

# Health Care Research: Old Wine in New Bottles

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Thank you for inviting me to participate in UVA's **History of Health Sciences Series**. My hope is that this brief discussion of **Health Care Research's** evolution over the centuries may help to place contemporary pursuits in some historical perspective. As in all branches of enquiry each generation benefits from the prior contributions of our predecessors. As one observer of the passing scene put it: "If you see a tortoise on a fence post, you know it didn't get there by itself!"

First let me offer a few comments on the nature of **Health Care Research**. It is an eclectic "field," not a discipline or a specialty. A wide range of theories and methods are employed depending on the questions asked or the problems addressed. The boundaries are, and undoubtedly should remain, vague. Tendencies to balkanize or splinter the field into separate camps--even factions--should be shunned. Clinical epidemiology, technology assessment, critical appraisal, cost-effectiveness and cost-benefit analyses, clinical decision-analysis, operations research, health systems research, and health services research can all be accommodated under the rubric of **Health Care Research**. All use epidemiological and statistical methods combined with others derived from population-based sciences such as economics, demography, and survey research, as well as behavioral sciences such as medical anthropology and sociology, and clinical psychology. The overall label under which the enterprise operates is of much less importance than an appreciation of the broad range of functions carried out under its banner. The over-arching goal of Health Care Research is to inform and improve the processes and outcomes of care for individual patients--one at a time. Now widely accepted as an essential academic activity, dedicated units have been established in most medical schools.

For centuries cynics, scholars, and scientists have questioned the benefits of medical interventions in relation to their hazards and costs. The contemporary versions of the questions our predecessors raised continue to emphasize the need to equate value received with money spent. Answers to those questions require measures of outcomes, risks, access, appropriateness, costs, and collective responses to public perceptions, expectations, and needs.

Discourses such as this customarily begin with references to one or more of Mr. Jefferson's perceptive observations: I dare not make an exception. He emphasized a central tenet of all health care--past, present, and future--when in 1807 he wrote his friend Dr. Caspar Wistar that:

I would wish to have the young practitioner, especially to have deeply impressed on his mind the real limits of his art, (**there were no "hers" in those days**) and that, when the state of his patient gets beyond these, his office is to be a watchful, but quiet spectator of the operations of nature, giving them fair play by a well-regulated regimen, and by all the aid they can derive from the excitement of good spirits and hope in the patient. 1

Towards the end of these remarks I return to Jefferson's emphasis on the central roles of caring and hope in all medical practice and to the contribution of **Health Care Research** to their assessment. Let me now illustrate the evolution of the field with selected examples.

The first physician to ask seemingly impertinent questions about medical care was undoubtedly the 17<sup>th</sup>-

century polymath Sir William Petty (1623-1687). In spite of an impoverished childhood Petty attended universities in Britain, Holland, and France and at the age of 28 was appointed Professor of Anatomy at Oxford. From this vantage point he exercised broad influence on the public policies of the day, especially as the author of a seminal volume entitled: **Political Arithmetic**. In this and other writings, Petty stressed the need to quantify the outcomes not only of the welfare and social services but also of health services. His skepticism about the benefits of medicine foreshadowed those of many succeeding clinicians, epidemiologists, economists, politicians, and others concerned with the improving health services. Although widely acknowledged as the father of economics and epidemiology, let me quote several observations which also mark him as the father of **Health Care Research**:

The method I take is not yet very usual; for instead of using only comparative and superlative words, and intellectual arguments ... I have long aimed to express myself in terms of number, weight, or measure; to use only arguments of sense, and to consider only such causes, as have visible foundations in nature; leaving those that depend upon the mutable minds, opinions, appetites, and passions of particular men, to the consideration of others. 2

Listen to Petty challenging his colleagues in the Royal College of Physicians by asking:

1. Whether they take as much medicine and remedies as the like number of any other society.
2. Whether of 1000 patients to the best physicians, aged of any decade, there do not die as many as out of the inhabitants of places where there dwell no physicians.
3. Whether of 100 sick of acute diseases who use physicians, as many die and in misery, as where no art is used, or only chance. 3

Petty also questioned the adequacy of the hospitals of the day, albeit with data and methods that left not a little to be desired by present-day standards, even those currently employed by the U.S. Health Care Financing Administration! He wrote:

