Epidemiology and Health Policy: Prevention Initiatives, Resource Allocation, Regulation, and Control

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THE COST OF HEALTH CARE is soaring. The affluent society demands the best available treatment for each person, yet the available resources are limited. Therefore, in the decision process, one has to look for objective criteria to rank the competing needs. In simpler words, what must be provided and what can be eliminated?

Competing Needs

The competing needs of health care delivery revolve around preventive care versus curative care, the strengthening of community medicine versus the development of hospitals, the expansion of environmental controls versus introduction of sophisticated instrumentation, supporting nursing homes for the elderly versus a network of home care and, last but not least, health education versus provision of health services.

These deliberations concern a basic triad—start, cancel, and continue. Within this triad, the questions follow the classical epidemiologic quintet: what, where, when, who, and why. What should be started or cancelled? When, where, and who should be involved, and the most important question—why?

Epidemiology provides guidelines for confronting and handling needs. Health policy is the end-product of the melding of needs, the resources available, and political pressures. I define the term "political" to mean extra-scientific considerations; these include the lobbying of government officials, lawyers, mayors, and other persons who are often motivated by the necessity to do something for or against or just by the need to prove that they care.

Swine Flu—A Vivid Example

Some excellent examples of such health policy deliberations have been marvelously documented in the history of the swine flu vaccine affair by Neustadt and Fineberg (*1*). There was the apparent epidemic, harrowing memories of 1918, an election year, a potential budget of $140 million that could or should not be used for a nonexistent but probably imminent disaster, and three basic issues:

1. Should an immunization campaign be started?
2. Would stockpiling of vaccine be sufficient?
3. What other health needs would be compromised if $140 million were spent on this venture?

The following excerpts (*1*), attributed among others to David Sencer, then Director of the Centers for Disease Control, to Reuel Stallones, Dean of the School of Public Health at the University of Texas, and to some anonymous observers, illustrate the alternative considerations that were applied.

> There was nothing in this for CDC except trouble. Here we were at the end of one flu season with time to try to do something before the next flu season. The obvious thing to do was immunize everybody. But if we tried to do that, guide it, help it along, we might have to interrupt a hell of a lot of work on other diseases . . . work here, and in the states, a lot of places.
>
> Then if a pandemic came, lots of people—maybe millions—would be angry . . . because they couldn't get shots when they wanted . . . Or they got sick of something else that they mistook for flu and thought our shots weren't working. Most people in this country (including half the doctors) call all kinds of things flu that aren't. As for "another 1918," I didn't expect that, but who could be sure? . . . It would wreck us.
>
> Yet, on the other hand, if there weren't a pandemic we'd be charged with wasting public money . . . crying wolf . . . causing all that inconvenience for nothing . . . and not only the people who got shots . . . the people who administered the shots . . . our friends out in the states . . . what would they think of us? It was a no-win situation . . . we saw that . . . talked about it . . . (p. 11)
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> This was an opportunity to try to pay something back to society for the good life I've had as a public health doctor. Society has done a lot for me—this is sheer do-goodism. It was also an opportunity to strike a blow for epidemiology in the interest of humanity. (p. 12)

Suppose there is a pandemic accompanied by deaths. Then it comes out: "They had the opportunity to save life; they made the vaccine, they put it in the refrigerator . . . " That translates to "they did nothing." And worse "they didn't even recommend an immunization campaign to the Secretary." (p. 14)

I told the President that this was no-win position politically. There was no good to come of it as far as the election was concerned . . . if there was no pandemic a lot of people would have sore arms in October. If there were a pandemic, no matter how much we'd done it wouldn't be enough and he'd be roundly criticized. (p. 25)

. . . the net result might be a speculative spate of new stories and editorials which either scared people or presented them with the impression of an imminent national emergency or made it look as though the President couldn't make up his mind. (p. 28)

Decision-Action Model

The art of epidemiology involves the ability to use 2 × 2 tables and present them on 2 × 2 slides. So let me try to put the matter into perspective with a policy decision model stage 1 (fig. 1). The optimal situation is having adequate resources for the right needs or when no resources are allocated in the absence of needs. The two problematic states are when money is spent on redundant items and, even more awkwardly, when no money is available for top priority topics. The consequent action process, as shown in the policy action model stage 1 (fig. 1), should be to continue evaluating the two optimal states, to cancel the redundant programs, and to mobilize support for new programs for which no money has been allocated.

Since public health officials do not work in a vacuum, we must take a second look at the model when political pressures become operative. The matrix will then look like policy decision model stage 2 (fig. 2). With the stage 2 model, we still have two optimal situations, that is, when resources meet needs in the presence of positive pressure and when resources are kept from being spent on a redundant project when no political pressure is applied. On the other hand, the decision maker must now cope with several additional complex situations. Positive political pressure is helpful when you have no money for the right cause or when money is spent on the wrong issue. It is dangerous, however, when you are pressured to spend money on redundant needs or dissuaded from organizing support for the true needs. Still, the situation is most detrimental when, for political reasons, you may have to stop a funded priority program or fund an unneeded one.

