

The Development of Modern Epidemiology

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Health services research and epidemiology

Kerr L. White

Personal experiences

Immersion in economics, especially the views of John Maynard Keynes, Eliot Dunlap Smith, Ida M. Tarbell, and Thorstein Veblen, at McGill and Yale universities as an undergraduate and graduate student in the 1930s stimulated my curiosity about the impact of social and economic factors on health and disease. A stint in a factory personnel department, organization of a successful employees' strike and Second World War army experiences abroad under-girded my decision to study medicine. In the late 1940s McGill provided superb clinical education but painfully tedious public health lectures that featured detailed specifications for digging pit privies and canning tomatoes. In my final year, however, I encountered John Ryle's (1889–1950) slim volume *Changing disciplines* (Ryle 1948). Here was the former Regius Professor of Physic (Medicine) at Cambridge embracing both clinical and population perspectives in his new Institute of Social Medicine at Oxford. We corresponded about my spending a year with him but sadly he died prematurely.

Ryle's example strengthened my resolve to complete residency and fellowship training in internal medicine; that was where the profession's intellectual and academic power resided. Prior to the advent of the randomized clinical trial (RCT), 'tests' of the benefit of cortisone involved asking patients hourly whether they 'felt better' or advising them to 'take this—you'll feel better'. The Professor of Medicine, J. S. L. Browne, encouraged my unorthodox interests in questioning the therapeutic impact of physicians' authoritarian certitude about many interventions. He introduced me, a Canadian, to Lester Evans of the Commonwealth Fund in New York who, in turn, referred me to the first new post-war medical school at the University of North Carolina (UNC) where the opening gambit was a 1952 seminar on 'Needed research in health and medical care'. Jerry Morris gave the key-note address which he later enlarged in his classic volume *Uses of epidemiology* (Morris 1957).

Joining UNC's Department of Internal Medicine without formal training in epidemiology (i.e. the study of that which is upon the people) it was my good fortune to work with such innovative investigators as epidemiologists Sydney Kark and John Cassel and biostatistician Bernie Greenberg. They indoctrinated me into the concepts and methods of epidemiology and health statistics. Early publications in the 1950s included the first population-based survey of cardiac failure (with Michel Ibrahim); the first analysis of outpatient medical errors disclosed by record audits (with Bob Huntley); and the first state-wide investigation of patient referral patterns to consultants and academic medical centres (with Frank Williams). These were not problems that appealed to our biomedically oriented colleagues who considered them 'weird'.

The evolution of health services research (HSR) has had many twists and turns. It is the purview not of a single discipline but rather of a wide range of scientists with varied skills whose task is to investigate a hugely expensive and mal-distributed essential human service enterprise. Of the three venues for investigating problems of health and disease—the individual, the laboratory, and the population—the great bulk of HSR has in common the population perspective. Epidemiological methods and 'epidemiological thinking', based on fundamental contributions of earlier French,

Belgian, and British statisticians, are central features. In addition to trained, certified, and self-proclaimed physician and non-physician epidemiologists, HSR is conducted by administrators, anthropologists, clinicians, demographers, economists, nurses, political scientists, psychologists, social workers, sociologists, statisticians, and others. Although the majority embraces the population perspective, most also incorporate one or more of the administrative, biomedical, clinical, financial, organizational, psychological, and socio-economic world views (White *et al.* 1992).

The United States National Academy of Sciences' Institute of Medicine defined HSR in 2000—its most recent iteration—as 'the multidisciplinary field of inquiry, both basic and applied, that examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health-care services to increase knowledge and understanding of the structure, processes, and effects of health services for individuals and populations'. At its founding in 1957, the British Society for Social Medicine stated that its turf encompassed 'epidemiology, the study of the medical and health needs of society, the study of the provision and organization of health services and the study of the prevention of disease'. The terms employed in the overlapping sub-fields of HSR include in alphabetical order: clinical economics, clinical epidemiology, clinical evaluative sciences, evaluative health sciences, evidenced health care, evidenced based medicine, health economics, health policy research, health systems research, health-care research, medical care research, outcomes research, patient care research, population health research, technology assessment, translational research, and probably others. They are used alone or in combination; distinctions are often difficult and there is little point in trying since labels come and go—as many have (Daly 2005).

Initially epidemiological concepts and methods were employed by physicians without formal training. The latter only began in 1918 with Wade Hampton Frost (1889–1938) at Johns Hopkins and in 1928 with Major Greenwood (1880–1949) at the London School of Hygiene and Tropical Medicine (LSHTM). From its earliest days epidemiology buttressed by the mounting importance of bacteriology had focused largely on communicable diseases—then and still an enduring 'bug hunt'. Only later, primarily in Britain, did epidemiologists start tackling non-communicable disorders. Academic interest in evaluating medical care manoeuvres and the workings of health services was minimal until mid-century.