That London Hospitals are better and more desirable than those of Paris, for in the best at Paris there die 2 out of 15, whereas at London there die out of the worst scarce 2 out of 16, and yet but a fiftieth part of the whole die out of the Hospitals at London, and 2 out of 5 or 20 times that proportion die out of the Paris Hospitals which are of the same kind; ... We Infer that either the Physicians and [Sur]geons of London are better than those of Paris, or that the Air of London is more wholesome. 4

Petty's early foray into "evaluative research," "quality assurance," and other manifestations of so-called "cost containment" forever changed the face of clinical medicine as well as the methods for making political choices bearing on health. Through his introduction of **political arithmetic**, and his advocacy of what he once called **political medicine**, Petty introduced quantification to link what later became three related branches of learning: economics, epidemiology, and political science. On his death, his friend Samuel Pepys found him "the most rational man that ever he heard speak with a tongue." Major Greenwood (1880-1948), the first Professor of Medical Statistics and Epidemiology at the London School of Hygiene and Tropical Medicine, regarded Petty's work as flawed in many ways. Nevertheless, Greenwood had enormous admiration for his contributions and wrote that "anybody who has felt ... exhilaration ... in the doing of sums concerning biological problems, feels his heart [was] warmed by the arithmetical knight errant who had so many statistical adventures."<sup>5</sup>

Not forgetting the essential role of the 18<sup>th</sup>-century French statisticians in helping to sort out the benefits of medical interventions, I turn next to a remarkable French clinician of the 18th and 19th centuries, Pierre-Charles-Alexandre Louis (1787-1872). Useful as statistical concepts and methods were, the unequivocal commitment of a credible practicing clinician was required to demonstrate their utility for the advancement of medicine. Louis applied statistical techniques to clinical investigations and founded what he called **the numerical method**. Innate curiosity, skepticism towards the received wisdom handed down by academic authorities, and an inherent capacity for logical thinking set Louis apart from his colleagues. For example, others had questioned the efficacy of blood-letting, but he demonstrated statistically, or provided "proof" as it was called at the time, that this treatment was not only useless but often harmful. The following quotation illustrates Louis's approach and, parenthetically, records what is probably the first use of the French equivalent for the term "efficacious":

In any epidemic ... let us suppose 500 of the sick, taken indiscriminately, to be subjected to one kind of treatment, and 500 others, taken in the same manner, to be treated in a different mode; If the mortality is greater among the first, than among the second, must we not conclude that the treatment was less appropriate or less efficacious in the first class, than in the second? ... [I]t is impossible to appreciate each case with mathematical exactness, and it is precisely on this account that enumeration becomes necessary. By so doing the errors (which are inevitable) being the same in both groups of patients subjected to different treatment, mutually compensate each other, and they may be disregarded without sensibly affecting the exactness of the results. 6

Although Louis's studies incurred the wrath of many fellow clinicians he put numeracy on the clinical map. He challenged the notion that the experience of individual physicians with individual patients was a reliable guide to understanding the origins of disease or its prevention, diagnosis, treatment, and prognosis. His use of the laws of large numbers to identify regularity in the patterns of diseases as well as to minimize observational error harked back to William Petty.

But Louis did more than lecture and give clinics. He supported his students in organizing a weekly self-learning tutorial known as the **Society for Medical Observation**. An unidentified participant in an early exercise of what we now call "critical appraisal" gave this account:

The members were arranged around a table that occupied three sides of the room, and each person had paper and pen or pencil before him. He was prepared ... to note the most trivial omission or a too inconsiderate deduction made by the reader. Each subsequently criticized the paper from these notes. This was done in the keenest manner. Louis, as President, summed up the result of the meeting by not only criticizing the reader, but also his critics' remarks.<sup>7</sup>

Recourse to facts and figures in place of the vague theorizing that characterized most of medicine at the time was Louis's epoch-making contribution.<sup>8</sup> He formulated what came to be known as Louis's rule: "Whenever practical, reduce observations to a numerical expression."<sup>9</sup> Louis probably influenced more medical men to undertake scientific investigations than any of his contemporaries. He had an enormous impact on clinical practice both in France and abroad.<sup>10</sup> Indeed, a plausible theory asserts that Louis's **numerical method** was the intellectual antecedent of what is now called "clinical epidemiology." His ideas were transmitted through the numerous British and American clinicians who studied with him.<sup>11,12,13</sup>