The suggested course of action is diagramed in policy action model 2 (fig. 2). We must continue, nevertheless,

Figure 1.

Policy decision model stage I

Needs \ Resources	Postive	Negative
Positive	Optimal	Wasteful
Negative	Redundant	Optimal

Policy action model stage I

Needs \ Resources	Positive	Negative
Positive	Evaluate	Argue for
Negative	Cancel	Evaluate

Figure 2.

Policy decision model stage II

Political Pressure	Needs \ Resources	Positive	Negative
For	Positive	Optimal	Helpful
	Negative	Dangerous	Detrimental
Against	Positive	Detrimental	Dangerous
	Negative	Helpful	Optimal

Policy action model stage II

Political Pressure	Needs \ Resources	Positive	Negative
For	Positive	Evaluate	Endorse
	Negative	Argue against	Fight
Against	Positive	Fight	Argue for
	Negative	Cancel	Evaluate

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to evaluate the optimal states, cancel the redundant ones when the politicians are with us, take advantage of the political pressure for unsupported needs, argue the case when the situation seems dangerous. But my foremost admonition is—do not hesitate to fight the two detrimental situations even if, in the final outcome, it means losing your job.

Preventive Initiatives

Although I have elaborated on the political aspects, they are by no means the dominant feature of the decision process. Most often the choice is between a number of lifesaving procedures. I will use a few real life examples, first in the context of preventive initiatives and then with regard to resource allocations, although these two topics are interrelated.

Israel, like many countries, continued to vaccinate for years against a nonexistent disease—smallpox. When we tried to stop it, preaching that the risk of inoculation far exceeded the potential benefits, we were confronted by enormous pressures from medical and army circles. Nobody was ready to face the risk of even one case occurring in the future, to say nothing of the fact that we were planning to eliminate the only vaccination in Israel that was compulsory by law.

I have already mentioned some of the considerations in starting a new immunization program in connection with the swine flu outbreak. We in Israel have struggled with some of these decisions a few years ago, endeavoring to introduce nationwide mumps vaccination. We asked ourselves how far should we, as health planners and health providers, go to ensure the highest possible immunization coverage? Also, should we publicize widely the minimal but existing complications, or play them down, taking the risk of future litigation, and so keep high the proportion of the population covered. Recently we have been faced with a few score damage suits by parents of children seriously affected by the pertussis vaccine, who claim that they had not been told of a potential danger. A public advisory committee that I appointed did not come up with a clear-cut answer, and I assume that we shall have to continue monitoring complications; continue assessing the risk-to-benefit ratio; continue referring to, but not spelling out, the possible danger; and continue picking up the tab. However, we did learn a lesson; we changed our insurance policy.

Consideration of cost effectiveness (*2*) becomes even more essential when dealing with cancer and other chronic diseases. Screening has become in recent years the magic slogan, but critical case-control evaluation of screening may be most difficult. Can anybody today start a critical randomized study of cervical cancer screening? Nor can one try to evaluate coronary care units critically through a randomized study. Has anybody examined the contribution to the decline in U.S. heart disease mortality (*3*) made by the millions of dollars spent on the Framingham studies, or are we just witnessing two coincidental effects? Truly, the Framingham group has led in preaching a prudent diet, cessation of smoking, detection of occult hypertension, physical activity, and a more relaxed way of life (*4*). Can we really reduce heart disease mortality by fighting these risk factors? "Mr. Fit" may show otherwise (*5*).

Israeli data generate similar reservations. No major dietary changes have been undertaken by the population, people still smoke like diesel engines, they are under continuous stress, and yet their heart mortality rates (*6,7*) are also going down. Is it possible that there is no genuine decline in incidence, but that the better mortality statistics represent better survivorship, attributable to earlier hospital referral or to improved hospital treatment? Solving this riddle is of major importance to health administrators and policy makers, since, if the first alternative is true, we should continue pouring money into primary prevention and major health education programs. But if the other one is correct, then major financial efforts should be made to develop further mobile coronary units and strengthen available treatment and rehabilitation centers.

In reality, just a few of the so-called chronic diseases are fully preventable, and even with these, our efforts have been directed to decrease the magnitude of the risk, rather than to eliminate the cause itself. For instance, we do not ban smoking, we do not ban asbestos, we do not ban radiation, nor vehicles and planes; we do not even ban alcohol, while the harmful elements we have banned (for example, pesticides, dyes, and hard drugs) contribute only marginally to the debilitation load.

