical barriers, contamination),

d) inadequate due to lack of generalisability because of atypical clinicians, patients or treatments.

Why we need observational studies to evaluate the effectiveness of health care Black N BMJ 312, 11, 1215-8

age, co-morbidities) , and patient characteristics which might weaken experimental results are controlled out.

Considerable use has been made of administrative claims data for HTA analysis of effectiveness in healthcare systems based on insurance principles. The US PORT studies provide the notable examples[14]. This approach however has been criticised[15] for potential bias. The NHS, for whatever reasons, has been much slower to use such data[16]. The effectiveness oriented HTA of IVF by Templeton provides an important exception, however [17].

Equity/diffusion HTAs

Equity/diffusion HTAs emphasise differentials in receipt or use of a particular service over time. Equity concerns require data on which groups receive (effective) treatment with groups capable of being defined in many ways (sex, age, ethnicity, severity, geography). Uneven diffusion of HTs can be seen as the opposite side of the equity coin, and requires data on the use of HTs by time and place. The current "variations" literature is noteworthy for being almost entirely founded on routine data[18].

As HTs diffuse, they are often used to treat patients outside the groups included in the trials. The benefits of treatment plausibly vary according to patient characteristics such as age, co-morbidities, severity of the condition, patient attitudes and circumstances. In determining the optimal levels of particular treatments for specific populations (indications for treatment) , such data are required but are seldom available. Development in routine data, particularly electronic patient records and record linkage offer scope for collecting data on such patient characteristics.

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[14] PORT references to follow.

[15] Sheldon T Bypass the PORT BMJ 1996.

[16] The development of Contract Minimum Data sets and a clearing house for the national dissemination of these mark important developments in RD. The implications of planned developments in routine data such as electronic patient records and a single NHS number, will increase the scope for use of routine data.
The NHSE's Information Management and Technology strategy (ref) contains a five point vision which i) has information which is person based,
ii) with integrated systems and
iii) information derived from operational systems
iv) which are secure and confidential, and
v) shared across the NHS.
Part of this strategy involves a move to computerised casenotes (electronic patient records or EPRs) linked to clinical workstations could make these part of routine data, subject to confidentiality arrangements. The development of a unique NHS computable number for each patient, implemented from 1995, will enable casenotes to be linked between hospitals and with GPs. Despite their antecedents in the Oxford Linkage Study with its epidemiological focus, these developments have received very little attention outside the NHS IT world. Conventional approaches to routine data may be rendered obsolete within the next five to ten years. Any project to do with use of routine data in HTA should take such plans, (including the risks of non-achievement or delays in the strategy) fully into account.

[17] Templeton A. , Morris JK Parslow W. Factors that affect outcome of in vitro fertilisation treatment. IVF Lancet, 348, 1402-6, 1996.

[18] Acheson report on Inequalities in health, Department of Health, 1998.

Cost related HTAs

Cost related HTA can be seen as including cost effectiveness analysis, 'Cost of Illness' studies, cost consequences analysis and cost impact studies. Of these, cost effectiveness analysis (used here as in Gold et al to include CUA) is by far the most complex as it requires data on both outcomes and costs. Economic evaluations are often tagged onto clinical trials of efficacy, with outcome data customised and cost data based, at least partly, on routine data.

The degree to which cost estimates can be generalised has only recently become an issue of debate among health economists. Economic evaluations can be divided between those which employ unit costs (such as those from routine NHS Financial Returns) and those which estimate unit costs anew (usually relying to some degree on routine data such as average pay scales). Either routine data (such as HES) or casenotes (which are being routinised - see above discussion) are often used in such studies to estimate levels of service use, particularly those which are not encompassed by the specifics of the intervention being studied. The resulting service use estimates are then combined with unit cost data to estimate total costs.

The issues around use of experimental versus observational data in economic evaluation has been recently explored by Drummond (1998) who has argued that while observational data should not generally be used to distinguish differences in therapies, they can be used to estimate the economic consequences of such differences[19].

