THE TRANSITION FROM SAMPLE TO POPULATION EPIDEMIOLOGY

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ABSTRACT: This review is based on analysis of original research reports in one 2006 volume from each of three major epidemiology journals: The American Journal of Epidemiology, The International Journal of Epidemiology, and the European Journal of Epidemiology. A total of 149 research reports were included in the review. The pattern that emerged from the analysis was the tendency towards large epidemiological studies that utilise all available population-based data without resort to sampling. The tendency was to use data in existing data bases instead of field data collection. Developments in information technology enabled linkage between various data bases to extend the range of hypotheses that could be tested. The transition from sample epidemiology to population epidemiology had advantages and disadvantages. The main advantage was external validity (results of the study were applicable to the population). The main disadvantage was loss of internal validity that could be achieved in small studies with higher data quality and personal familiarity of the epidemiologist with the data. It is envisioned that in the future web-based data collection will be feasible. It will also be possible to use a wider range of data routinely collected online on citizens including credit card, shopping, and other financial transactions. (JUMMEC 2007; 10(2):3-15)

KEYWORDS: Birth cohort, defined population, data linkage, large data set

Introduction

Epidemiological research is moving in several directions. One of the most exciting being the transition from research based on population samples, using subjects counted in the tens or low hundreds, to the start of large population-based studies, using subjects counted in thousands and millions.

The preference for large studies was either motivated by editorial policy or was motivated by the fact that authors increasingly submitted large studies. The connection between the two motivations is undeniable. There were, however, small studies with subjects in the low 10s that got published because of their quality (1) but these were an endangered species.

A theoretical discussion can be made about what the main driver of the new epidemiology is. Is it a desire for large studies (possible only with use of large data bases) or is it availability of large data bases (no need for sampling since the population data can be analysed easily)? My inclination is to the latter option because large studies are way above the minimum study size required for statistical validity.

Three epochs in the development of epidemiological research in relation to data collection can be identified. The pre-1950 epoch can be called sample epidemiology because studies were based on data collection from samples with the attempt being made to make the samples as small as was compatible with statistical validity. The number of subjects was in the tens or low hundreds which minimised the cost of epidemiological research. The second phase, 1950-1980, witnessed larger studies using cohorts and defined population groups that became increasingly easy to assemble because of developments in information technology. The third epoch starting about the year1980 witnessed the emergence of a brave new world of epidemiological research using large population and health data bases with the number of subjects counted in the hundreds of thousands. By the early 1980s, information technology had developed to the level that

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epidemiologists could study the whole population without the need to sample or use specific cohorts. That was the birth of what I want to call population epidemiology. The transition from sample to population epidemiology, with serious practical and theoretical implications, has produced an arm chair epidemiologist who designs and analyses large data studies using information from data bases many of them already online.

I am proud of having witnessed the birth of population epidemiology. I was in the generation of epidemiologists who in the early 1980s made the transition from using hand calculators to desk top personal computers for data analysis. The newly developed information technology led to far-reaching changes in the practice of epidemiology. Epidemiologists realised that basic socio demographic and health-related data about the whole population was collected routinely and was stored unused in government and non-government electronic data bases. They also realised that the new information and communication technology could enable them identify and follow up research subjects as well as collect data from and/or about them without even meeting them physically. The ability to link various data-bases enabled assembling data on a single individual from several data bases and to carry out arm chair *adhoc* research. A new era for epidemiology had dawned.

Before the information age, we distinguished between the field epidemiologists (who collected and analysed data) from the arm chair epidemiologists (who dabbled in theoretical epidemiology) and did not want to 'dirty' their hands with field data collection. Today, arm chair epidemiologists collect and analyse data while sitting in their offices.