Resource Allocation

A major obstacle in initiating or stopping a health program is that, in public health practice, we usually go

for the dramatic and seemingly obvious course of action, and in consequence we tend to discriminate against the silent but more widely distributed problems. The TV appearance of one child who may die of liver disease and may benefit from a liver transplant is a more powerful image than thousands of scattered anonymous infants who will die from infection or malnutrition and whose deaths are truly preventable.

Similarly, continuous media exposure of one patient with an artificial heart is more dramatic and, unfortunately, more effective in sensitizing the public than thousands of heart victims in routine rehabilitation programs. Epidemiology has to move in, in such situations, and provide facts, figures, and projections to create a more rational perspective.

On January 1, 1965, there were 12 patients with end-stage kidney disease in Israel who would have qualified for hemodialysis (*8*). On January 1, 1983, there were more than 900. No major epidemic led to this dramatic increase; it stemmed from the availability of treatment, and the decision that every patient deserving this treatment will get it. Similarly, there were 750 open heart operations in 1977 and close to 2,000 in 1982. Again, the increase occurred due to a change in policy. Were these the right decisions? Are we right to spend 10 percent of the nation's hospital budget on care for terminally ill cancer patients or $600,000 on a joint replacement for a single hemophiliac child, as happened recently?

All public health officials strive to give the optimal treatment to everybody, but it is usually the other patient who pays for it. While the facilities for renal, heart, and cancer patients were increased in Israel, the list of elderly patients waiting for nursing care has also increased. At the same time, the range of infant mortality between affluent and less affluent districts in Israel continued to be 3 to 1, and the mortality among premature babies increased because not enough money was provided for additional neonatal pediatric units.

Admittedly, we do monitor and learn. We have studied the mortality patterns in distinct sections in Israel (*9*), delineated some causes for the differential rates of infant mortality, and started a nationwide intervention program to bridge the gaps between high and low mortality regions. But we shall never have all the money we want to support the needs that we decide are of utmost priority. Even if the United States overcomes its economic problems, and even if Israel discovers enormous oil fields, we shall never be able to cover all the priorities. Therefore, we must struggle continuously with the balance-of-power seesaw by shifting priorities and having the courage to stop outmoded and non-cost-effective programs and fit new ones into the same framework. This process of shifting is demonstrated in the policy action model stage 3 (fig. 3).

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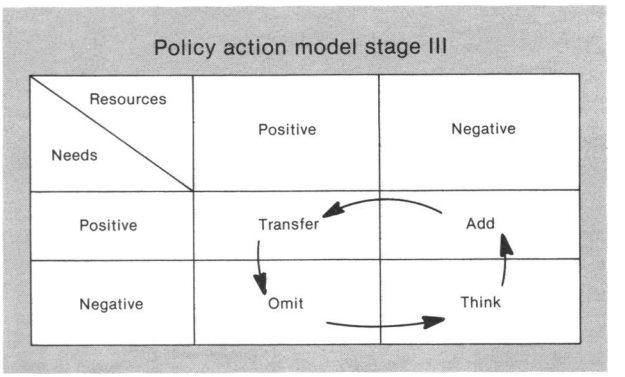
Figure 3.



In the infectious disease area, for example, by discarding smallpox and BCG vaccination, we can now accommodate, at least in part, the needs for mumps and rubella vaccination. Indeed, additional funds will definitely be needed, since new programs are always more costly than old ones, and you can never discard the old ones completely. Still, we have the core for a new beginning. In the field of chronic diseases, the situation is less obvious and more complex. New needs are being forced on us at a tremendous pace and, if they are translated into dollars, they mean insurmountable costs. These costs apply as well to nursing home beds, kidney dialysis units, coronary bypass procedures, and successive generations of sophisticated imaging machinery. Therefore, the decision process may be more lengthy and, therefore, moral and ethical considerations may have to be employed.

Regulation and Control

I would like to move next to a different array of problems—the regulation and control of drugs, medical