Between 1820 and 1861 about 700 American physicians travelled to Paris for postgraduate studies, especially with Louis. Of these 67 eventually became professors of medicine.<sup>14</sup> Among the Americans

who sat at Louis's feet were two of Boston's better known clinicians. First, there was Oliver Wendell Holmes (1809-1894) with his unwelcome observations on the origins of puerperal fever. Arguing persistently against the use of popular nostrums and quackery, Holmes deplored the lack of efficacy exhibited by most contemporary medical maneuvers. In the view of one authority, he should "be ranked as America's first outstanding epidemiologist."<sup>15</sup> There was also Henry Bowditch (1808-1892), physician and physiologist who, on his return from France, developed a life-long interest in public health. Concern for broadening the horizons of medicine included his founding and chairing of the first State Board of Health in Massachusetts in 1869. He also advocated the creation of similar Boards of Health in all states.<sup>16</sup>

The best known of the New York City physicians who studied with Louis were Francis Delafield (1841-1915), author of a major pathology textbook, and Alonzo Clark (1807-1887), a pioneer in American medical education. Both were on the faculty of New York's College of Physicians and Surgeons and both taught William Henry Welch (1850-1934), later Dean of Johns Hopkins' School of Medicine and founder of its School of Hygiene and Public Health. There are other links from Louis to major leaders of the American academic medicine. These include William W. Gerhard (1809-1872), a prominent Philadelphia clinician, academician and "perhaps the most brilliant American pupil of Louis"<sup>17</sup> and William Pepper (1843-98), also of Philadelphia and the University of Pennsylvania, who was editor of the first large American System of Medicine, leader in medical education, and sometime provost of his university.<sup>18</sup>

In Britain there was no forum, apart from the **Statistical Society of London**, in which intensive scientific discussions could take place not only about clinical and population-based problems, but also about research methods in medicine. This was especially true for those concerned with the increasingly urgent drive to discover means for preventing recurrent massive epidemics in Britain and the continent--to say nothing of the rest of the world.

The first move was made by one J.H. Tucker who was probably a surgeon. In letters to the **Lancet**, in 1848 and 1849 he urged formation of a "society" to coordinate measures against cholera. On March 6, 1850, he announced the formation of **The Epidemiological Society**.<sup>19,20</sup> This was no tiny elitist organization open only to the properly anointed. Rather it was a broad-based initiative directed at informing the profession, the public, and its divided politicians about the rampant epidemics afflicting all citizens. A prominent politician and aristocratic landholder, Anthony Ashley Cooper (1801-1885), later Earl of Shaftesbury, provided not only political and social credibility as a member of the newly established Board of Health but also enormous energy.<sup>21</sup> So highly was Ashley-Cooper regarded by the scientific establishment, his fellow politicians, and the public generally that he was asked to preside at the initial public meeting of **The Epidemiological Society**. A meeting held not in some remote hall but in the quarters of the Medico-Chirurgical Society.<sup>22,23</sup> Among the 200 people attending were prominent members of the medical profession including such luminaries as Thomas Addison, the Society's first treasurer, Richard Bright of Guy's Hospital, Sir Charles Hastings, founder of the British Medical Association, John Haviland, Regius Professor of Physic (Medicine) at Cambridge, T. Clifford Allbutt, later also the Regius Professor of Physic at Cambridge, Sir John Simon, Medical Officer of Health for London, John Snow, anesthetist and epidemiologist, and T. Spencer Wells, later Hunterian Professor of Surgery and Pathology.

From its inception, Louis's spirit seems to have been present as the regular gatherings of the **Society** became the birthplace of modern epidemiology and of several elements of **Health Care Research**. At the inaugural meeting Benjamin Guy Babington, a leading clinician and Fellow of the Royal Society, was elected president. Setting forth the objectives of the new society, he emphasized the need to guard against "errors," stressed prevention as the top priority, and observed that "statistics, too, have supplied us with a new and powerful means of testing medical truth, and we learn from the labours of the

accurate Louis how appropriately they may be brought to bear upon the subject of epidemic disease." 24

If the Society focused its initial efforts largely on communicable or contagious diseases that was because those were the principal threats to the population's health at the time. The members recognized a much broader mandate, however, and committees were appointed to examine a wide range of problems and issues. These embraced virtually all aspects of clinical medicine and the public's health. Included were not only the contagious diseases but also the investigation of chronic diseases through the "continued fever" committee, examination of the adequacy of health services through the "hospitals" committee, and the study of health "manpower" supply through the "nurses" committee. They even discussed the provision of "home care" through the latter committee. 25 The same statistical and epidemiological tools could be used whenever and wherever appropriate for the investigation of group and population phenomena.

