

A PUBLIC HEALTH VIEW OF VACCINATION

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Among public health programs, vaccination has proven to be the most dramatically effective and affordable of all. It is the single most cost-beneficial medical procedure available and certainly the simplest to perform. It has had a profound impact everywhere on childhood morbidity, mortality and disability. This effect has been especially dramatic in developing countries. As we have heard this week, there is promise for vaccination far exceeding all that has been accomplished to date. But such miracles will be realized only if vaccination programs can be sustained, and provided that sources of funds can be found for the new vaccines to be given to the susceptible populations needing them. In this context, my remarks necessarily address primarily but not exclusively the needs of the 75% of the world's population now living in developing countries--a population accounting for 98% of all infant deaths.

During the past twenty years, the global Expanded Program on Immunization has created a remarkably effective vaccine delivery structure throughout the world. This has been characterized as the most extensive, successful and far-reaching social program ever launched. There is truth in that assertion. In most countries, it is now administering to more than 75% of all children six antigens--diphtheria, pertussis, tetanus, measles, poliomyelitis and tuberculosis (1). This is a dramatic change from only 20 years ago

epidemics erupted in large cities across the country. Complacency was the cause. However, we are beginning to learn that immunization levels cannot be sustained as an incidental by-product of our existing clinical care systems. Prevention services have not been and are not now a priority of most such systems (4).

What we are learning is that specifically targeted programs for the management and for the marketing of vaccination programs are necessary in most countries if immunization levels are to be sustained. Different areas have successfully used different approaches. Of particular interest are Latin America's National Immunization Days, now being conducted twice annually in most countries. They are heavily promoted by creative marketing, imaginatively utilizing the mass media, and supported by community outreach programs which enlist numerous private and voluntary organizations (5). In Brazil, such National Immunization Days have been conducted annually for 15 years with 90% of children being reached each day, a level comparable to what was achieved during its first few years. Traditionalists said that such interest could not be sustained year after year. The Brazilians pointed out that they had managed to stage Carnival every year for centuries and with good reception every year.

The United Kingdom has employed a different but no less successful approach. It has developed a national computer registry which documents the immunization status of all children. Through the registry, reminder notices are sent to parents and caregivers to remind them when vaccinations are due. The success of each provider in meeting stated

targets is monitored. A cash bonus is awarded each year to the provider who fully vaccinates 90% or more of children enrolled in his practice (6). Vaccination levels in the United Kingdom are now over 95%--the highest anywhere in the world.

In sum, it has become clear that for successful vaccination programs to be sustained, there is need for the continuing attention of a small but dedicated staff who can monitor immunization levels, who can assure good surveillance of the vaccine-preventable diseases, and who can regularly evaluate and redesign strategies and marketing programs appropriately. The number of countries with programs so constituted is growing.

The second critical challenge is to identify the needed resources for vaccine research and development and for the purchase of new and improved vaccines. This problem is acute. The global program for vaccination so far relies almost entirely on the same six antigens with which it began in 1974. Although none is fully satisfactory in terms of both efficacy and stability, none has been significantly improved or altered in more than 20 years. It is to me a sobering reflection--as I hope it is for you--to appreciate that none of the magnificent advances and discoveries of the past 20 years have yet been translated into benefits for the 75% of the world's children living in developing countries. And, at this time, there is no global strategy for doing so.

The addition of new products also implies greater costs. Such vaccines as the acellular pertussis, hepatitis B and hemophilus influenza vaccines are more costly to produce and understandably will be more expensive to customers because of the need to recover research, development and new production expenses (7). An even greater challenge looms in developing and bringing to market vaccines which are critical to the third world but of little interest to industrialized countries--for example malaria, schistosomiasis and cholera vaccines.

If we are to do more, added resources will obviously be needed. The availability of resources is and has been a limiting constraint. Heroic efforts have been made to interest bilateral assistance agencies and the UN in augmenting support for vaccination programs. UNICEF has been most helpful as have several national authorities and International Rotary has raised more than \$300 million in support of polio eradication. Moreover, for the present global program, expenses have been held down as the vaccines are being sold at concessionary, marginal cost by European and Canadian manufacturers. Such is possible for vaccines with a large market in industrialized countries and whose research and development costs have long ago been recovered. Now, however, we face new scenarios.

