

28 Medical Research, Technology, and Improved Health Care

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This chapter investigates a number of questions to explore the relationship between research and technology advances and improved health care. Three questions are basic. Do medical research and technology advances really lead to improved health care? My answer is yes, but not always. How well does the linear model of science application work? It works extremely well for basic science, but it works extremely poorly for clinical research, which frequently appears to be a random activity rather than a linear model. How well do new findings and technologies reach practitioners? Usually not very well at all, and there are many flaws and gaps.

Let me step back to the first decade of the twentieth century, 1900–1910, to put this in an historical context. At the beginning of that decade medicine was a journeyman’s trade. It had very little scientific basis to it, only some anatomy. In that decade we had Wilhelm Conrad Röntgen and his X-ray machine, which was rapidly adopted beginning in 1906. We also had Joseph Lister and his principle of asepsis, which was actually discovered about 20 years before but was finally adopted in that decade. Lister’s work allowed surgery to move forward and it reduced hospital infections. That decade also saw the Flexner Report which linked medicine to academic institutions and began providing the field with an intellectual home and basis.

L. J. Henderson, one of the partners in the Henderson-Hasselbach equation, became a sociologist after he completed his education in bio-

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chemistry. He initiated the sociological research tradition in this country at Harvard University. He said, "sometime during the year 1906 the random patient encountering the random physician stood for the first time in the history of mankind to benefit from the encounter." That decade, 1900 to 1910, was the beginning of the scientific basis of medicine. And we were off to the races.

We saw the rapid growth of third-party payment systems beginning with Blue Cross in 1929, and Blue Shield in 1939. In the 1940s, we moved to employer purchase of health insurance, with favorable tax treatment subsequently enacted.

We then saw the Hill-Burton program in which the federal government paid for the renovation and modernization of hospitals. We had the beginnings of the rapid growth of the National Institutes of Health as a home for the funding of research. We also had government subsidization of medical education. Science continued to advance and even accelerated. That advance was helped by the flow of dollars from insurance companies as well as from the federal government.

Over the next quarter of a century, we had a virtually unlimited flow of dollars and an increase in service-delivery capacity. The increase in new knowledge translated into new technologies that were rapidly diffused and adopted because of the flow of dollars.

By the late 1980s, however, trouble signs were appearing. We read reports of overuse of services and misuse of technology. We had a cost explosion with costs increasing 15 to 20 percent a year, along with increasing documentation of very poor instances of quality of care.

We speak of the American health care system today as the best in the world. But it is a health care system that has up to 98,000 deaths a year from medical errors. It is a health care system where 20 percent or more of furnished services are unnecessary or inappropriate. It is a health care system where costs are again on the rise and will return back to the level of the late 1980s in real terms in the near future. It is a health care system that has 44 million Americans uninsured, and the rate is growing. For every one percent increase that is above inflation in health care costs we add another 200,000 to 300,000 Americans to the ranks of the uninsured because their employers cannot afford to purchase insurance. Or, increasingly, because the workers are offered insurance in their workplace and turn it down.

Why do we have these problems? First, it is not an inadequate science base, although we have much more to learn and much more to

go forward with. Rather, on the clinical side, it is the failure to apply what we know.

How well does a linear model of science application work? It works very poorly for clinical research, in part because the questions are extremely complex and because of the difficulties in determining outcomes and in controlling across population groups. For example, look at coronary artery bypass surgery or coronary angioplasty, the rotorooter for the heart blood vessels. The first question is a simple one: Does it open up the vessels? Yes, but it is not enough to open up the vessels. Do the vessels stay open? Usually, but that is not enough either.

Does the technology increase blood flow through the heart? Now we are beginning to get to an important physiological variable. And the answer is yes, usually. But that is not enough. Does the technology make people live longer? Now we are getting to a point where we can begin to assess outcomes. When you look at technology in fields other than health, you want to know if the technology works. But you do not have to worry about the application of the technology to a series of conditions and people.

Is the technology more successful for some coronary vessels than others? This is an important question that was answered early on: yes. Do some doctors and hospitals have better results with an identical technology than do other doctors and hospitals? The answer is a resounding yes. You cannot look at just the technology and its effectiveness. You have to look at who is using it and under what circumstances. The literature is very clear. Hospitals and doctors that do the procedure very frequently have much better outcomes at a much lower cost than do doctors who perform the procedure infrequently. And yet we have coronary bypass units in small community hospitals scattered throughout the country that are doing one or two procedures a week. The flaw is not in the technology; the flaw is in the application of the technology. The flaw is in the selection of individuals who are the right candidates for that technology. We have a good body of knowledge, and we are not applying that knowledge properly.

Further, by the time we have answered the questions raised at the beginning of the chapter, there is already a whole new generation of new technology and our findings are not applicable to this technology. We have just finished studying yesterday's technology and now we have to start again with today's technology.

We have the same questions with an insulin pump. It is a simple little device and a nice little technology. Does it pump insulin from here to there, from outside to inside the body? Yes, but that is not enough. Does it keep the insulin at physiological levels? That has to do with what the patient eats. If the patient does not eat, he or she will become hypoglycemic. That is not the pump's problem necessarily: It is the application of the technology to the care of the individual. The real question is: If you use the pump instead of insulin injections, do you decrease the rate of diabetic complications over the next 25 years? Do you have better health outcomes? That is a tough piece of research to do because you are talking about a very long time frame, unless you can develop some markers and measures that will shorten that time frame.