The leaders of The Epidemiological Society included academicians and practitioners intent on addressing the full scope of their social and professional responsibilities. If membership did not include the Royal College of Physicians' full roster, many of its most distinguished Fellows, the heart of Britain's medical establishment, were participants. As a body the Society represented a cross-section of Victorian medicine that demonstrated a deep commitment to the scientific investigation not only of diseases but of health services.

Benjamin Babington died in 1866 as had most of the Society's other founding members during the decade of the sixties. Towards the end of the century the Society met only for an annual dinner, the last being the Commemoration Dinner in 1900. Derived from seeds planted by Louis and his predecessors, a brief half century in the gestation of the epidemiological perspective drew to a close. It had been overtaken by the growing dominance of research in the bacteriology laboratory as microorganisms became the focus of medical enquiry. Curiosity about patients' behavior and about the environments in which they are born, lived, worked, and died declined.

Such was the influence of Louis's **numerical method** that in 1832 a group of the foremost American physicians who had studied with him formed a second analog of the Parisian **Society for Medical Observation** to be known by the same name. This was long before German-trained physicians in America, steeped in the emerging experimental methods of the bacteriology laboratory, in 1908 formed the **American Society for Clinical Investigation**. In the United States as in Britain observing the natural history of disease, classification, and measurement, together with critical appraisal of interventions through use of the numerical method, gradually fell into disfavor. Like **The London Epidemiological Society**, the American Society for Medical Observation seems to have disappeared. If the clinicians who labored in these vineyards were not labeled "epidemiologists," and if the thinking of these physicians was not epidemiological in character and much of their work **Health Care Research**, it is difficult to know how to characterize it. For this we have to credit Louis, his statistical forbears, and colleagues. Following his death in 1872, however, Louis' influence among clinicians languished in France, Britain, and the United States. Interest in the critical study of groups of patients and in medical numeracy waned. The population perspective disappeared from medical education, research, and practice for three quarters of a century.

No account of Health Care Research should omit the seminal contributions, a century ago, of that remarkable nurse, statistician, administrator, and political advocate Florence Nightingale (1823-1910). Among her many accomplishments she set forth the contents of the first Uniform Hospital Discharge Data Set. She argued that analyses of this information could correlate mortality rates with diagnoses and treatments to determine the proportions of hospital beds and interventions associated with functional restoration versus death.<sup>26</sup>

Nightingale's unorthodox and unwelcome initiatives were followed several decades later by pleas for the application of these ideas first by a British and then by an American surgeon. In Britain, E.W. Groves argued in 1908 that all operations should be registered uniformly. He wrote:

If ... a surgeon makes a specialty of some disease or operation and tabulates all his own results, or another by chance has some notable successes and records them, or the author of a textbook collects published records of various writers and summarizes them, is it not obvious that such a collection of figures will represent the best and not the average?<sup>27</sup>

A few years later, a Boston surgeon, Ernest A. Codman, attempted to introduce a system for assessing the outcomes of clinical care at the Massachusetts General Hospital. In a classic paper entitled **The Product of a Hospital** he wrote:

One might say that the instruction of the students is irrespective of the results to the patients, but let us suppose, in surgery, for example, that all operations which have been watched by these students have been misdirected efforts at the cure of disease, and the students have learned to do something which is not worthwhile and does not really improve the patient. The product of a hospital in this case, even as regards student instruction, would be nil--even worse than nil. We are, therefore, referred again to the classification of disease and the results to the patients, because a student would naturally wish to receive his (**no "hers" yet**) instruction at a hospital where the treatment was shown to be of benefit to the patient. We may then say that the product of a hospital in medical education, like the product of a hospital in the number of cases treated, depends on whether or not the cases are well treated ...<sup>28</sup>

For his pains Codman was roundly attacked by his colleagues and had to move to a more modest institution. The ideas and methods of these two pioneers were forgotten for three decades.

In the mid-1930s another English physician, J. Alison Glover, wrote a series of articles describing wide variations in tonsillectomy rates for children living in otherwise similar cathedral towns, in matched industrial cities, and among different surgeons. <sup>29</sup> To this day his finding of small area variations is referred to as **The Glover Phenomenon**. In the mid 1950s I first learned about these critical observations from the writings of Professor Jerry Morris of the London Hospital Medical School.<sup>30</sup> Several years later in the face of strong opposition from clinical colleagues and hospital administrators I was able to install the first American population-based hospital discharge abstract system in all Vermont hospitals. Shortly thereafter I persuaded one of our graduate students at Johns Hopkins to take a job in Vermont analyzing this unique gold-mine of accumulating data. Since then Jack Wennberg has become an international authority on small-area variations. He has reported widespread differences in the rates for many medical and surgical interventions in otherwise similar jurisdictions, as well as unexplained variations in selected procedures between major medical centers such as those in Boston and New Haven. Although Wennberg now heads a large **Center for Evaluative Clinical Studies** at Dartmouth, these phenomena still cry out for explanation almost 60 years after Glover's first report and 300 years after Petty's observations. <sup>31,32</sup>