Methodology of the review

Original research reports that involved data collection and analysis were identified in volume 163 of the *American Journal of Epidemiology*, volume 35 of the International Journal of Epidemiology, and volume 21 of the *European Journal of Epidemiology*. The following basic characteristics of each report were abstracted: type of study design (cross-sectional, case control, and follow up), type of study population (defined group, general population, and ongoing study), type of data collection (new data collection, routinely collected data, previously collected data), and total study size. The mean number of subjects was computed for each grouping of research reports. The computations were carried out separately for studies below 100,000 and those above 100,000 subjects. Excluded from the computation of means were research reports based on large national populations like that of the US.

Statistical Results of the Review

The mean number of subjects in birth cohorts at enrolment was 13,614. Table 1 shows the mean number of research subjects according to study design and data collection methods for the rest of research reports. The data shows a tendency towards large studies above 1000 research subjects.

Table 1. Statistical results of the review: mean number of subjects

		Mean (for no. of subjects <100,000)		**Mean (for no. of subjects >100,000)**	
		Defined groups	**Population**	**Defined groups**	**Population**
Cross-sectional	Newly collected	2,627	10,275	6,240,130*	-
	Routinely collected	810	13,963	-	925,704
	Previously collected	1,245*	1,067	-	-
Case Control	Newly collected	1,840	1466		-
	Routinely collected	1,330	1628	1,194,357	-
	Previously collected	-	-	-	-
Non-birth Cohort	Newly collected	4,038	-	246,146*	-
	Routinely collected	28,293	31,164	1,299,177*	-
	Previously collected	56,214*	-	-	-
Randomised	Newly collected	3186*	-	-	-

* Based on a single research report

Sample Epidemiology

To understand the brave new world of population epidemiology, we need to remind ourselves of the erstwhile sample epidemiology. In this review, the word population is used in its true meaning of referring to a large number of humans and not in its statistical meaning that refers to a set of objects (humans, non-humans, or events) with a common observable characteristic or attribute.

Before the information age, epidemiologists made other researchers envious because they could get information easily from small samples and could make inferences about the general population at minimal expense. Sampling for survey research underwent a lot of change since it was first introduced in the closing years of the 19th century. Sophisticated sampling methods and theories were developed to ensure that sample-based inferences reflected population reality. Statistical analytic techniques suitable for small samples (the student *t* test and Fisher's exact tests) were developed for analysis of very small samples because large sample statistics did not give valid answers. The vision was to be able to reach valid inferences using hand calculators and from the smallest sample possible.

In the early period, there was no alternative to small samples. Sophisticated data management and data analysis software capable of handling large data sets were not yet available. Epidemiologists preferred sample to population studies because data collection from a sample was logistically easier and financially more cost effective (the biggest impact from the least expenditure in terms of manpower, time, and money). Data from samples was considered more accurate and of higher quality because the epidemiologists had a smaller number of research subjects to work on and could have 'personal' knowledge of the research subjects and their data. This knowledge could enable epidemiologists spot inconsistencies and errors in the data. It could also enable them identify potential confounders more easily and realistically.

A sample was supposed to be a representative subset of the population but this might not be true in practice and disastrous conclusions could result as happened in the US presidential election of 1936 (2). Sampling started by defining a sampling frame which was enumeration of the population by sampling units (a technical term for individuals to be sampled). The arduous task was assembling the sampling frame; the actual sampling being thereafter relatively easier.

At the beginning simple random sampling was used when the population was approximately homogenous. It was realised that simple random sampling did not perform well in representing various sub-groups of a heterogeneous population. Stratified random sampling was developed to make sure that that the eventual sample correctly represented the population heterogeneity. In this type of sampling the population was divided into approximately homogenous groups and simple random sampling was carried out in each group separately with the samples derived being combined to make the study sample. Other techniques used to improve the practical logistics of random sampling were: sampling with unequal probabilities (if it was desired to over-represent one segment of the population), systematic sampling, cluster sampling, and multi-stage sampling. Development of computer technology and existence of databases on local and area wide networks make simple random sampling much easier because construction of sampling frames became easier and databases over long distances could be sampled and analysed while sitting at one's office desktop computer.