Besides the direct cost of health technologies, cost effectiveness analysis requires data on the knock on effects with economic consequences. Since these often happen outside the time frame of clinical trials, they tend to be based on modelling, in turn

Besides cost effectiveness analysis, 'Cost of Illness' studies use data on levels of service use to estimate the total costs attributable to particular diseases. Whatever the value of 'cost of illness' studies, estimation of the cost impact of particular health technologies is essential if policy makers are to take costs into account. For example the potential cost impact of recent drugs such as Viagra and Orlistrat, have been subject of concern over their possible cost impact. Part of the brief of the recently established National Horizon Scanning Centre includes carrying out cost impact analysis of new HTs.

Overall, it is arguable that few HTAs, other than those concerned solely with efficacy (assessed in RCTs using customised data), are 'routine-data free'. Given the increased emphasis on cost effectiveness in HTA the importance of routine data is likely to continue to increase. Trials could, in theory be nested within routine data frameworks without the need for bespoke data collection if the routine data were sufficiently inclusive and reliable.

In practice, however, the use of routine data is limited by not only the problems of scope and reliability, but also the perceptions of scope and reliability, which in turn

[19] Experimental versus observational data in the economic evaluation of pharmaceuticals Drummond MF (details to follow).

create a vicious circle of non-use and therefore non-refinement and non-quality control.

Requirements of routine data for use in Efficacy/effectiveness and Equity/ Diffusion HTAs

HTAs concerned with efficacy/effectiveness ideally require routine data which mirrors the items collected in controlled trials. Specifically this implies:

- Clearly identified interventions/HTs
- Clearly identified patient characteristics for cases and controls, including
  (i) health state before intervention and
  (ii) ditto post intervention.

While these criteria might seem to rule out use of routine data, particularly in relation to outcomes, further reflection suggests a less negative conclusion. First, some clinically rich datasets have been developed which contain patient health states (or reasonable proxies- see below) Second, health states can sometimes be assessed at a population rather than individual level. For example, national screening programmes can be evaluated on the basis of the occurrence of cases at national level.

The identification of a clearly defined intervention/HT can be direct or indirect. Drugs and surgical interventions tend to be directly noted in routine data. Indirect attribution of interventions can be made where well established interventions can be expected to have taken place. Examples include resuscitation of people who are brought to hospital unconscious. Emergency diabetic admissions can be assumed to be stabilised. Similarly with stroke and AMI patients. Failure to do so should be picked up by audit and internal quality control. Thus although routine data systems on hospital use tend to omit medical treatments, they can sometimes (but not always!) be implicit.

HTAs concerned with Equity/diffusion considerations need less information. It remains necessary to have the HT identified (directly or indirectly) plus the patient group (equity) or place. Routine datasets have been extended in recent years to include group identifiers (ethnic group) and postcoding of patients records in the UK has enabling linking to Census of Population enumeration districts.

Useful routine datasets for Efficacy/Effectiveness and Equity/diffusion

Four types of databases with potential for use in HTA can be distinguished as follows:

i) *'HT+P'* datasets, that is those which include identification of a HT and of patients (directly or indirectly).
ii) *'HT only'* by time for specified populations usually national,
iii) *'Outcomes only'* datasets which contain data on outcomes or health states without HT or patient
iv) *Census based* datasets.

Systems enabling linkage to mortality or to Census of Population data are discussed separately.

i) HT+P Datasets

To qualify, databases must contain data specify a particular HT, plus it must identify patients either directly or indirectly (eg. age, sex, condition etc.). Appendix 1 lists 61 such datasets although around 20 of these are regional cancer or leukaemia registers.

Within this group of databases, it may be useful to distinguish a) registry type databases, b) enhanced administrative datasets and c) population based datasets[20].

In registry type databases, outcomes (or good proxies) tend to reported, linked to well defined effective interventions. One good example is the HFEA database in which successful conceptions are reported as the outcome of IVF. The Downs Syndrome Cytogenic Register reports on the number of terminations of foetuses diagnosed with the syndrome. While this may be a controversial outcome, it casts some light on the debate about the effects of this diagnostic service.

Some datasets report on numbers of patients alive subsequent to use of a HT designed to extend life. Examples include the Renal Registries in England & Wales and in Scotland, the Transplant Support Services Authority (TSSA) and the pilot Coronary Care Audit Database (CCAD). Similarly the National Prospective Monitoring Scheme for HIV provides data on drugs and CD4 blood count (a good proxy since it defines the transition from HIV to AIDS).