Seminal contributions by physicians during the 1940s and 1950s were provided by James C. Doyle who documented a widespread epidemic of unnecessary hysterectomies;<sup>33</sup> by Mindel Sheps who provided the first theoretical discussion of problems and issues to be addressed in measuring the quality of hospital care;<sup>34</sup> by Virgil Slee and his colleagues who developed early methods for evaluating internal medicine;<sup>35</sup> by Paul Lembcke who demonstrated the power of medical audits to assess the adequacy of procedures such as appendectomies and pelvic surgery;<sup>36</sup> and by Jerry Morris and his colleagues who documented substantial variations in case fatality rates between teaching and non-teaching hospitals.<sup>37</sup>

The most important advance in **Health Care Research** and related investigations during the 1940s and 1950s was provided by the late Sir Austin Bradford Hill. Lateral thinking enabled him to apply to medicine lessons learned from agricultural studies conducted by his fellow statistician Sir Ronald Fisher in the 1920s. As second Professor of Statistics and Epidemiology at the London School of Hygiene and Tropical Medicine, Bradford Hill introduced the **Randomized Clinical Trial (RCT)**. He advocated its use as the central experimental strategy for measuring the intrinsic benefits of a clinical intervention, maneuver, or service. In his 1951 address at the Harvard Medical School Bradford Hill set forth the principles underlying this new method for advancing clinical medicine and Health Care Research. He observed that:

The art of applied [medical] statistics is compounded of two things--a knowledge of statistical methodology and a wide and detailed knowledge of the data to which that methodology is to be applied. I should hesitate to allocate a relative importance to each of these two aspects, but I hold firmly that both are essential and that the use of a method, however erudite, without a parallel and exact knowledge of the data under study can be, indeed is likely to be, most dangerous.<sup>38</sup>

Important questions, clinical contexts, and feasible methods are all involved in advancing the field of **Health Care Research**. Other methods such as triangulation, pattern recognition, longitudinal and cross-sectional surveys, regression analysis, and meta-analysis are widely employed and each is useful in appropriate situations. The RCT, however, is best at distinguishing the relative impact of a specific intervention from currently intangible therapeutic factors.

During the first part of the 20th century these diverse advances had yet to coalesce as a recognized area of scientific enquiry. Strengthened, however, by new applications of statistical methods developed by epidemiologists, social scientists, survey statisticians, and pioneering clinicians a new field emerged gradually in the mid-1950s. At a 1959 meeting in Washington, D.C. of two NIH Study Sections, those for **Hospital and Medical Facilities** and for **Nursing**, a new name was sought for this revived concern with the adequacy and appropriateness of "medical care," "patient care," and "hospital and medical facilities." The term **Health Services Research** was suggested by some unheralded participant in that meeting.

A couple of years later I was asked to chair the newly established **Health Services Research Study Section**. To stake out this largely undefined domain we adopted methods that had been used successfully by the original Molecular Biology Study Section to develop that field. We commissioned and published a series of scholarly papers describing the genesis, current status, and opportunities for **Health Services Research**.<sup>39</sup> We introduced small grants for young investigators, career awards, and grants for **Health Services Research Centers** modelled after the highly successful **Clinical Research Centers**. We supported the establishment of new journals such as **Medical Care and Health Services Research**, organized **Health Services Research Sections** (now combined with clinical epidemiology) at the annual national medical meetings, and promoted international exchanges. About 1966, based on a sketch drawn on a checkered table cloth in the bar of Chicago's Palmer House Hotel, I joined with others to lobby the Federal bureaucracy and Congress for establishment in 1968 of the **National Center for Health Services Research**. This entity gradually metamorphosed into what is now the **Agency for Health Care Policy and Research**.