Ideas for evaluating the relative benefits, risks, and, only recently, the costs of medical interventions and health services are, however, not entirely new and they are far from free of political reverberations. The first twentieth-century manifestations of curiosity about clinical ministrations in medicine's hallowed halls are attributed to the Boston surgeon, Ernest A. Codman (1869–1940). Shunned by Harvard's Massachusetts General Hospital for attempts to document hospital surgical outcomes he resigned to start his own 'End Result Hospital' from whence he published all errors (e.g. 123 in 337 patients). Later J. Alison Glover (1876–1963), a UK Health Officer, identified wide disparities in children's tonsillectomy rates among otherwise similar geopolitical jurisdictions—the 'Glover phenomenon' (Glover 1938). Paul A. Lembcke (1908–64), a distinguished epidemiologist at Johns Hopkins in the 1950s, is best remembered for reintroducing Florence Nightingale's and Codman's insistence on auditing hospital outcomes (Lembcke 1956). Sadly Glover's and Lembcke's findings attracted little interest from the broader medical profession.

Times have changed, and now most medical and public health schools in the developed world, and many elsewhere, have units or departments whose titles vary but whose major function is HSR. In the latter part of the twentieth century epidemiological, i.e. population-based, thinking in one guise or another played a necessary, if not always sufficient, role in the rapid ascendancy of HSR. Its origins warrant recounting.

In 1946 the United States Congress passed the Hill-Burton Hospital Construction Act to improve services nationally, especially in underserved areas. Research directed at improving

hospital facilities began in 1949, but not until 1955 did Congress provide the first \$1.5 million for 'research in hospital *operation and administration*'. Two unsung Federal bureaucrats persuaded Congress to add these funds and a new mandate that included something called 'medical care research':

The widest latitude is allowed by the wording of the law to permit such research and demonstrations in the hospital *and related fields* [emphasis added]. There is almost universal agreement that required information is lacking in many unexplored areas. At the same time, it is recognized that there are few current methods that are not susceptible to improvement

(Cronin and Block 1956).

About 1956 a small body conducting what we called patient care research (later medical care research), supported by the new Hill-Burton research funds, started meeting periodically to discuss findings. The largest group (Bernard Greenberg, Robert Huntley, Frank Williams, and the present author) was at the University of North Carolina; others were at Cornell University Medical School (Barbara Korsch, George Reader, and Doris Schwartz), the New York City Health Department (Paul Densen and Sam Shapiro), and Harvard's Beth Israel Hospital (Sydney Lee, Cecil Sheps, and Jerry Solon). Later the renowned annual Atlantic City Meeting was added to our venues. There, amidst gatherings of the major medical scientific bodies, we presented our work at the 'patient care research section'. By the 1960s, however, our enthusiasm for this grand venue had waned as biomedical research increasingly dominated the interests of most attendees. There was no longer an academic meeting place or professional home for the expanding band of young academics exploring the workings of patient care and health services.

Responsibility for reviewing applications for the new Hill-Burton research funds was assigned in 1955 to the US National Institutes of Health's (NIH) Division of Research Grants. A mixed bag of study sections with such labels as sanitation, public health methods, and nursing (concerned with patient care) existed and now there was to be a newly established Hospital Facilities Research Study Section; I joined it in 1957. These and seven barely related study sections were designated the 'Health Services Group'.

To consider future research needs bearing on provision of health care the Hospital Facilities Research Study Section took the initiative by establishing a subcommittee. In March 1959 responding to its solicitation for ideas I wrote:

Should we not encourage the redefinition of 'hospitals' and possibly of the [Hospital Facilities Research] Study Section's functions? ... Should we not spell out what is either stated or implied in the Hill-Burton Act that we are concerned with all facilities, including private physicians' offices, health centers, clinics, diagnostic facilities, industrial health offices, rehabilitation centers, health departments, outpatient departments and inpatient services, both general and specialized, to the extent that they contribute to the medical care needs of society? We have certainly reviewed and sponsored grants in many of these areas.

Should we not encourage studies and approaches that have as their base the health problems of the populations concerned rather than the institutions currently serving those needs? What are the medical care needs of various groups? Who are the patients? Which populations need care—preventive, diagnostic, therapeutic, and rehabilitative?

What economic, social, psychological, cultural, and informational factors inhibit or facilitate access to the best medical care at the earliest phases of disease? Who is to render this care? What health personnel must be educated or trained? How can these professional workers best be organized? What facilities are needed for them?

Perhaps the Study section should have its name changed to the Health Facilities Research Study Section or the Medical Care Research Study Section.

Later in the spring of 1959, following deliberations of that subcommittee, a joint meeting of the Nursing and Hospital Facilities Research Study Sections considered their missions. In 2000 no minutes of that historic meeting could be found in the NIH archives but Cecil Sheps (another Canadian), former Chair of the latter study section, and I, the only living members of that gathering, compared recollections. Neither recalled who introduced the term ‘health services research’ but both enthusiastically favoured it and are certain the new label arose at that meeting. The group unanimously recommended that it supplant the current term Hospital Facilities Research Study Section, much preferring it over other labels such as medical care research, health facilities research and health resources research. On 1 September 1960, James Shannon, Director of NIH, officially decreed the change to Health Services Research Study Section. But a name change does not a research ‘field’ create and certainly not a distinct ‘discipline’.

In the interim, my 1959–60 sabbatical year had included formal courses in epidemiology and health statistics at the LSHTM with Donald Reid and Bradford Hill, an intellectual base with Jerry Morris at the London Hospital, extensive visits throughout the UK and Europe to individuals concerned with health services and related epidemiological research, and induction into the International Epidemiological Association (IEA) which had been founded in 1954. To these collective experiences and the friendships established I owe most of the ideas and methods used in attempts in the USA to ‘spread the gospel’ of HSR—a phrase employed by Robert Cruikshank, the IEA’s first president.