Cancer registries provide data on the progression or staging of disease but although they contain treatment data (to varying extents), the lack of well established effective interventions makes them less useful than some of those discussed above. Differences in survival rates internationally and for particular cancers have spurred action in the re-organisation of cancer services. Should an effective treatment for a particular cancer emerge, its effect would on survival would be captured in the cancer registries.

The Cystic Fibrosis Register reports on the number of patients with this disease and also on the number using Dnase, a drug treatment of limited effectiveness.

Enhanced Administrative Datasets

The prototype of ib) 'Enhanced Administrative Datasets' is the Hospital Episode Statistics (HES) and its Welsh and Scottish equivalents (CEPW and COPPISH). These large databases (10m records annually in England alone) contain demographic, administrative and clinical data. By including surgical interventions, a range of important HTs are identified. As discussed above, some medical treatments can be inferred from these data. Outcome data, however are limited to deaths while in

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[20] A more formal sub-categorisation is as follows:
Group 1a): to include datasets meeting the criteria of: individual/patient level data, + identification of HT in greater detail than standard classifications (such as OPCS4) + some outcome data (either directly or via linkage).
Group 1b): those datasets meeting the criteria of individual/patient level data, identifying the HT using standard classifications such as OPCS4 + some patient identity + some outcome data (either directly or via linkage). (Key datasets include HES, and the various cancer registries.)
Group 1c): those datasets meeting criteria of: aggregated patient level data + identification of a HT, with some outcome data (often implicit). National programmes whose effectiveness can be assessed at a population level would be included.

hospital (which is useful for some procedures, not least as epitomised by the Bristol experience). Destination on discharge (to normal home, other hospital or nursing home) can act a proxy for outcome for certain conditions (such as stroke). More specific outcome measures are being developed (readmission rates for particular conditions, 30 day mortality etc). The use of the single NHS number on this dataset will enable records to be linked from year to year and to other datasets. Postcoding already enables linking to small area statistics.

Aggregated Datasets useful for population effectiveness

Group i c) 'Aggregated Datasets useful for population effectiveness' is classed as belonging to this premier group for the following reasons. Although patients are not identified at an individual level, population level data can be used to assess the effectiveness of specific interventions aimed at populations. One example is the national immunisation and vaccination programmes. Since the effectiveness of these interventions are well established, data on the coverage of such programmes is sufficient for assessing their overall effectiveness. Other examples include screening programmes such as the national breast and cervical programmes, where again coverage and pathology reports make up the critical target variables.

ii) 'HT only' datasets

Group ii) datasets contain data on HT by time but without any linkage to patients or their conditions. The prime example here is the Prescription Pricing Authority data which specifies the number of each drug dispensed in the GMS in each UK country each year. Such datasets are useful for equity and diffusion. These data are fed back to GPs via PACT and play a role in monitoring and controlling prescribing.

The General Practice Research Database and the Morbidity Survey in General Practice, located above under i a) complement and extend the PPA data by providing on a sample basis additional data.

Other databases in this heading include the silicone breast implant register, the wheelchair/artificial limb data and family planning data.

iii) 'Outcomes only' datasets

Group iii) specify outcomes or health states but without necessarily reporting either the HT or the patient Three types can be identified: adverse events, certain disease specific databases, and health surveys. While adverse event type datasets can be useful for assessing the performance of organisations, the other two types have little to offer HTA.

Adverse Events/Confidential Enquiries

Under the Adverse Events heading are not only Adverse Drug notifications (which do identify the relevant HT) but also Confidential Inquiries into selected causes of death (Stillbirths, Perioperative deaths, Maternal deaths, suicides) . These tend to apply to

relatively rare events and although they do not identify a HT, they raise questions about the inappropriate or non-use of a HT. The function of these databases is essentially audit, but at a national level, mandated by the Department of Health. These provide useful assessments of the effectiveness of the relevant overall system and indicate the need for more detailed inquiry.