**During the 1960s and 1970s two major contributions provided lasting legacies that have guided succeeding generations in their quests to improve the quality and distribution of health services. The first was Avedis Donabedian's seminal partition of medical care analyses into the elements of structure, process, and outcome.<sup>40</sup> A classic article in the Milbank Memorial Fund Quarterly preceded by a dozen years the publication of his widely acclaimed treatise entitled Explorations In**

**Quality Assessment and Monitoring.**<sup>41</sup> The second volume, published in 1972 in Britain, was a slim classic by the late Archie Cochrane entitled *Effectiveness and Efficiency: Random Reflections on Health Services*.<sup>42</sup> At our first meeting in 1959 Archie disparaged my interest in applying epidemiological methods to health services research saying that it was not "proper epidemiology", whatever that was! Subsequently he apparently underwent a remarkable transformation and carried out noteworthy health care studies that culminated in his clinical gem. *Effectiveness and Efficiency* went through two large initial printings, was translated into French, German, Italian, Polish, and Spanish, and was reprinted in English in 1981. Introduction of Cochrane's thinking to American audiences resulted from the Council of the Institute of Medicine being persuaded to authorize the purchase of several hundred copies for distribution at our 1973 annual meeting. Those of you who have read this little gem will recall Cochrane's observation that contemporary health care systems are reminiscent of a crematorium--so much goes in and so little comes out!

In 1955 the Hill-Burton Act provided the first Federal funds for research dealing with "medical facilities and hospitals" and with "patient care." At the University of North Carolina our group, employing the term Medical Care Research, successfully applied for one of these grants. An initial project to examine the quality of inpatient care in the North Carolina Memorial Hospital was roundly rebuffed by our colleagues in the Department of Medicine. We were advised "that this is a university hospital where we set the gold-standards for care; there is no need to enquire further about quality in this institution!" However, since our group ran the Outpatient Department, we undertook to evaluate our own performance. In spite of vigorous efforts to provide exemplary care we found much room for improvement and so acknowledged in a 1961 article.<sup>43</sup> Several years later at Johns Hopkins, I encouraged another of our graduate students, also Chief Resident on the Osler Medical Service, to undertake a similar study at the Hopkins Hospital. He too was rebuffed. Nevertheless, he successfully carried out the study at the Baltimore City Hospital. The alarming finding that 74% of the ambulatory patients received unacceptable care was published in the *New England Journal of Medicine*.<sup>44</sup> On the strength of this he was then allowed to conduct an identical study in the Hopkins' Outpatient Department with similar results. Today as Vice-Chairman of UCLA's Department of Medicine and head of the RAND Corporation's Health Program, Bob Brook is an international authority on outcomes and appropriateness research.

Almost 30 years ago I first met Sir Douglas Black, an eminent clinician, medical statesman, and early participant in medicine's technological revolution. A canny Scot, he is a renowned nephrologist, former Professor of Medicine at the University of Manchester, one-time Chief Scientist in the U.K. Ministry of Health and Social Security, and most recently President of the Royal College of Physicians. With a wry sense of humor, Black once gave me a set of what he called "daft laddie" questions. Over the years I have treasured and publicized them to summarize what Health Care Research is all about. Answers to Black's questions also provide excellent counsel for those setting health policies and organizing services. Addressed to advocates of any new medical intervention as well as to defenders of old practices, several of his penetrating questions run as follows:

1. What are the aims of the treatment, procedure, or service in question?
2. How many people, and of what kind, are potentially eligible for help from these interventions?
3. What proportions of these people actually get help?
4. What determines who gets this help, and who does not?

**5. Does this intervention do any good or make a discernible difference? If so, how much difference does it make? To whom?**

**6. What does this treatment, procedure, or service cost? How do these costs compare with those of potential substitutes? Who pays?**

**7. What does the public--those served, those eligible but not served, and those ineligible--think about the intervention?**

**8. What impact might the intervention make on the demand or effectiveness of other treatments, procedures, or services?**

**Health Care Research invokes organized curiosity to answer questions such as Black posed and politicians of all persuasions ask with ever increasing intensity.**

**I return now to Jefferson's observations quoted at the outset of this review. In elucidating the roles of caring and hope, Health Care Research can make important but as yet not widely acknowledged contributions. For starters, consider William Osler's observation in the British Medical Journal of 1910:**

**Faith in St. Johns Hopkins, as we used to call him, an atmosphere of optimism, and cheerful nurses, worked just the same sort of cures as Aesculapius at Epidaurus. 45**

**Sixty years later at the Johns Hopkins Hospital buttons worn by the staff bore the message: "Caring is part of the cure." This institution-wide campaign to make both professional and support personnel recognize their own therapeutic powers was based, perhaps unknowingly, on scientific knowledge.**