In the UK, Walter Holland, trained at the LSHTM and Johns Hopkins was a leading player in broadening the applications of epidemiology and especially its role in HSR. In 1962 he joined St Thomas’ Hospital’s Medical School, London and in 1964 founded the first ever Department of Clinical Epidemiology and Social Medicine. A majority of its many publications, especially those dealing with outcomes, are best categorized as HSR. One of Holland’s more influential contributions questioned the benefits of multiphasic screening—a notion being aggressively touted in the USA. Over the decades, in addition to fostering the development of HSR, Holland has trained and mentored numerous distinguished UK epidemiologists as well as others from distant lands, including the USA (Holland 2002).

Meanwhile, in 1962, on assuming chairmanship of the Health Services Research Study Section (the only member with training or experience in epidemiological research), I selected as its new Executive Secretary, Thomas McCarthy PhD. During our initial discussions McCarthy, having just completed an NIH grants associates training programme, emphasized that study sections in addition to ‘reviewing research grant applications’ were responsible equally for ‘defining and developing their respective field, stimulating needed research and improving the field’s quality and credibility’. McCarthy was impressed by the work of the Biophysics and Biophysical Chemistry Study Section in developing its new and comparatively unknown field. Based on their experiences we proposed strategies for promoting the strange new arena of HSR. Our ideas were endorsed enthusiastically by all study section members save one—a state Commissioner of Public Health. He argued that ‘the government’ had no business investigating the clinical activities of doctors and hospitals.

Pursuing five major initiatives over several years we:

1. developed criteria for and funded four types of research—exploratory, pilot, project, and program grants;
2. made ‘evangelical’ site visits to educate applicants who proposed tackling complicated problems with trivial methods and vice versa;
3. developed criteria for and generously funded a core of health services research centres at major research universities;

4. described the field's current status by commissioning and publishing 14 papers by eminent academics delineating many facets of health services amenable to scientific and scholarly inquiry (Mainland 1966);
5. visited major organizations concerned with the provision or over-sight of health services, e.g. the American Medical Association, the American Hospital Association, the US Center for Communicable Diseases, the California Health Department, and Puerto Rico's health department, new medical school, and regionalized health services.

All this was not accomplished easily. Officials of the then US Department of Health, Education, and Welfare (DHEW) denied us permission to visit the American Medical Association claiming we were 'treating with the enemy'. We went anyway and the bill was paid. Similarly we were denied approval to send study section members to visit British and Scandinavian sites of emerging health services research on the grounds that we could contaminate the 'American way' by 'picking up a lot of "socialistic" ideas'. We sent them anyway and the bill was paid (McCarthy and White 2000).

A new field requires several types of enabling 'tools' to thrive. For example, little HSR can be accomplished without primary databases. Florence Nightingale designed the first hospital discharge abstract form in the 1860s and the UK introduced its Hospital In-Patient Enquiry (later the Hospital Activities Analysis) in the 1950s. With these in mind our group at Johns Hopkins organized three international conferences to examine the need for and recommend examples of uniform minimum data sets (UMDS) for ambulatory care visits, hospital discharge abstracts, and long-term care status abstracts. Over the years the DHEW, its National Center for Health Statistics (NCHS), and other bodies adapted and adopted UDMSs; they have made possible much HSR.

Ambulatory care was a black box insofar as medical education and organization of services were concerned. Modelled after early 1950s surveys by the Royal College of General Practitioners and the UK Registrar-General's Office, the NCHS initiated in 1974 the National Ambulatory Medical Care Survey (NAMCS) designed by our group at Johns Hopkins using epidemiological survey methods (Tenney *et al.* 1974). The NAMCS' periodic reports described the largest component of health services—the content of office-based care—and became the most sought after in NCHS history. Ambulatory care research, especially the study of 'episodes of care', stimulated creation of the 'International Classification of Primary Care' (ICPC) to augment the International Classification of Diseases (Lamberts and Wood 1987). It is now incorporated in the US National Library of Medicine's Unified Medical Language System (UMLS).

A new field requires its own journals. The first was *Medical Care* started in 1963 by Bram Marcus, medical correspondent for *The Observer* of London, and published by Pitman's. Unfortunately interest flagged and as an Editorial Board member I learned of its imminent demise and negotiated transfer to the USA for publication by J. B. Lippincott; it flourishes to this day. In 1963 the American Hospital Association sought NIH funds for a new journal to be called *Hospital Research*. A study section team went to Chicago to help them understand that if they wanted the money they should broaden their horizons and call the journal *Health Services Research*. Reluctantly they agreed and the journal flourishes to this day. In 1970 Vicente Navarro, a protégé of John Brotherston's at the University of Edinburgh, my first student at Johns Hopkins, and now a professor there, founded the *International Journal of Health Services*. Although emphasizing policy issues it frequently includes articles that invoke HSR to inform the positions taken.