Disease Registers of limited usefulness for HTA

The various Disease Specific Datasets and traditional disease registers (the blind, deaf physically handicapped etc). These differ from the registers classified in group ia) above by lacking data on HTs. Registers of the number of people who are blind or deaf are of little use for assessing current HTs but could provide a sampling frame for new HTs. The estimation of the impact of cochlear implants, their coverage and the selection of patients for trials could come from such sources.

Health surveys

Health surveys also provide outcome type data without identifying either patients or HTs. The main UK surveys are listed in Appendix 1. Without linkage to HTs these datasets have little to offer HTA.

iv) Census related datasets

The decennial Census of Population which contains some questions on long standing illness must be included in any inventory of datasets, not least because it provides the denominator for epidemiology. Beyond this a number of long standing studies based on record linkage to the Census have developed, most notably the Longitudinal Study. This study is based on linking an anonymised 1% of the 1961 Census to vital events (deaths, births) using the NHS Central Register. Only by linkage to datasets which identify a HT (such as HES) can such datasets be of use to HTA, and then mainly for assessment of equity/diffusion.

Linkage enabling systems

The two main linkage enabling systems are Central Health Register Inquiry Service and postcodes. Linkage by CHRIS by means of the NHS number enables records with that number to be linked. The most immediate scope applies to Hospital Episode Statistics, along the lines of the Oxford Record Linkage Study. As the use of the NHS number extends to cover other health services, more integrated records can be built up.

Inclusion of UK postcodes on any records enables that record to be linked to enumeration districts in the Census of Population. This approach has been used in deriving capitation formula which adjust for socio-economic conditions[21].

The criteria for classifying the datasets potentially useful for efficacy/effectiveness and equity/diffusion are summarised in Table 1.

[21] R Carr Hill et al A formula for distributing NHS reveneus based on small area use of hospital beds, Univ of York, Sept. 1994

Table 1
Criteria for classification of grouping of routine datasets

Group	HT	patient data	pop. data	outcome	pop/ place	comments
i) *H+P* (has HT + patient identification plus some outcome data.	yes	yes	yes (if not patient id.)	varies	varies	outcome may req. linkage patient data may be implicit (eg screening programs)
ii) '*HT Only*' (has HT by time, national)	yes	no	yes	no	yes	useful for diffusion or equity studies
iii. '*Outcomes only*' (outcomes/health states without HT or patient identification)	no (maybe implicit)	no (pat. id. Confidential	yes	yes: morbidity or mortality	no	eg Adverse Events, Confidential Inquiries, Health related surveys
iv. Populations (Census of Population, Longitudinal Study etc.)	no	yes	yes	yes: mortality	no	

Routine data and Cost related HTAs

Although not all HTAs include costs a similar set of distinctions can be made as above. Remarkably few cost related datasets specify HTs of the 127 NHS Financial Returns for England only 8 were considered to have any possible use for HTA and most of these required linkage to other data. Two main exceptions exist - the costs of drugs dispensed in GMS (PACT - published by the Prescription Pricing Authority) and the recently published unit costs for acute hospitals at HRG level.

Four different types of cost related routine datasets can be distinguished:
a) *HT unit costs*, that is unit costs which are directly linked to specific HTs, with sub-classifications linked to levels of patient treatment
b) *Grouped HT unit costs.* These are the unit costs of groups of different, related HTs/treatments
c) *Linkable unit costs*, that is unit costs based on combining of two data sets, at least one of which is routine
d) *Survey unit costs*, that is unit costs based on special surveys, whether one off or repeated or updated annually.

Table 2 classifies these cost related datasets, The key is the identification of a HT and the attribution of a unit cost to it. The same definition of routine data applies to the cost side as to outcome side - regularly, consistently collected in more than one site.

HT unit costs

The most readily available unit costs are prices, which apply when the NHS purchases a HT from some other organisation. Prices for products purchased from the pharmaceutical industry provide the obvious example. Although by number, drug prescriptions constitute the most commonly used HT, they account for only around 12% of NHS spending.