Probability theory enabled inferring sample data to target population. Probability theory also enabled assessment of precision and avoidance of bias in sample selection. If the sample was selected at random and if the assumptions of the central limit theorem held, sample data represented accurately the underlying population probabilistic events and sample distribution corresponded to the population probability mass function or the probability density function. Relationships found in samples were inferred to be the same as those in the population and sample data was used to predict population parameters. The validity of inferences based on samples was not questioned for a long time however a few doubts did surface for example extrapolation from sample to the general population was found to be unreliable empirically (3).

Concern about precision and bias was always a nagging problem in sample epidemiology for fear that public health decisions based on sample data might not reflect the reality in the population. Despite all measures taken to ensure that samples accurately represented population experience, epidemiologists were aware that sampling errors and sampling biases were inevitable. Statistical theory and practice therefore, developed to characterise and measure the magnitude of sampling errors and sampling biases and thus be able to assess their impact on the conclusions from data analysis. The accuracy of estimators could be expressed as a function of sample size, population size, and probability characteristics. It was therefore, obvious that the larger the sample the more precise were the estimates. The problem of precision was addressed by giving effect measures with 95% confidence intervals quoted around them to indicate the degree of precision. The larger

the sample size, the narrower the confidence interval, and hence the higher the precision. There reached a point at which further gains in precision were not worth the expense of increasing sample size. Techniques for dealing with bias (confounding, misclassification, and selection biases) were developed to prevent bias at the design stage or cure it at the analysis stage.

Epidemiological studies based on birth cohorts

Birth cohorts were used over the past half-century to provide longitudinal and cross-sectional information (at 'sweeps' carried out every few years). The primary motivation was mostly from governments that wanted to obtain data for formulating health policies (4, 5). The study of birth cohorts enabled understanding the natural history of morbidity as well as the longitudinal relationship between risk, disease, and health-related behaviours (4). Theay could have the advantages of being national in representation if recruited from the general population (5, 6). They had the advantage of longitudinal data collection (5) which enabled linkage of childhood experience with adult disease outcomes (4). Data quality was high because of trained and experienced researchers (5) who worked on the same study for years. Comparisons among cohorts enabled studying secular changes in risk factors and disease outcomes as well as the relationship between the two. Usually cohorts generated more data than the investigators desired or could analyse. There were therefore, a lot of data archives that could be mined by later researchers. Data from birth cohorts was increasingly available to other researchers (7) sometimes on online for free or at a fee (4).

Table 2 shows details of birth cohorts covered in this review. The cohorts were recruited as babies born in a certain week of a year in the whole country (4), a city (6), or a part of the country. The cohorts were followed up until adulthood. Data was collected either from the whole cohort or from a sample (5). Collection from the whole cohort was preferable to sampling (8). Birth cohorts could also be animals for example a birth cohort of cattle was studied to investigate BSE (9).

Table 3 shows the range of information collected from birth cohorts. Data collection was more frequent in infancy and childhood but less frequent in adulthood (5). Data was collected by postal questionnaires (5), interviews by trained researchers (5) or by telephone. In many cases, information was obtained directly from data bases of routinely collected administrative, vital, and health data. This was possible because of data linkage using unique identifying numbers enabled assembling data from population registers, disease registers, pharmacy records, hospital records, conscript data, and death registers (7, 10). Some cohorts were based solely on data linkage for example the Stockholm Birth Cohort Study of 1953. Linkage to parents' data was also done (10). Record linkage also enabled tracing from anonymized records by matching certain variables (10, 11).

The main cause of loss to follow up was change of address by participants who failed to notify the study administration of their new address (4). A second cause was refusal to participate at subsequent sweeps. Death was a minor but expected cause of loss to follow up. A few were lost due to emigration.