The 'tools' required by a new field of enquiry are undoubtedly necessary but far from sufficient. Educational opportunities are essential for aspiring young investigators—especially physicians, since clinical activities of all kinds are a central feature of HSR. As an internist with epidemiological

training and experience I had concluded that one of the saddest episodes in the annals of medicine's mission to respond to society's health problems was the Rockefeller Foundation's decision in 1916 to establish schools of public health isolated intellectually, physically, and organizationally from medical schools. Although an understandable response by the Foundation to growing concerns about unaddressed public health problems, the unanticipated consequence of the decision was effective segregation of the population from the clinical and emerging biomedical perspectives. The Epidemiological Society of London, founded in 1850, was composed largely of physicians; epidemiology had long roots in clinical medicine. After 1916 in the USA and in many other countries, epidemiology's relegation to the new schools of public health deprived medical students and their faculties of experience with the requisite concepts and methods for examining the risks and benefits of medicine's interventions at both the individual and population levels (White 1991).

To restore this dysfunctional imbalance our Johns Hopkins department created a hybrid educational experience that enabled interested Hopkins' hospital house staff to integrate courses in epidemiology and HSR with their clinical training. This was not done easily. We had to overcome countless conflicting governance rules in Hopkins' separated schools of medicine and public health such as: hours of 'work', clinical rotation and course schedules, conference hours, semester dates, parking regulations, secretarial salaries, and more. We succeeded in attracting many superb candidates who on completing their training received MSc or DSc degrees. Training involved joint exercises with our other departmental graduate students who had prior degrees in, for example, economics, engineering, hospital administration, nursing, and sociology. With initial support from the Carnegie Foundation and the Commonwealth Fund, and then from the Robert Wood Johnson Foundation, the Clinical Scholars Program, as it was labelled, has flourished for over 30 years, spread to other sites and trained almost 1000 physicians in HSR. Most physicians currently leading this field have been Clinical Scholars.

There was also the matter of a Federal institutional research and funding body similar to NIH's components. Following a 1966 study section meeting in Chicago, Tom McCarthy, two other DHEW officials, and I repaired to our hotel's bar. On the back of a paper napkin we drafted a statement of the mission and organizational relationships of such an entity and labelled it the National Center for Health Services Research (NCHSR). We hastened to Washington, DC where the Association of American Medical Colleges (AAMC) was holding its annual conclave. Over the weekend as McCarthy and colleagues prepared a descriptive brochure I persuaded Bill Hubbard, AAMC president, to let me address the gathering; he agreed. Stony silence met my remarks; strange enquiries labelled 'health services research' should not be allowed to impinge on the deans' growing preoccupation with ever more generous NIH funding for biomedical investigations. A few of the more curious did pick up our brochure.

Nevertheless, all members of the study section supported our proposed NCHSR and I successfully lobbied senior DHEW officials about the need for it. Two exploratory commissions endorsed the idea and my testimony before Senator Ted Kennedy's Congressional Committee was well-received. In 1968 the US Congress established the National Center for Health Services Research and Development (NCHSRD). There is reason to believe that Shannon, a strong supporter of HSR, favoured placing the new centre in NIH where its credibility would be clearly vouchsafed. Unfortunately Shannon became seriously ill and the NCHSRD was placed inappropriately in the newly created and untested Health Services and Mental Health Administration (HSMHA) of DHEW. Paul Sanazaro was appointed founding director and Tom McCarthy his deputy (Flook and Sanazaro 1973).

I chaired the Center's Scientific and Professional Advisory Board (SPAB) that included such eminent scholars as Martin Feldstein, Eliot Freidson, Bob Haggerty, Gordon McLachlan, and Rosemary Stevens (two UK representatives for cross-fertilization). When asked about an early

meeting Sanazaro had with then DHEW Secretary Wilbur Cohen he reported that the Center's charge was to 'increase access to health services, improve quality, and reduce costs'. When asked how long Cohen gave the NCHSRD to accomplish all this Sanazaro replied 'six months'. The SPAB was flabbergasted but their advice to avoid over-promising and under-producing was ignored and the NCHSRD plunged ahead. During the ensuing years Congressional dissatisfaction mounted as problems of access, use, quality, outcomes, and costs of care remained unresolved. The Center never really overcame the over-promising. Sanazaro left in 1973 and was succeeded by other directors with limited expertise in research bearing on the provision and evaluation of health services.

During its first 20 years the Center funded much of the seminal research in HSR and initiated many useful contributions. One example was the development of government-wide software for use in the embryonic, but sadly ignored until recently, Electronic Health Record (EHR). Another was creation of the large-scale experimental medical care review organizations—an early national look at 'quality'. Unfortunately the NCHSRD focused excessively on health services investigators as its 'customers' to the neglect of politicians, administrators, other academics, and the public. During the early 1980s annual budgets were reduced by half (\$80 to \$40 million) with some improvement in 1987 to initiate the Medical Expenditure Panel Survey which, using sophisticated epidemiological methods, continues to this day. Nonetheless, the NCHSRD remained an obscure bureaucratic entity whose mission was poorly understood and whose products were of little help to busy members of Congress and the White House. That is except for the dramatic findings of two of our epidemiologically trained former Hopkins students, financed in part by the NCHSRD, Jack Wennberg and Bob Brook.

In 1962 while at the University of Vermont (in the first US medical school department labelled 'epidemiology') John Last (editor of the IEA's *Dictionary of Epidemiology*) and I, with the help of a generous NCHSRD grant, undertook to install in that small state a universal hospital discharge abstract system based on the UK Hospital Inpatient Enquiry. The opportunity to undertake this manageable task had made the Vermont job offer unusually attractive. The objective was to audit Vermont's use of hospitals much as Nightingale, Codman, Lembcke, and Glover had urged for 100 years. It was not an easy task and included my being paraded before the state medical society charged with trying to hatch a communist plot.

