The Metro Firm Trials and Ongoing Patient Randomization

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Many large hospitals in Europe and North America have teams of physicians who care for groups of patients. New patients are assigned to a team in rotation. The first patient goes to team A, the second to team B, and so on, over and over. This is usually done to equalize the work load of the teams. The teams can include physicians, nurses, and other staff. They are responsible for outpatients, inpatients, or both. Although these arrangements have been in existence since the turn of the century, no one has ever taken advantage of such an arrangement to accurately evaluate the effects of changes in care and done this on an ongoing basis.

The 700-bed Cleveland Metropolitan General hospital (Metro) has four such teams, called "firms," of general internal medicine physicians who work with nurses and other allied health personnel. Each firm has 18 physicians, 28 inpatient beds, and an outpatient clinic. From 1976 to 1981 all new patients were assigned in rotation. Starting in 1981, patients were assigned by a computer program that generates the numbers 1, 2, 3, and 4 continually in random sequence. This random assignment provides excellent assurance that the four groups of patients are nearly identical. If the assigned firm's inpatient unit is full, the patient is "boarded" on another unit until a bed is free and then the patient is transferred.

In every hospital, hundreds of changes in the organization and delivery of medical care are made in the belief that such changes provide better care and/or more efficient care. Only a small fraction of these changes are carefully evaluated to show whether this belief is correct.

Because patients are different, evaluation of medical care is particularly difficult. One has to be sure that observed changes in the results (for example, better care or lower cost) are due to the care itself rather than to patient differences. The history of medicine is marked by unevaluated, probably harmful, treatments, from blood-sucking leeches to surgical lobotomies for mental illness, which have been applied to tens of thousands of patients. There is a continuing need for careful evaluation so that such useless and harmful procedures happen less often in the future.

Since 1981 at Metro, the four firms and their similar patient populations have been used to evaluate an ongoing series of changes. In these trials, a change is put in place in two randomly chosen firms, while the other two firms are left as they are to serve as controls. To increase the assurance of comparability, since 1983 all new resident internal medicine physicians have been randomly assigned to one of the four firms. These residents remain with their firm for the three years of their training.

USING THE FIRMS

A series of trials has been carried out under the direction of David Cohen, M.D., using the Metro firms. These studies asked such questions as: Does feedback to resident physicians about the cost of the laboratory tests they order reduce their use of tests? Yes. Do reminders to carry out appropriate preventive procedures for ambulatory patients increase their use? Yes. Does better organization of outpatient care reduce the cost of inpatient care? Yes.

We describe two trials in more detail. One focused on better quality of care and the other on lowering costs. Ordinarily at Metro, intravenous or IV therapy (feeding patients fluids by tube into an arm vein) was managed by the regular nurses and physicians. Some physicians thought having a specialized IV team would reduce the rate of infections and complications (phlebitis). The IV teams were put in place in two firm inpatient units, and the percentage of patients on IVs with infections was compared with firms managing IVs in the usual way. The patients of the specialized IV teams did have significantly fewer infections. The teams had 15% compared to the control groups' 32%. Very serious complications were reduced from 2.1% to 0.2% by these specialized teams. As a result of this evidence, the specialized teams were used in all four firms. Later, during a cost-control drive, it was proposed that the IV teams be eliminated.

However, by showing the evidence of their efficacy, the IV team members kept their jobs, and the patients continue to benefit.

The hospital now has a new computerized information system, which includes information about patients, their physicians, the firm they are assigned to, laboratory tests, and drugs used. In the second study, Charles Hershey, M.D., and colleagues used this firm-and-information system to enlighten physicians about drug usage. They sent a computerized message to two firms suggesting that physicians substitute less costly drugs for an expensive, but otherwise similar, drug and indicated how much money each doctor could save by doing so. Then, using the same information system, they measured the effect of this message. They found a significant substitution effect for the experimental firms (see Table 1). What was of particular interest about this trial was the very low cost of carrying it out. Because of the ongoing randomization and the computerized information system, the additional cost for this study was less than a thousand dollars. The largest cost was the time Dr. Hershey took to write the report for publication.

GENERALITY OF FINDINGS

It is legitimate to ask whether Metro and its patients are representative of all large North American hospitals. What works at Metro may not work at other hospitals. Even so, just improving care at this one hospital is a good thing to do. Other hospitals could develop similar systems of ongoing patient randomization to their own benefit.