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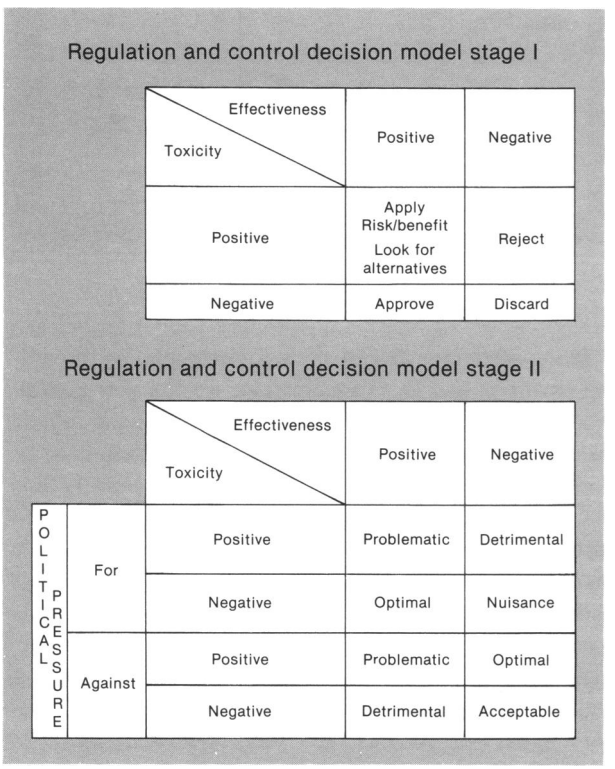
Figure 4.



devices, and food. If we try again to apply a 2 × 2 table, the resulting decision model for regulation and control is depicted in figure 4.

The only definitive action to be undertaken is when the substance is effective and lacks toxicity. Yet, the interim situation, when the substance under study is effective, but also carries a central element of toxicity, is the most challenging one, and it forces us to apply risk-benefit criteria or look for other alternatives, or both. This situation is often complicated when political pressure is present, be it pressure from industry, pharmaceutical agencies, consumer groups, or other lobbyists. The net effect is illustrated in regulation and control decision action model 2 (fig. 4).

Two of the situations just described are detrimental, but, fortunately, rare—when there is pressure to approve an ineffective but toxic substance or when excessive pressure is exerted to discard an effective nontoxic one. The major problem that remains is the regulation and control of an effective, but slightly toxic substance either in the presence of positive pressure, usually from industry, or a negative force, usually consumer agencies. The table summarizes the current experience and state of the art for some of the more common substances.

Some examples for current practice regarding the regulation of selected toxic substances

Action taken	*Substance*
Rejected	Rely tampons
Limited	Chloramphenicol, nitrates
Monitored	Oral contraceptives, chemotherapy, radiation
Evaluated	Coffee, saccharin, sodium
Kept irrationally	Asbestos, tobacco, alcohol

The major determinants in current practice are the availability of alternatives, firmness of data, and magnitude of deleterious effects as well as economic considerations. Thus we are ready to undertake the risk of the pill since available alternatives are less satisfactory and the magnitude of the risk is low. However, no chances are taken with certain brands of tampons, since the risk is obvious and alternatives abundant.

Saccharin and coffee are good examples in this context. On the basis of human case-control studies in which carcinogenic effects of saccharin or coffee, or both, were examined (*10–13*), coffee might have been the substance that should have been banned first. Yet most of the zeal and anger of consumer groups and of radical legislators has been directed at banning saccharin.

Why saccharin and not coffee? Is the coffee industry's lobbying power stronger? Are we biased by the mere thought of a coffeeless coffee break? Can we not imagine asking a friend, "Will you come for tea?" Is it the lack of a satisfactory alternative? Yet saccharin was once almost totally excluded from food in the United States, and the final decision has been deferred only due to congressional pressure.

In Israel, we did not face lobbying by industry, and the equivalent political body did not interfere. Thus, to a certain extent, the decision was entirely in our hands. Still, the data were not adequate to make such a decision, since the alternate risk of excess sugar consumption could be stronger. But the data were also insufficient to make the opposite decision. Thus, when I was asked to approve diet cola, I declined, fearing that an additional load of a dose-dependent substance may tip the delicate balance.

Prospect

Epidemiology, which is often defined as the study of rates and distributions, may shed light on the darkness of administrative routines. Therefore, if it is properly applied, it should help us, the wandering scientists in Bureaucracy to utilize quantitative methods and scientific criteria in the labyrinths of the decision process.

To examine more rigorously and to decide more precisely is, after all, our main responsibility. It is also our duty to the people we serve.

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Uses of Epidemiology in the Development of Health Policy

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EPIDEMIOLOGY IS WIDELY but quietly used in policy formation. As its use increases, basic systems of data collection, analysis, and distribution must be improved throughout the nation.

For example, the core of epidemiology is to (*a*) define the distribution of a disease or condition, (*b*) define the determinants, and (*c*) define the effects of that disease or condition. The basic tool of this process is the definition and interpretation of ratios between numerators and denominators. As a result, the outcome of epidemiology is highly dependent on a system that collects the right things and collects them right. Some basic improvements are now taking place in this collection system.

I will first describe some general trends in epidemiology and policy and then look at some specific recent examples from the Centers for Disease Control (CDC).

The use of epidemiology is increasing as is the acknowledgement of epidemiology's relevance in public health policy. It is no longer an academic practice, nor is it a phenomenon of the developed world. In the past 30 years at CDC alone, we have trained more than 1,200