After my move to Johns Hopkins in 1965 one of our students, Jack Wennberg (also a McGill medical school graduate), at my suggestion, took a job in Vermont to undertake the hospital studies we had proposed. Wide small-area discrepancies were found not only with tonsillectomies (70% versus 20% by age 12) but also with Caesarean sections, spinal fusions, mastectomies, and coronary by-pass surgeries. His classic 1973 paper in *Science* established the depth and extent of the ubiquitous problems with variations in resources, utilization, and outcomes, demonstrated the practicality of using claims (discharge abstract) data for research, and challenged the received wisdom that 'more treatment is better' (Wennberg and Gittelsohn 1973). Wennberg, cerebral, well-versed in theory, and persistent, pursued path-breaking research and educational programmes as he created his internationally acclaimed Dartmouth Center for Evaluative Clinical Sciences. Among its many publications is the famed *Dartmouth Atlas of Health Care*. Based on Medicare data for the elderly, it graphically depicts nationally unexplained and unwarranted small-area variations in the overall costs of care and the rates for common procedures; the Glover phenomenon writ large. Discharge abstract data for the rest of the US population is still unavailable—a major limitation to investigating hospital activities generated for the entire population.

Bob Brook, a Resident in Internal Medicine at Baltimore City Hospitals (a Johns Hopkins programme), while a Clinical Scholar in our department, wanted to pursue ideas generated

by the 1962 UNC analysis of outpatient medical errors. He was forbidden to undertake a similar study at the Johns Hopkins Hospital. Accordingly, he conducted the study at the Baltimore City Hospital—a Hopkins affiliate. Brook's landmark *New England Journal of Medicine* paper, also in 1973, created a substantial stir by setting forth the many serious medical errors uncovered (Brook and Appel 1973). Brook, innovative, persistent, and articulate, mentored numerous acolytes and produced an extensive series of articles documenting dramatic variations in the frequencies, outcomes, and effectiveness of diverse treatments. He established an international reputation from his bases at the University of California (Los Angeles) as Professor of Medicine and Public Health and the RAND Corporation where he is vice-president and director of its health programme.

Wennberg's impressive testimony, bolstered by Bob Brook's equally voluminous studies, was accorded great weight by the US Congress. Together they were largely responsible for renewed and wider Congressional and professional support for HSR as NCHSRD approached a near-death experience. Their strategies with Congressional and White House colleagues enabled Wennberg and Brook to play essential roles in broadening the moribund Center's base and mission. In 1989 Congress substituted the term 'care' for 'services', added 'policy' to its title, dramatically expanded the mandate to include outcomes research and transformed the NCHSRD into the Agency for Health Care Policy and Research (AHCPR). Of greater significance, the enabling legislation elevated AHCPR in the bureaucracy to a par with NIH and increased its budget substantially, albeit to only about 1% of NIH's. Nevertheless, for five more years under the leadership of yet another director with modest experience, AHCPR underwent endless turbulence in productivity and perceptions by politicians and health professionals.

In 1994 Cliff Gaus, former Chief of the Office of Research and Demonstrations in the Health Care Financing Administration (HCFA), and another of our Hopkins' students, was appointed AHCPR's second director. In spite of his epidemiological orientation, extensive research and governmental experience, political astuteness, and gregarious nature, the agency's mission was again brought into question. Many factors were at work, including a dramatic change to Republican dominance in Congress. The tipping point was AHCPR's publication of evidence-based 'best-practice' guidelines for assorted disorders, including 'low back pain'. With devastating effect this treatise was attacked aggressively and relentlessly, both academically and politically, by orthopaedic surgeons, especially the North American Spine Society.

Almost every critic seemed to deplore the government-developed guidelines but believed that the gathering and synthesis of epidemiological and outcome data in advance of promulgating the guidelines was extremely valuable and could not be accomplished without government assistance. After extensive consultation with hospitals, health-care 'plans' and professional groups, Gaus terminated the original guideline exercise and created a new programme consisting of 12 evidenced-based practice centres. With the focus changed and better partnerships achieved with most health-care stakeholders, Congress gave AHCPR a new lease on life and continued funding. The development of evidence-based guidelines by health-care organizations has flourished ever since.

Gaus decided that AHCPR needed new leadership, and in 1997 brokered the appointment of John Eisenberg, Chair of the Department of Medicine and Physician-in-Chief at Georgetown University, as his successor. Eisenberg was a brilliant choice. Not only was he a superb clinician and politically skilful but he was a nationally known health services investigator trained in economics, widely experienced in epidemiology, and former chair of the Physician Payment Review Commission. With yet another name change in 1997 to the Agency for Healthcare Research and Quality (AHRQ), the Federal focus of HSR flourished under Eisenberg as

never before; staff, budgets, grants, reports, and support grew rapidly. Both political parties, as well as academic and professional organizations, recognized its critical role in improving the country's increasingly tattered and costly health services. Eisenberg's untimely death in 2002 was a severe blow to the entire HSR establishment but he left an institution (as well as its building named after him) that enjoys well-earned national and international reputations.

Carolyn Clancy, originally appointed by Cliff Gaus as Director of the Center for Outcomes and Effectiveness Research, succeeded Eisenberg. She was trained in clinical epidemiology when both were at the University of Pennsylvania.