**Awareness that "caring" was a beneficial force derived originally from the classic experiments conducted jointly during the decade 1927 to 1937 by investigators at Harvard University and the Western Electric Company's Hawthorne plant near Chlcago.<sup>46</sup> Their studies were designed initially to determine the extent to which variations in the ambient conditions and physical environment of the workplace affected the productivity of employees. The investigations were extensive and complex, involving six women who constituted a discrete social group in a dedicated working environment. The six operators assembled telephone relays--the dependent variable measuring productivity. In brief, the investigators found, to their great surprise, that no matter what changes the company introduced in the experimental situation productivity improved. When the wattage of light bulbs was increased, production went up; when it was decreased, production went up! This ubiquitous phenomenon has been referred to ever since as the Hawthorne Effect--a Heisenberg effect in human interactions. In other words, the observer's influence is always present in the clinical, research, and educational environments. In two series, the Hawthorne Effect at the Western Electric plant was associated with mean increases in productivity of 12.6% and 15.6% respectively.<sup>47</sup> Whatever else they did, the company "cared," and "caring" became the operative influence in the work environment.**

**The Hawthorne Effect permeates health services at both the micro and macro levels; to ignore its presence in the context of the individual clinical encounter, the provision of health services, or in research studies involving human subjects, is to omit an essential part of reality. Its importance to the health care field specifically was documented by ingenious studies conducted during the 1960s by Professor Reginald Revans, also of the University of Manchester. He showed that, when size**

and other factors were controlled, hospitals where supervisors employed authoritarian attitudes and behavior, compared to those where permissive and supportive management styles prevailed, had much higher rates of staff turnover, especially for nurses, and longer lengths of patient stay for six common medical conditions and six common surgical conditions.<sup>48</sup>

A better known psychophysiological intervention that improves health status is the Placebo Effect. For centuries a wide assortment of sometimes innocuous, often unpleasant and costly, and frequently dangerous, interventions has been employed by doctors of all persuasions to alleviate pain and suffering. The tendency has been to attribute their benefits to unknown factors assumed to be of little or no consequence said to be "just the Placebo Effect." Serious scientific attention to the importance of the phenomenon, however, dates only from the early 1950s.

One of the first investigators to draw the medical profession's attention to the Placebo Effect was Henry K. Beecher, Professor of Anaesthesiology at Harvard. His classic paper entitled *The Powerful Placebo*, reported fifteen studies of patients suffering from nine conditions with a mean placebo response rate of 35.2% and a range of 15% to 58%.<sup>49</sup>

More recently, Howard M. Spiro, Professor of Medicine at Yale, confirmed Beecher's figure of 35% as a reasonable estimate of the Placebo Effect's overall beneficial influence. He notes, however, that in clinical trials of Duodenal Ulcer the benefit may amount to 70% or more with an overall rate of at least 50%. More interesting still are the variations in the Placebo Effect among countries and institutions. Spiro writes:

A very interesting study was conducted in the United Kingdom a few years ago. An antiulcer drug was compared to a placebo in a trial carried out in Dundee and in London. The study was identical at both hospitals, but the healing rates for placebo were quite different: in Dundee 73% of ulcers healed on a placebo, in contrast to only 44% in London. The reasons for the differences in the healing rates in the two centers were unclear to the observers, who wondered whether there was a difference in the patients, in the doctors taking care of the patients, or in someone's expectations of cure. A study in the United States foreshadowed this observation. In one hospital... antacids relieved pain 79% of the time, but in another hospital the same antacids were effective only 17% of the time. In one hospital placebos gave relief to 45% of the patients, but in another only 25% were helped. In both the British and American studies the experimental design, definition of terms, and criteria were the same, but the responses were different, suggesting there are fundamental differences in responses to placebo as well as therapy.<sup>50</sup>

These findings imply the presence of mixtures of the Hawthorne and Placebo Effects. Perhaps they could be considered together as Factor "X". The presence of substantial variations in the behavior of groups and institutions has important implications for Health Care Research, for population-based medicine, and especially for clinical practice. Such studies also help to document the importance of distinguishing between the assessment of "efficacy" under rigidly controlled conditions and the assessment of "effectiveness" in which interventions of established "efficacy" are applied in diverse clinical, institutional, and community settings.

From the available evidence we may conclude that the Placebo and Hawthorne Effects associated with most interventions, maneuvers, or services designed to be "helpful," "healing," "educational," or "informative" make an overall contribution to beneficial outcomes that approaches 50%--not a trivial benefit. Conversely, negative influences, including undesirable, even harmful, side-effects, may be equally great, although, to the best of my knowledge, they have

not been studied as extensively as the positive effects. When these components of care go unrecognized the unanticipated financial costs can mount rapidly.