Recorded losses to follow up were small. In 2004, 16,078 members were traced; this represented 91% of the 17,634 recruited in 1958 in the British Birth Cohort (4). At age 53, 82.6% of the original 1946 British Birth Cohort was contacted and they provided

Table 2. Studies of birth cohorts

Authors and Ref	Years	Place	Title	No of Subjects
1. Wadsworth *et al.* (5)	1946	UK	1946 National Birth Cohort	16,695
2. Leon. (11)	1950-	UK	The Aberdeen Children of the 1950s Study	12,150
3. Osler *et al.* (7)	1953-	Denmark	The Metropolit 1953 Danish Male Birth Cohort	12,270
4. Stenberg *et al.* (10)	1953-	Sweden	The Stockholm birth cohort of 1953	15,117
5. Power *et al.* (4)	1958-	UK	1958 British Birth Cohort	17,000
6. Elliott *et al.* (12)	1970-	UK	1970 British Birth Cohort	17,287
7. Victoria *et al.* (8)	1982	Brazil	The 1982 Pelotas (Brazil) Birth Cohort Study	5,914
8. Inskip *et al.* (6)	1998-	UK	The Southampton Women's Study	12,579
			Mean	13,614

Table 3. Data collected from birth cohorts at various phases of the life cycle

Ante-natal:	Socio economic data, socio demographic data, maternal smoking, maternal hypertension, labour and delivery, ante-natal care.
Infancy:	Birth weight, perinatal morbidity, neonatal morbidity
Early childhood:	Nutrition, immunisation, anthropometry, morbidity, development (physical and cognitive), education
Later childhood:	Morbidity, Behaviour, Anthropometry, Vision, Psychological assessment, Development: cognitive, education
Adolescence:	Morbidity, behaviour, anthropometry, vision, development, puberty, education
Young adulthood:	Morbidity, vision, psychology, anthropometry, smoking, alcohol, physical exercise, education, work fertility, contraception, sexual practice, health KAP
Middle age:	Reproductive history, emotional problems, morbidity, nutrition, cardiovascular assessment, respiratory assessment, anthropometric assessment, cognitive assessment, mental health assessment: depression, midlife/menopausal issues, neurological assessment, hearing, life style: alcohol, smoking, drugs, religious practice; health seeking behavior: exercise; vision; hearing; work; partnerships
Others:	Environment, health services utilisation

information (5). The Stockholm Birth Cohort of 1953 had an attrition rate of only 4% (10); this being explained by the ability to trace persons using large databases. The Aberdeen Study was able to trace 99% of the original cohort using government records (11). Losses to follow up due to refusal were also low. In the 1958, British birth cohort refusal rates were 7.1% at age 23, 11.1% at age 33, and 13.2% at age 42 (4). Follow up of children in the Southampton study was 95, 93, 86, and 81% at 6 months, 1 year, 2 years and 3 years respectively (6). Losses due to death in the 1946 British Birth Cohort were 8.7% at age 53 (5). Losses due to emigration were 8.6% (5) and to living abroad were 2.2% (5). Problems of attrition progressively lessened over the past twenty years because of availability of government or health insurance records about citizens that enabled tracing those who had changes addresses. Some information about those lost to follow up could still be obtained from data bases such as those of health insurance (5), cancer registries (5), and population registers.

In the pre-1980 era, fewer variables were collected because the work was manual and too much data could not be handled efficiently. Limited funding sources could also have contributed to limiting the amount of information collected. With availability of information technology and more funding as the value of cohort data was appreciated by funding sources, more data was collected. However, not all of the data was collected directly from the cohort participants. Researchers had access to population and health data bases and using various forms of data linkage could obtain information on cohort participants.

Data collection over a long period spanning decades had its own problems. It was difficult to maintain consistency of the data for accurate longitudinal analysis because the type and may be the quality of data collected could change with time. The relevance of some forms of data could also vary with socio-demographic changes and development of biomedical knowledge. Over long periods of follow up of up to 50 years, administrative and scientific responsibility for the cohort changed from one institution to another accompanied by changes in procedures (4). The coverage and objectives of the study could also change in response to new scientific knowledge or social and lifestyle changes in the community. In some cases, cohorts were abandoned and some were revitalised later when funding became available and new interests developed (11).