AHRQ has done as much as any US Federal or non-profit entity to foster recognition of epidemiologists' essential contributions to the improvement of health services. Its tortuous political, labelling, and budgetary travails are testimony to the need for better professional and political understanding of the population perspective in addition to the biomedical (Gray *et al.* 2003). The Commonwealth Fund, Kaiser Family, Kellogg, MacArthur, Pew, Robert Wood Johnson, and Rockefeller foundations and the Milbank Memorial Fund, have all actively supported HSR and its epidemiological component. The latter foundation during the 1970s and 1980s, under Robert Ebert, former Dean of the Harvard Medical School, had a substantial programme training young American clinicians at the LSHTM under the late Geoffrey Rose—chosen because of his clinical experience and orientation. Many are now leaders in HSR.

Theory is also essential. During the last half century no one contributed more to the underlying theoretical framework for most HSR than the late Avedis Donabedian (1919–2000), an unusually modest and unassuming physician with epidemiological training and a towering intellect. Starting in the 1950s at Harvard and later at the University of Michigan, single-handedly, he wrote numerous papers and a classic three-volume treatise that divides and dissects health services into the basic modalities of 'structures, processes, and outcomes'. Written with unusual insight, clarity, and wit these volumes must surely be the contemporary 'bible' for this nascent brand of scholarship and science (Donabedian 1980, 1982, 1985).

Another requirement for any new field is a 'club'—a professional home. In 1981 two of our epidemiologically oriented Hopkins' students, Cliff Gaus and Bob Blendon, Chair and Professor of Health Policy and Management at Harvard, established the Association for Health Services Research (AHSR) (now Academy Health) with a current membership of over 4000. The AHSR, of which John Eisenberg was also a former president, contributed mightily to building broad-based support for the ever more vigorously focused incarnations of the evolving NCHSRD, AHCPR, and AHRQ. In addition to its annual scientific conferences Academy Health sponsors symposia, conducts short courses, and distributes the field's major journals including *Health Services Research*, *Health Affairs*, and the *Milbank Quarterly*.

Clinical epidemiology, a subset of HSR (or sometimes vice versa), has an illustrious history, although the current label was not formally introduced until 1938 when John Paul, Professor of Medicine at Yale, described the concept and its tasks in his presidential address to the elite American Society for Clinical Investigation (Paul 1938). On several occasions Jerry Morris was a visiting professor at Yale and he and Paul must have exchanged many perceptive clinical and epidemiological insights. These surely were not lost on the late Alvan Feinstein (1925–2001), Sterling Professor of Medicine and Epidemiology at Yale, who in addition to directing one of the most successful Clinical Scholars programmes was a prolific and innovative contributor to the theory and methods of clinical epidemiology. As both a clinician and an epidemiologist he developed, among other metrics, diverse indices for assessing clinical states and the changes wrought by physicians' interventions (Feinstein 1985). Widely regarded as the father of modern clinical epidemiology, Feinstein's neologisms and harsh critiques were not always welcomed by more orthodox epidemiologists based in schools of public health.

In 1979 the Rockefeller Foundation (RF) inaugurated the International Clinical Epidemiology Network (INCLEN), its latest investment in epidemiology and its largest health programme ever. The Foundation had provided the initial funds to found the IEA in 1954 and intermittent support thereafter. Ideas generated during the 1960s and 1970s at IEA seminars in the Caribbean, India, Latin America, and the Middle East that introduced clinicians to epidemiological concepts and methods generated the ideas underlying INCLEN. The RF-funded training centres in medical schools at McMaster and Toronto universities in Canada, the universities of Pennsylvania and North Carolina in the USA and the University of Newcastle in Australia. By 2005 INCLEN had provided master's level training in epidemiology to over 1400 young clinicians, statisticians, economists, and social scientists from over 50 medical institutions in more than 30 largely developing countries on five continents. Working in clinical epidemiology units (CEUs) with about nine members each, their mission is to promote 'equitable health care based on the best evidence of effective and efficient use of resources ... and to train leaders in health care research' (White 1991).

Suzanne and Robert Fletcher, both professors and clinicians at the Harvard Medical School (formerly at McGill and UNC) and both our Hopkins Clinical Scholars, have been major contributors to the ever-evolving HSR field. In 1982 they published the first textbook on clinical epidemiology, now in its fourth edition (Fletcher and Fletcher 2005). Their extensive research, consulting, teaching, joint editorship of two major journals (*Journal of General Internal Medicine* and *Annals of Internal Medicine*) and especially their central role in INCLEN's evolution have brought them global recognition. Singly and in tandem they have done as much as any one to generate widespread acceptance by fellow clinicians of the central role that HSR can play in bettering the health-care enterprise.

A Canadian now, David Sackett was American born, educated, and trained. Charismatic, out-spoken, and innovative, he has been a dynamic leader in HSR and clinical epidemiology as well as a leading contributor to INCLEN. He was founding chair of the Department of Clinical Epidemiology and Biostatistics at McMaster University's newly launched medical school in 1967, and a major factor in that institution's rise to global eminence. Sackett credits some of his future educational methods to attendance at one of the annual workshops on HSR and RCTs we held at Hopkins in the late 1960s, co-sponsored with the Association of American Medical Colleges. His accomplishments at McMaster and later at Oxford included training a generation of world-class investigators and teachers in clinical epidemiology. Critical of the limited perspectives of 'public health epidemiology' and 'big E' as Sackett calls them, he may be regarded as a major proponent if not the father of evidence-based medicine (EBM)—a hybrid of epidemiological analysis and clinical insight.