There have been many other contributors to the evolution of Health Care Research and those interested will find 100 of them represented in a recently published volume entitled *Health Services Research: An Anthology*.<sup>51</sup> The questions first posed by Sir William Petty of the 17th century, Louis of the 18th, Florence Nightingale of the 19th, and Ernest A. Codman and J. Alison Glover in the early 20th, finally are attracting broad-based attention from the health care establishment. Founded in 1981, the Association for Health Services Research now has over 1800 members including some 300 physicians and 115 institutional members. Most North American, European, and Australian medical schools and about 30 in the Developing World now have active programs that can be classified under the broad rubric of Health Care Research.

Having listened to all this some will ask: "So what? Medicine's only task is the care of sick patients who seek our services. We do our best and can't be bothered with these side issues." I believe there are at least four reasons why all clinicians and all medical schools should be deeply involved in answering the questions raised by William Petty three centuries ago and by Douglas Black three decades ago.

**First:** Health Care Research helps to improve clinical practice by providing methods for establishing the relative efficacy and effectiveness of our interventions. In turn, these are derived largely from fundamental biomedical and behavioral research. Contemporary Health Care Research shuns "rascal hunting". It employs a behavioral model to shift the entire curve measuring the quality of practice to the right. A rising tide of reliable information about the appropriateness, benefits, risks, and costs of clinical interventions lifts standards of health care for all.

**Second:** Health Care Research helps the profession respond to the growing expectation, indeed insistence, that health care be so organized and managed that the medical establishment in all its facets provides prompt and appropriate care for the individual and collective health problems of the populations who do the suffering and foot the bills. This goal can best be accomplished by determining what and where the people's problems are and what additional research or services are required to respond to them. A medical school can best set priorities rationally for clinical research, education, and service when it has available essential quantitative and qualitative information about the health status of the population served and measures of the outcomes of those services on that population.

**Third:** Health Care Research is an essential response to contemporary public and political preoccupation with receiving value for money spent, so-called cost-containment. As I have tried to illustrate, this requirement is not new. In the light of competing demands for scarce resources it is now close to the top of the political agenda in most western and developing countries. Science-based, compassionate, and appropriate health care is best provided in a cost-effective manner to all who can benefit when each component is clearly identified and called by its right name. By helping the health professions to eschew wasteful practices, medical schools can help to save scarce money for investment in vitally needed fundamental research. Demanding larger budgets for biomedical research is likely to have modest success until the great bulk of clinical practice becomes both more efficacious and more responsive to all the people's needs.

**Fourth:** Health Care Research helps to distinguish and assess the relative therapeutic role of Factor "X" so that it may be applied appropriately. Technological wizardry should not be confused with science and efficacious biomedical interventions should not be employed as "black

box psychotherapy." As Thomas Jefferson observed "care"-or what the rest of the world calls "love"--as well as "hope", "confidence" and "falth" are essential ingredients of clinical practice. Together they appear to account, on average, for about half of the perceived benefits of all health care. There is an urgent need to improve patient-physician communication so that both the patient's problems and the strategy for managing them, are clearly understood by all participants. This requires constructive use of the doctor's most powerful intervention--herself or himself.

This brief account of selected aspects of the history of Health Care Research may help to restore balance in our investigative portfolios. There are, in fact, three sites in which to study health, disease, and health care: the laboratory, the one-to-one clinical situation, and the population. One is not right or wrong, good or bad; each has its rightful place. The questions asked or the problems addressed determine the sites and methods to be used.

In science, measurement and counting offer the most practical bases for communicating and establishing consensual agreement. The essence of the method is "comparison" among sets of observations; these are reflected in statistical measures based on groups of people. "Statistical compassion" as well as individual compassion is required. But in quantitative efforts to help our patients it is worth recalling Major Greenwood's observation that "health statistics represent people with the tears wiped off." Nor should we forget that, as one well-worn aphorism puts it, "not everything that matters can be measured and not everything that can be measured matters!" Medicine is both a left-brain and a right-brain enterprise; one is not better than the other, both are essential.

In the Health Care Collection I have given to the Claude Moore Health Sciences Library the interested browser may discover fascinating links among the ideas discussed this afternoon as well as many others. At the least the Collection should help to advance the notion that Health Care Research is really old wine in new bottles.

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