The frequency and intensity of follow up varied according to availability of funding (8). Funding sources changed as interest in the cohort waned or grew (4). Funding agencies could develop fatigue in funding a study running over decades (8).

The impact of cohort studies on policy was profound (4). This is not surprising because this was their raison d'etre. They also influenced health knowledge and practice by their voluminous publications. As of 2006, a total of 900 publications issued out of the 1958 British

Birth Cohort (4). As of 2006, a total of eight books had been published from the 1946 British Birth Cohort (5). The 1953 Stockholm Birth Cohort Study generated more than 100 publications (10). The 1970 British Birth Cohort generated over 300 publications (12).

Epidemiological Studies Based On Defined Groups

Defined groups were used by epidemiologists to study disease consequences of specific exposures. Defined groups were opportunities of getting data from a captive population that was easy to reach. They were identified based on geographical / political units or a defining characteristic of relevance to health. Epidemiologic opportunism was used when participants in a previous study were identified as a defined group for new research (13, 14).

Many studies were based on groups defined on the basis of geography or institution. The Framingham Heart Study based on a middle class cohort in the town of Framingham in Massachusetts USA, was one of the most famous geographical cohorts. The Mexico City Prospective Study involved following up 150,000 adult men and women aged 35 years to study risk factors of mortality (15). The Guangzhou Cohort Study followed adults and collected biological samples (16). Several ways of assembling and studying cohorts were used. Some cohorts were assembled by linkage of databases (17). Some cohorts were recruited at a significant event such as entry into school (18). Geographically defined groups were often rural or urban communities (19, 25). Disease outbreaks on isolated islands provided opportunities to study a whole community (26). The information obtained was useful for outbreak control and also for further analysis of other epidemiological hypotheses.

Military groups were studied because of good military record keeping. Studies were made of military recruits, conscripts, volunteers (27, 29) and war veterans (30, 31). Educational institutions were used because of ease of subject identification, access, and follow up. Research was carried out in schools (32, 35) and universities (36). Civil servants were a very stable and a cooperative group (37) liked by researchers. Occupational groups with unique exposures were explored at low cost such as textile factories (38, 39) and pesticide workers (40). Research was based on groups that experienced an event of health importance such as birth (41) or travel overseas to disease endemic areas (42). Studies were carried out on population groups with unique characteristics such as homosexuals (43), and members of HIV clinics (44).

Health facilities such as physician clinics provided a good opportunity for recruiting study subjects (45, 46). Networks of general practitioners collaborated by providing research data on their patients (47, 48). Some of this data was available in databases (49, 50). Data was also obtained from prenatal clinics (51, 52) and obstetric practices (53). Expectant mothers provided a stable pool of subjects who could be observed over a period of time and whose children could be recruited into cohort studies. Research was also based on patients on the ward (54, 55).

Health insurance organisations (56) and health maintenance organisations (57, 58) recruited a large number of participants counted in the thousands and had records on them spanning a long period of time. They had a lot of routinely collected data that could be analyzed to test hypotheses about healthcare delivery systems. Health related data was obtained from hospital admission records (59, 61), hospital discharge records (62), and other hospital data (63, 64). Hospital medical record departments were a rich source of data that was not exploited because of missing and incomplete information. Use of medical records may need to be supplemented by interviews (65) to obtain the missing information. Biological specimens like blood were collected from visitors to health centres (66), hospitals (67), blood donation centers (68).

Completed or on-going cohort studies have been used as a convenient source of study subjects for new studies. This practice is becoming a regular feature of research (69, 70). Recruitment of research subjects from other studies is facilitated by availability of data on socio-demographic and biomedical variables. Even more important is availability of contact information and familiarity of the subjects with being participants in research.