How do new findings in technologies reach practitioners? Frequently, not very well at all. For example, surgeons were doing radical mastectomies for the treatment of breast cancer years after the research showed that a simple mastectomy or even a lumpectomy was just as effective. Another example is bone marrow or stem cell transplants for the treatment of breast cancer. The technology looked very promising on the basis of non-random clinical research. In the early 1990s a health plan in southern California looked at the literature and said there was no evidence that this technology is safe and effective for the application. The plan denied an individual a bone marrow transplant. The plan was sued and lost \$78 million, which was paid by the purchasers of the plan. That technology then became accepted practice. It even became required by law in many states. It is now required in the Federal Employee's Health Benefits Program. It had wide support in the medical profession and hence in the general population. The support was so strong that accrual to the appropriate clinical trials was greatly delayed because people did not want to be randomized. Ten years later we know that the technology is of no value. And for many people that technology is harmful.

We have substantial flaws in the conduct of clinical research and in disseminating its findings, but particularly in the adoption of the findings by practitioners. I could give many examples. Something as simple as an aspirin after a heart attack would help 98 percent of patients, yet only 35 percent are receiving it. The same situation exists with beta-blockers after a heart attack. I could go through a list of technologies where we have strong research literature but it is not being used, adopted, and applied by physicians.

To what extent should funds be allocated by disease burden between basic and clinical research? Basic research cannot be done by disease burden. By its very nature basic research builds a fundamental base. Frequently you do not know what you are looking for, or to phrase it differently, you do not know what the application will be for the research.

If you look at open-heart surgery again, what was the single most important piece of research that allowed open-heart surgery to go forward? It was an obscure piece of biochemical research that by serendipity led to the discovery of heparin to keep blood from clotting and therefore allowing extracorporeal circulation. The researchers working on that were not looking for a way to do open-heart surgery. They were looking at fundamental mechanisms of basic chemistry. Also, we should not let our political system divert money for basic science with the notion that it will be applied and all you have to do is to go to the laboratory and come out with the next big cure.

On the clinical side disease burden is an important variable, but it should not be the only variable. It should not be exclusive. For example, many technologies have been studied to help people with multiple sclerosis. As these technologies emerge, they are tried and virtually always found without value. The problem when you start directing research to diseases is if you do not have a fundamental understanding of the nature of the disease, its pathophysiology, and its cause, you are struggling in the dark experimenting with a variety of things. You need a fundamental understanding to move forward on the clinical side.

We need to set some priorities as a country for where we put our dollars, but we need to do so with a great deal of care. The cost-effectiveness of medical technologies is very difficult to measure, again, because of the problem of determining outcome for many conditions over a long period of time. Many people are attempting to do this in the drug area, often sponsored by drug companies. But they have not had very good results.

Getting adequate controls is very difficult. The better, more rigorous the design of the study, the tighter the controls, and therefore the bigger the problem of generalizability of the findings. If you have done a study on 40 to 50 year olds, can you apply the findings to people 65 and older? I could go across all sorts of demographic variables and ask that same kind of question. This is very difficult research to do to come out with findings that are timely, reliable, and generalizable.

Overall, many technologies are cost-effective on an individual basis, but not in the aggregate. For example, because of advances in technology

and anesthesia, cataract surgery is now a very simple procedure. When I was in practice a number of years ago, it was a complex and difficult procedure with people staying in the hospital for days after it. Is this treatment cost-effective for an individual? Yes, it is. On the other hand, today we are taking out cataracts that had minimal opacities in people who have minimal problems with reading and activities of daily living. In the aggregate, we are spending far more money. You could argue that the value to the individual is there, but it becomes a marginal value at some point. Since the Medicare program or insurance company pays for it, the cost approach is zero and the marginal value can approach zero.

We see the same thing with arthroscopy. Ten years ago if your trick knee bothered you twice a year, you would live with it and you would have two days of discomfort or trouble walking. Today you would have a diagnostic arthroscopy, which will not help anything except diagnose what is already known. Then you are going to have a therapeutic arthroscopy. The procedure itself is far more cost-effective, yet the aggregate costs are far higher. Again you get to the question of its marginal value for the cost involved.

Laparoscopic cholecystectomy is another example. Lots of gallbladders that used to be very happily residing inside somebody's abdomen have been removed because we have the technological capability to remove them. For most of those people the gallbladder could have just stayed where it was.

We have problems with cost-effectiveness. I break the effects of differential access into three categories. One is geographic access, which is rarely a problem. If there is money they will come. People in rural areas may have to travel a few miles and people in the cities may have to travel a few blocks to get the services. But the capacity will take care of itself as long as the dollars are there. Financial access is a real problem, certainly for the 44 million Americans who are uninsured, but increasingly for people who are insured as well. The third category is demographic access. There are wide variations and disparity in the use of technology, by gender and by race, that are totally unexplained. This is a mystery that remains to be solved.

In summary, medical research and technology advances frequently lead to improved health care, but not always. The process of research has its flaws, but the real flaws are in the adoption and application of that knowledge by practitioners. We can do better and we should do better.