What can we do? To simply sustain existing international support will itself be a challenge. Most countries are reducing international assistance budgets and given

current dissatisfaction with the United Nations system--and WHO in particular--UNICEF and WHO budgets are unlikely to grow.

Does the development and application of new vaccines warrant high priority, given the lengthy list of other demands for health care? In deciding this we need to be reminded that the dramatic gains in longevity and infant mortality over the past 30 years in developing countries, are almost wholly accounted for by vaccination programs. And, I would submit, prospects for achieving comparable gains through immunization over the next generation are at least as good. Should significant breakthroughs occur--perhaps, for example, the development of effective tuberculosis, malaria and/or AIDS vaccines--the pace of progress could double. No other measure in the entire health field begins to offer such promise.

It seems to me that a broader world needs to be educated in the vital role that vaccination plays in health; that in deciding public policy and examining the economics, vaccines are a unique product which differ significantly from pharmaceuticals and indeed from all other medical interventions; and that absent a cooperative planning and development effort we are in imminent danger of major disconnect between promise and delivery. It seems to me that a special cooperative effort is needed to address the problem. All of the principal actors need to understand the complex of relevant issues and problems and must together work out sensible strategies designed to achieve the best possible and most extensive use of vaccines. I believe it would be useful to convene a

consortium of national and international policy makers, private sector industry, regulatory authorities and the science community with a mandate for jointly exploring issues and options and seeking resolutions. Change is needed on many sides. I personally believe regulatory procedures could be greatly simplified and decisions speeded at no real risk; industrial marketing and sales people need to grasp a picture larger than the next quarter's profits; scientists must hear what is really needed in the field and what is not; and ministers and heads of state need to understand that there are other priorities in health than those argued by their personal cardiologist.

Let me touch on opportunities in two particular areas--research and development, and resources for vaccine purchase. Reality dictates that the bulk of research and development will have its primary base in industrialized countries simply because that is where most biomedical research facilities are located. Funding for such activities will have to derive primarily from the industrialized world. Here is a challenge. National research agencies and the development assistance community require education regarding the importance of expanding investment in this area. At present, resources are scarce indeed, in significant measure because development agencies have traditionally provided little money for research on health problems. There is precedent, however, to do otherwise. I would point out, in contrast, that research on international agricultural problems has been generously funded and to very good effect. It is apparent that for the health sector, we have not yet made a persuasive case. The agenda of the Children's Vaccine Initiative is specifically directed to this challenge.

The second important opportunity relates to the provision of added resources for vaccine purchase. As I have noted, it seems unlikely that international agencies will expand their efforts. The World Bank, however, has pledged to invest in health substantially larger funds than in the past--the figure of at least \$1 billion per year being cited. So far, little has been invested in immunization programs. Support for vaccine production and quality control systems, diagnostic facilities, research and infrastructure support would logically seem to fall within the Bank's purview. A most positive development is the fact that national governments have begun to assume ever greater fiscal responsibility for vaccine purchase, an effort pioneered by the Pan American Health Organization. In most countries, this effort could be significantly augmented. To do so, national health and finance ministries will need to be persuaded to examine questions of the comparative benefits of different health programs much as the World Bank did in its 1993 World Development Report on Health (2). From the Bank's analyses, it was all too apparent that the most productive national investments in health were vaccines. This is not yet widely appreciated. Most national health budgets even now provide for substantial purchases of pharmaceutical products intended for disease treatment, when, in fact, an investment in vaccines to prevent disease is clearly a superior choice. If manufacturers perceived that national authorities understood the importance of immunization and were willing to invest accordingly, I believe vaccine research and production would be sharply boosted.

Let me conclude by saying that the global immunization program which was launched only 20 years ago clearly represents one of the great achievements in public health of this century. I personally am persuaded that with competent international leadership fully supported by scientists, by industry, by regulatory authorities and by national governments, the world's health could truly be transformed over the next two decades. The problems are not insurmountable. However, they simply are not yet being addressed seriously.

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