Routine data on unit cost of non drug HTs has historically been much less common in the NHS. The National Schedule of Reference Costs [22] now provides data on cost per surgical HRG in each acute NHS hospital trust in England. The plan is to roll out this approach to costing the medical specialties next year and to reconcile the data with Trust annual accounts[23]. HRGs can be divided into those which identify a single technology and those which comprise a group of technologies. The former fit group a) in being HT unit costs, while the latter make up group b).

b) *Grouped HT unit costs*

HRG unit costs that refer to a group of HTs in a particular specialty are similar to the average cost per FCE per specialty which has long been available via the Trust Financial Return 2 (TFR2). HTAs have tended to use these in both cost per FCE and in terms of cost per inpatient day. Many but not all of the non-surgical costed HRGs

[22] The National Schedule of Reference Costs (NSRC) and National Reference Cost Index (NRCI) are shortly to be published by the NHSE. Reference cost treatment categories will be defined using HRGs
NSRC will provide data on the highest and lowest HRG cost trimmed, the average cost/HRG and the IQR
[23] Reconciliation with Annual Accounts will ensure that these data refer to costs rather than, as with GP Fundholder tariffs, prices.

will provide unit costs for groups of cases, which will necessitate further estimation to obtain the unit costs of particular interventions or HTs..

c) Linked HT unit costs

Many evaluations of other HTs (non drug, non-hospital) have had to improvise, either by combining customised data with routine data or by special surveys. Examples of the former include those HTAs which have combined data on number (and duration) of contacts with healthcare personnel (eg doctor, nurse) and valued this using national payscales. The most usual source for pay scales has been the Annual Pay Review Body Reports[24]. Any moves to local pay levels would pose problems for this approach. The reported 14 ways of costing a GP consultation[25] result from the lack of agreed routines in use of such data.

d) *Survey HT unit costs*

The annual report from PSSRU 'Unit costs of community care'[26], provides an example of the use of surveys to establish unit costs. This group might also include individual examples of bottom up costing to the extent that such costing is achieved without use of any routine data. Although such an approach is recommended in recent guidelines[27], few UK studies have attempted this. The degree to which it is possible to avoid any use of routine data is unclear.

Table 2
Grouping of cost related routine data sets

	Category	Routine datasets: examples	Comment
a)	*Direct HT Unit costs* (unit cost directly linked to HT)	PACT HRGs Reference Costs that are procedure or treatment specific	Drug prices reimbursed by NHS for GP prescriptions dispensed, excluding dispensing costs (Net Ingredient Cost). The National Reference Cost Schedule provides cost per HRG for each acute NHS Trust for 199
b)	*Grouped HT unit costs* (Unit costs linked to group of different, related HTs/treatments	HRGs covering group of procedures. Cost per FCE at specialty level (TFR2) Cost per package of care	Some HRGs group procedures of similar unit cos in the same specialty. HRG unit costs are based c TFRs, which apply at specialty level Packages of care apply to Social Services
c)	*Linked unit costs* (Require combining of two data sets, one of which is routine)	The labour unit costs of particular services are often estimated in bottom up HTAs using national NHS pay scales, combined with the time taken to perform some task	While the resulting unit costs are not routine dat the national pay scales arguably are.
	d) *Survey unit costs* (based on special surveys)	Unit costs of Community Care (PSSRU)	This DH sponsored annual publication provides unit costs on various services, 80%+ of which ar based on special surveys

[24] Both the Review Body for Nursing Staff, Midwives, Health Visitors and Professions Allied to Medicine and the Review Body for Doctors and Dentists Remuneration publish annual reports which include data on payscales.

[25] Graham B McGregor K What does a GP consultation cost? BJGP, 47, 170-2, March 1997

[26] Netten A, Dennett J Unit costs of community care PSSRU, Univ. of Kent, annual.

[27] Gold MR et al Cost effectiveness in health and medicine. OUP 1996.

Conclusions

A number of tentative conclusions are outlined below

First, this paper has offered some definitions of each of RD, HT and HTA. While the definition of HT has been well rehearsed (if not well resolved!) in the literature, the suggested definitions of both RD and HTA may act as a challenge to others to improve on them. In particular, we believe that it is important to distinguish HTAs relating to efficacy/effectiveness, to equity/diffusion and to costs. As we have discussed, there is scope for the use routine data in each of these but with greater scope the less the focus of the HTA on efficacy/effectiveness. Such HTAs will often require trials, partly because of the requirements in relation to measurement of outcome but particularly in relation to controlling for bias.