Epidemiological Studies based on the General Population

Large data studies attempted to collect information from the general population. This process was very daunting in the past when the decennial census was the only population-wide data collection undertaken. With availability of extensive data bases on social, health, and demographic variables about whole cities, districts, or even nations, collection of data from the general population has become an armchair exercise. Population-based research could be analysis of data from national health surveys (71). Such data was collected at great expense and was stored with minimal analysis. It was better for a researcher with a new hypothesis to analyse existing data than to go out to collect new data. Data covering several countries was obtained from international organisations such as the United Nations and the World Health Organization (72). Such data enabled study across many countries

of death rates (73), cancer incidence rates (74), and morbidity rates (75). Case control studies had been touted as having the advantage of getting information using a few subjects counted in the tens but the new era witnessed population-based case control studies with thousands of subjects (76, 86).

Studies were based on registries of diseases such as stroke registers (87), cancer registers (88, 89, 90, 91, 92), myocardial infarction registers (93), and congenital anomalies registers (94). Prescription data bases (95) could be linked with other data bases to explore many interesting hypotheses. Subjects identified from the electoral roll (96) could be recruited into research projects.

It was a bureaucratic paradox that a lot of socio-demographic and health-related data (census, vital statistics, and routine healthcare data) was collected at great expense with limited benefit. The data was a mine of information that researchers should have used to learn about health and disease in populations. Only a few statistics were usually published for administrative purposes. There were, however, some attempts to make use of that data. Using vital statistics data, analyses were made of death records (97, 104). Health data collected in the general population census contributed to public health (105). Disease notification and surveillance data was analysed (106, 111). With the ease of data access from databases, it was not surprising that one study might obtain data from more than one source for example data from vital statistics could be combined with data from a survey (112). Existing records of previously collected data were exploited with new analyses or repeat analyses using either new techniques or testing novel hypotheses. Analysis of historical data (113, 114) provided information on disease and risk factor trends.

Data linkage became an increasingly dominant mode of research. It enabled studying causal relations while controlling for a wide range of potential confounding variables. Vaccination data was linked to hospitalisation data (115, 116). The population register was linked with the psychiatry register (117), the multiple sclerosis register (118), social insurance data base (119), and mammography screening data (120). Birth data was linked to mortality data (121, 122) and health records (123). Census data was linked to mortality data (124, 125). Military data was linked to occupational, hospital, and death data (126, 127) as well as to population data (128). Autopsy records were linked to police records (129). Reproductive outcome data was linked to occupational data (130).

Even the random sample had a renaissance with many publications mentioning population-based random samples that were often very large (131). This was because the logistics of data collection were easier with large population-based data bases that supplied the sampling frame (132). Random samples were taken from towns (133), and population registers (134, 139), and schools (140). In the age of sophistication, reports of convenience samples were published (141) showing that old habits die hard.

The environment became a subject of intense political interest and spawned many studies. Existence of continuous environmental monitoring systems contributed to large data epidemiology. Studies were based on linking routinely collected environmental data with routine health data (142, 149).

Future frontiers

We can extrapolate into the future of population epidemiology. Web-based data collection will become common. Other data sources like credit card data will be used. Video recording of signs will be possible by video cameras attached to personal or laptop computers. Small hand held laboratories may be mailed to people in their homes and they may put biological samples like urine or saliva for analysis with the results being transmitted online to the data center. Some of these ideas look like science fiction today but could well become the daily reality within a few years.

Using online data collection may open up new frontiers but few epidemiologists so far have experience of virtual world research. A feasibility study of web-based questionnaires was carried out in Sweden (150). It investigated differences in response between a group invited to answer a web-based questionnaire and another group invited to answer a paper questionnaire. The web-based questionnaire had a higher response. There were no significant differences in socio-demographic and health-related variables between the two groups of responders. The investigators concluded that web-based questionnaires were a feasible tool for data collection in large population based epidemiological studies.

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