In the UK the Nuffield Trust (founded in 1940 as the Nuffield Provincial Hospitals Trust) under the leadership of Gordon McLachlan, then its secretary (i.e. president) established a field also called medical care research but, as in the USA, later termed health services research. In 1964 he began publishing through Oxford University Press an extensive series of research studies entitled 'Problems and progress in medical care: essays on current research in medical care'. Although initially focused on the workings of Britain's National Health Service they matured into largely generic investigations of problems facing health-care systems in developed countries. Most of the Nuffield-sponsored studies were conducted by epidemiologists in UK departments of social medicine (now public health medicine) and the LSHTM. In addition McLachlan inaugurated regular seminars, symposia, and the annual Rock Carling Lectures that stimulated the field by enabling academicians, practitioners, administrators, politicians, and the public to better understand the problems of health-care organization and services; all these have continued most recently under John Wyn Owen. Epidemiologists sponsored by Nuffield

included such pioneering luminaries as Archie Cochrane, Sir John Brotherston, Charles Florey, Walter Holland, George Knox, Bob Logan, Tom McKeown, and Jerry Morris; all produced major contributions to HSR.

Archie Cochrane is best known to the greater medical communities in the UK, USA, and elsewhere for his Nuffield sponsored Rock Carling Lecture 'Effectiveness and efficiency: random reflections on health services' (Cochrane 1972). At the 1974 Annual Meeting of the US Institute of Medicine we distributed a hundred or more copies of Cochrane's classic that McLachlan donated. Among the country's medical establishment these generated unprecedented interest in outcomes research and the need for improved understanding and training in epidemiology, especially as it concerned both clinical and public health interventions.

Another major continuing player in the evolution of HSR in the UK has been the King's Fund through its sponsorship of studies, lectures, publications, and seminars. The Cochrane Collaboration (named after Archie) started by Sir Iain Chalmers is a worldwide collection of entities, usually in academic institutions, dedicated to evaluating and disseminating the 'best' evidence from RCTs to support optimum clinical interventions and health services—EBM. Critical thinking on these matters may have originated with the 1971 report of the WHO Expert Committee on Health Statistics for which Georges Rosch (a Frenchman) and Sakari Haro (a Finn) argued persuasively for the distinctively different definitions of 'efficacy', 'effectiveness', and 'efficiency' (World Health Organization 1971).

Starting in the 1960s the UK National Health Service has devoted increasing resources for studies bearing on staffing, training, institutions, organization, and funding. To these in recent years have been added others focusing on services, safety, quality, and information. The most powerful initiative, light years ahead of similar efforts in the fragmented US 'system', and the largest globally, is directed at the installation by 2010 of an information technology system 'Connecting for Health' (CFH)—that includes electronic health records (EHR)—to link all physicians, hospitals, NHS staff, and 50 million citizens. This cornucopia of privacy-protected world-class epidemiological data should, if exploited creatively, place the UK in the forefront of HSR, to say nothing of health informatics. Another recent UK creation is the National Institute for Health and Clinical Excellence (NICE) which publishes guidelines for the cost-effective management of diverse clinical disorders and public health interventions that are largely evidence-based using epidemiological methods.

The National Centre for Epidemiology and Population Health at the Australian National University, created following recommendations in a 1985 national survey of public health education and research, has an HSR component. There is a Canadian Health Services Research Foundation for conducting and supporting the field and the New Zealand Health Technology Assessment Unit in the Christchurch School of Medicine does outcomes and related research for both New Zealand and Australia. For 40 years Finland's Social Insurance Institution has had a strong HSR component to guide that country's health policies.

The US National Library of Medicine's National Information Center for Health Services Research and Technology Assessment (NCHSRITA) created a video depicting the history of HSR from the days of Sir William Petty (1623–87) and has a website listing three single-spaced pages of US and international entities involved in the field (www.nlm.nih.gov/hsrinfo/alphahsr.html). Many employ epidemiological concepts and methods—even when they don't know they are.

The IEA has been a major player in 'legitimizing' HSR. The earliest members were largely concerned with non-communicable diseases in contrast to others in the USA and Eastern Europe who believed that communicable diseases are the only 'true' province of epidemiology. Gradually the IEA embraced both these areas but not HSR. I vividly recall Archie Cochrane telling me in 1959 that he did not think epidemiology had any role to play in the assessment of medical care; times,

problems, and people change. After numerous, often heated, debates the IEA accepted as members those working in the emerging sphere of HSR and related areas. In fact it opened membership to anyone interested enough to complete a brief application form and pay an annual fee for the world-class *International Journal of Epidemiology*.

What then is health services research? It is a broad amorphous field to which many disciplines contribute, but epidemiology with its population perspective and statistical methods is central. As in other applications of epidemiology, the record for HSR is variable. There is an increasing abundance of first-rate work but there is also too much activity directed at unimportant problems where ropey data are massaged with ever-fancier mathematical manoeuvres. Not everything that 'counts' can be counted. Qualitative research can also contribute to HSR. At its best this burgeoning field strives to foster and enhance the care of individuals—one by one—as well as the populations from which they come with science-based, compassionate, effective, and efficient services.