Second, technology is rapidly changing the scope for use of routine data in HTA. The increasing data capture of details (capta) of healthcare using computers is transforming the meaning of routine data. Although healthcare spending on computerisation has lagged other sectors[28], there are already signs of how healthcare is being transformed. Electronic Patient Records, computerised work stations, bar-coding, use of smart cards, telemedicine are only some of the key developments. Improved methods of coding (Read) and grouping (HRGs, HBGs) may facilitate extraction and collation of real time data which may for the first time contain clinical health state data. Tighter requirements for accountability will lead to better quality data. The challenge may be around how best to absorb and interpret the enormous amount of routine data that will shortly be available within healthcare. HTA has the opportunity to become routinised to the extent that it rises to this challenge.

Third, and for the above reasons, the common equations 'routine = rubbish and customised = good' is much too simple. The scope for reliable, validated routine data is increasing rapidly and there are examples of excellent datasets which have already been used for HTA as with the HTA of IVF which has impacted on national policy. That said, it must be noted that the bulk of routine datasets collected by the NHS are of no use to HTA, a finding which is particularly true of Finance Returns. Ideally to be useful for HTA, a dataset should identify a HT, its outcome and its unit cost. The one dataset which has long identified unit cost, the PACT data from the PPA, lacks any data on patients, thus precluding any information on outcomes. Some of the more recent developments with registry type datasets could include unit cost but none does so at present.

Fourth, the biggest weakness with routine datasets relates to lack of data on outcomes required to assess Efficacy/effectiveness. Some valuable databases have been identified which relate HTs to well defined outcomes (conceptions, deaths). While these datasets provide valuable information, trials will continue to be required for assessing many HT, particularly those that are new.

Fifth, for assessment of Equity/Diffusion, routine datasets provide clear indications of differential patterns of service use. Ingenuity in linking these to other datasets,

[28] FT ref to follow

notably to the Census of Population has indicated problems and led to policy changes (eg capitation formula based on linking census to hospital use data).

Finally, we would argue that knowledge of routine datasets and their potential use in the different kinds of HTA constitutes an essential part of the skill requirements for HTA.

Appendix 1

Group 1a - Registry Type Datasets:

Specific definition of HT- standard or greater than 1b
Individual patient identifier
Outcome information greater than 1b

	England	Wales	Scotland	NI	Patient ID	Coding	Outcome
HFEA	✓	✓	✓	✓	✓	Text Format	Conception. Mandatory report
UK Cystic Fibrosis	✓	✓	✓	✓	✓	CFIDS	Biochem. data, clin trials
National Down Syndrome Cytogenetic Register	✓	✓	✓	✓	✓	Own plus OPCS, DHA	?
UK Transplant Support Service Authority (UKTSSA)	✓	✓	✓	✓	✓	?	Survival, Follow-up, re-transplants
The UK Diabetics Dataset	✓	✓	✓	✓	✓	None	Annual Review
National Prospective Monitoring Scheme (NPMS) (HIV)	✓				✓	CDSC class. ICD-9 & 10	Drug, CD4
Intensive Care	✓	✓	✓		✓	Own	Discharge/death
Central Cardiac Audit Database (CCAD)	✓				✓	ICD-10, OPCS-4	Post procedure, readmission, death
Renal Registry	✓		✓		✓	Inhouse, EDTA, ICD-10, Read OPCS	Drugs, trials, death
Hip Fracture			✓		✓	Inhouse	Recovery details & abilities, death
St Mary's Maternity Information System (SMMIS)	NW Thames				✓	ICD-9 & 10	Birth, baby details
Regional Leukaemia Registers					✓	ICD-10, haematologist classification	Death, treatments
Regional Cancer Registers					✓	ICD-10, OPCS-4, ICD-0	

Group 1b - Enhanced Administrative Datasets

Limited outcome information
HT defined by standard codes
Individual patient identifier