If similar studies were carried out in several such hospitals, we could begin to learn how representative Metro really is. One such program has been started at University Hospitals of Cleveland, where all new ambulatory patients cared for by the general medicine clinic are now randomly assigned to one of two teams of physicians by the last digit of the patient's Social Security number. Even numbers go to one team, odd numbers to the other. The clinic director, Victoria Cargill, M.D., is now completing a trial to see if it is more effective

Table 1 Mean charge for drugs used before and after computerized feedback of information to physicians; comparing experimental and control firms 1984–1985

	Before Study Started			*At End of Study*		
Firms	*Mean Drug Cost**		*Standard Deviation***	*Mean Drug Cost*		*Standard Deviation*
Experimental	$8.44	±	1.28	$8.22	±	1.01
Control	$8.56	±	1.89	$8.79	±	0.83

* These costs are based on the use of three common drugs by 48 physicians. The difference between the control and experimental firms at the end of the study is significant and very unlikely to have occurred by chance (Hershey, Porter, Breslau, and Cohen, 1986). Although these differences may look small per prescription, this difference applied to all firms at Metro would result in a savings of $6,500 per month.

** A standard deviation is a measure of spread or variation. In many distributions about two-thirds of the data fall within a distance of 1 standard deviation from the mean and about 95% fall within 2 standard deviations.

to have nurse practitioners rather than the resident physicians screen for colon cancer. Dr. Cargill found that patients seen by the nurse were much more likely to send their take-home test results back to the hospital for evaluation and, if need be, follow-up evaluation and treatment.

The earliest known randomization of patients for the purposes of evaluating treatment was published in 1931. (Amberson et al. divided 24 tubercular patients into two comparable groups of 12 each, then matched them in pairs. By a flip of a coin one group of 12 was chosen to be treated with sanocrysin and the other became a control group.) But it was only in the 1950s that randomization began to be applied widely. Single randomized trials can be very expensive—some have cost more than a hundred million dollars. If such studies lead to more rapid diffusion of beneficial treatment or discourage a costly, worthless treatment, however, the worldwide benefits would be well worth such large costs. We may hope that making good evaluation less costly, less difficult, and more routine will lead to more of it. Efficient, repeated evaluation of changes that lead to better care is the special contribution of ongoing patient randomization. It is a general idea that could be applied outside the health care field.

The world has no large set of organizations prepared to carry out medical evaluations through experimentation at a moment's notice in hospitals. By and large each experiment has to be organized separately at considerable expense, and because it is organized especially for the occasion, it does not exactly represent the medical practice that is in place in the institutions. Therefore it is difficult and expensive to get evaluations of technologies done in the medical and health fields.

On the other hand, the same thing used to be true of the field of sample surveys. Every sample survey had to be set up from scratch because no national organization was in place, and so surveys were especially expensive because of organization and start-up costs. Now there are many national organizations that can carry out surveys quickly and economically because the organization and the expertise are all there and ready to go. We need such an arrangement for the evaluation of medical technologies. Such evaluations must be done primarily through *experiments,* which are much harder to execute than sample surveys. Thus it is important to have a collection of organizations (hospitals with firms) ready to carry out evaluations through experimentation with medical technology.

PROBLEMS

1. New patients are randomly assigned to the firms in order to provide the best assurance that the patient groups cared for by each firm are similar. If these patients need care, from then on they go back to the same firm. As time passes do you think the patient groups seen by the firms will continue to be similar? Explain your answer.

2. Do you think you could apply this concept to a large high school or college? How would you do it?
3. Can you pick some other organizations where this concept could be applied? What organizations? How would you do it?
4. In Reykjavik, the capital of Iceland, there are three government hospitals. On the first day, all emergency patients go to hospital A, on the second day, all go to hospital B, on the third day all go to hospital C, then the cycle is repeated continuously. The Ministry of Health has asked you to advise them about the quality and cost of care in their hospitals. What would you do? (You might measure quality of care by death rates, length of sickness, or time lost from work.)
5. You are responsible for stopping drug smugglers at the Miami International Airport where thousands of passengers arrive every day from many countries. You are in charge of 200 customs inspectors. Every passenger passes through one of your 20 customs checkout stations. You have lots of ideas about different ways to find drugs, but you are not sure they will really work. (For example, you could have every large suitcase opened and inspected. But this would take longer than opening just suspicious suitcases, and passengers get upset when they have to wait in line too long.) Explain how you might find out if your ideas are good ones.
6. You are assistant to the president of an international company that owns 2,000 retail ice cream stores. The vice president for marketing wants to offer cinnamon-flavored cones with red spiral stripes in addition to the usual brown-colored cones. The president has asked you to develop a plan to evaluate this and other new ideas. What would you do?

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