Myriads of HSR studies exist. In addition to those already mentioned here are four more, with a salient finding from each, to illustrate the scope of HSR and its potential for impact upon health policies. In 1961 using survey data of our own as well as that from UK and US sources, and a model devised by John and Elizabeth Horder of London, my UNC colleagues (Bernie Greenberg and Frank Williams) and I published an article in the *New England Journal of Medicine*—'The ecology of medical care' that included a diagram of nested squares. In a population of 1000 adults in the course of a month 750 experienced some kind of health problem, 250 consulted a physician, nine were hospitalized, five were referred to a consultant, and one entered a teaching hospital where the great bulk of medical education takes place. We argued the case for increased emphasis on what we called 'primary medical care' (unaware at the time of the 1918 Dawson Report advocating 'primary care') and more balanced exposure of medical students to the full range of the population's health problems in the community. The results were questioned vigorously at the time but they have been duplicated in several different settings and as recently as 2006. The article and diagram have been widely reproduced in textbooks and anthologies, referenced in many other venues, and used for teaching and policy discussions for over four decades.

In 1971 the RAND Corporation (Joe Newhouse) inaugurated the large-scale Federally funded Health Insurance Experiment by creating an independent health insurance company that covered some 8000 people in 2750 families across the USA. Bob Brook, our Hopkins student, was recruited by Newhouse to head the health and quality parts of the experiment. Families were randomly assigned to policies with either no cost-sharing or 25, 50, or 95% co-payments and a maximum annual payment of \$1000. In addition, the maximum amount a family could pay was related to their family income. Another group of families was randomly assigned to one of the country's best health maintenance organizations (HMOs). Their use of health services was recorded and their health status was assessed at entrance, annually, and on termination over 3- to 5-year periods. Multiple reports and articles recounted the experiment's ground-breaking findings. These included demonstrating that cost-sharing reduced equally both 'necessary' and 'unnecessary' use and health-care spending as well. The overall conclusion that cost-sharing did not affect either the quality of care or health status for the 'average' person enrolled in the study was hotly debated but resulted in dramatic changes in classical health insurance plans so that most now include higher cost-sharing. The additional finding that families randomized to the HMO received quality of care equal to those in fee-for-service arrangements resulted in efforts, for better or worse, to increase the 'managed care' market in the USA.

From 1964–76 the World Health Organization/International Collaborative Study of Medical Care Utilization (WHO/ICSMCU) was led from Johns Hopkins but involved essential academic and government colleagues from the seven participating countries: Argentina, Canada, Poland, the UK, the USA and Yugoslavia. We developed instruments and training manuals in four languages

and conducted household surveys of almost 50,000 individuals from probability samples of 1000 families in each of 12 study areas in the seven countries; individual area response rates ranged from 90 to 99% and overall was 96.6%. The many relationships among standardized measures of 'need', 'use', and 'resources' were examined extensively. Two volumes, over 60 articles, and countless graduate theses resulted. Among the many findings of imbalances and distortions was demonstration of the relationship between a population's experience of unmet need for a physician (i.e. the percentage of all persons with perceived morbidity of the highest degree of severity within the last 2 weeks who, although wanting to contact a physician for their health problem, were unable to obtain one) and consumption of the area's short-term hospital bed nights (corrected for import and export of hospital use). Regardless of the ratio of short-term hospital beds to the area's population the greater the measure of unmet need the greater the use of hospital bed nights. In other words relatively high rates for the volume of hospital nights are inversely related to the availability and accessibility of ambulatory care. A long-held view that if you build hospital beds they will be filled was contradicted. Adequate access to primary medical care appeared to reduce hospital admissions.

Barbara Starfield, creative, determined, and highly knowledgeable was the first faculty colleague I appointed at Hopkins in 1965. She has had a remarkably productive career with an abiding focus on the content, quality, distribution, and essential role of primary medical care as the underpinning of any balanced health-care system. Of her books and many other publications, documented with exacting details over four decades, those comparing primary-care workforces, costs, and health outcomes in 13 developed countries, if carefully studied by politicians and health 'policy-makers', should have the greatest impact. She found the USA to be in last position, with the lowest ratio of primary-care physicians to specialists and the highest for per capita health-care expenditures. Among the 13 countries, the stronger the primary-care component the lower the costs and the better the outcomes.

Health services research and its analogues are now part of the fabric of the bulk of academic medicine—if not yet universally. A few medical school deans, editors of major journals (*Annals of Internal Medicine* and *The Lancet*) and members of many governmental and philanthropic grant-making bodies have backgrounds in HSR. Hospital and outpatient formal and informal curricula more often than not now incorporate elements of the field.

We may conclude, then, from this half century's scientific odyssey that, by playing a central role in the evolution of HSR, epidemiology has contributed substantially to diminishing the power of authoritarian pronouncements by eminent figures on medical decision-making, therapeutic interventions, health-care organization, resource deployment, and professional education. Biomedicine now has HSR colleagues to ensure that the fruits of its labours are translated effectively and efficiently into better care for individuals and populations. The labels attached to these diverse endeavours will undoubtedly change in the future as they have in the past but epidemiology surely will be the dominant discipline.

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