	England	Wales	Scotland	NI	Patient ID	Coding	Outcome
General Practice Research Database (GPRD)	✓	✓	✓	✓	✓	OXMIS / Read	Drugs, prevention
Trauma	✓	✓	✓	✓		AIS, ICD-10	Timings, drugs, discharge, death
Hospital Activity	✓	✓	✓		✓	ICD-10, OPCS	Discharge, baby
Congenital Anomaly Register and Information Service (CARIS)		✓			✓	ICD-10, Read 4	Risk factors, diagnosis, anomalies, pregnancy outcome
Cancer Registry (National)	✓	✓	✓		✓	ICD-10	Death, treatment

Group 1c - Aggregated Routine Datasets Useful for Population Effectiveness

Outcome implicit
Population/programme HT identified
Data at aggregated level

	England	Wales	Scotland	NI	Patient ID	Coding	Outcome
Immunisation Programs	✓	✓	✓		×	×	Nos treated
Cervical Cytology Screening -Numbers	✓	✓	✓		×	×	Nos screened
Cervical Cytology Screening -Pathology	✓	✓	✓		×	×	Results (numbers of)
Community Dental Health Services	✓	✓	✓		×	×	Nos screened
Breast Screening	✓	✓	✓		×	×	Nos screened

Group 2 - Single HT Datasets which can identify distribution

Used for diffusion and/or equity
Time
Place
HT identified

	England	Wales	Scotland	NI	Patient ID
Prescribing Analysis and Cost (PACT)	✓	✓	✓		
Breast Implant registry	✓	✓	✓	✓	✓
Radiology & Nuclear Medicine	✓	✓	✓		Total nos
Family planning	✓	✓	✓		Total nos
Chiropody	✓	✓	✓		Total nos
Sexually transmitted diseases -new cases at GUM clinics	✓	✓	✓		Total nos

Group 3a - Confidential Enquiries/Mortality Audits/Datasets indentifying an outcome or technology - without patient identifier

	England	Wales	Scotland	NI	Patient ID
Adverse Drug Events					
Confidential Enquiry into Stillbirths and Deaths in Infancy	✓	✓	✓	✓	✓
Confidential Enquiry into Perioperative Deaths	✓	✓	✓	✓	✓
Confidential Enquiry into Maternal Deaths	✓	✓	✓	✓	
Confidential Enquiry into Suicide					
Abortion Notification	✓	✓	✓		

Group 3b - Disease Specific Datasets & Central Collections

	England	Wales	Scotland	NI	Patient ID
AIDS/HIV Surveillence	✓	✓	✓		
Communicable Disease Register	✓	✓	✓		
National Congenital Malformation Register	✓	✓			✓
Drug Misuse	✓	✓	✓		
Continuous Morbidity Recording Project			✓		
Blind or Partially Sighted Register	✓				Total nos
Deaf or Hard of Hearing Register	✓				Total nos
Physically handicapped Register	✓				Total nos
Regional Congenital Malformation Registries					✓

Group 3c - Regular Surveys with Health Status or Outcome Information

Fourth National Survey of Ethnic Minorities 1993-4
British Household Panel Study
Family Resource Survey
General Household Survey (GHS)
National Diet and Nutrition Surveys
OPCS Surveys of Psychiatric Morbidity
National Child Development Survey(NCDS)
Health Survey for England 1995
Health Promotion Wales Lifestyle Surveys - Health in Wales Surveys, Welsh Health Youth Surveys
Welsh Health Survey

Group 4 - Population, Vital Statistics & Linkage

NHSCR/Births & Deaths Database
Birth and Death Database
Population Census
Census Samples of Anonymised records
Longitudinal study

GROUP 5 - RD sets useful for other health service activity information

	England	Wales	Scotland	NI
Annual Medical and Dental Workforce	✓	✓		
Chronically Sick and Disabled Persons Act 1970 Return under Section 17(2)	✓		✓	
Complaints		✓	✓	
Demand for Elective Admission	✓			
Informal Patients and Patients detained under the Mental Health Act	✓	✓		
NHS Day Care: Availability and Use of Facilities - Form KH14	✓	✓		
NHS Pharmaceutical Services	✓	✓		
Patient Care in the Community: Community Psychiatric Nursing	✓	✓		
Patient Care in the Community: District Nursing	✓		✓	
Patient Care in the Community: Mental Handicap Nursing	✓	✓		
Patient transport services		✓		
Practice and Surgery details			✓	
Waiting lists	✓	✓	✓	