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VACCINATION POLICIES AND PRACTICES
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"VACCINATION POLICIES AND PRACTICES"

It is, for me, a pleasure — and an honor — to participate in this Sixth Annual Fenner Conference on Medical Research and to have the opportunity to pay tribute on his 80th birthday to one of the world's foremost virologists, a respected colleague, a friend, a medical statesman and as fine a smallpox warrior as any who engaged that virus in the quest for its eradication.

More than 17 years have now elapsed since the last smallpox patient, Ali Maalin, became ill, and almost 15 years since routine smallpox vaccination was stopped throughout the world. For peoples everywhere, the eradication of smallpox was hailed as an epochal event. That program began in 1967 when health staff from countries across the world joined under WHO leadership in a campaign to eliminate a disease. It is important to recall that in 1967 there were more than 10 million smallpox cases, and over 2 million deaths. Under the threat of smallpox, almost all countries supported national vaccination programs even though they had had no disease themselves for many decades. Australia, protected by distance and better able to screen visitors than most, was one of very few countries which did not routinely vaccinate its population. However, all tourists were required to present, on arrival, a yellow vaccination booklet which attested to the fact that the traveller had been vaccinated against smallpox within the preceding three years. And I would note that England and Germany then both maintained, on standby, large hospitals which were opened and occupied only when cases of smallpox were imported into their country.

All that is now history — the 10 million patients each year, most of whom were hospitalized where hospitals existed; the 2 million deaths; the several hundred thousand persons who annually were blinded; the vaccination cards; the one billion plus vaccinations performed each year; the quarantine officers and the fear. The annual cost to the world to accomplish this task over a 15 year period was U.S. \$20 million. The savings, each year, are estimated to be more than 50 times this amount — and dozens of smallpox hospitals have been released for the hospitalization of other patients. A British medical journal called the achievement "a triumph as great as any in the entire history of medicine."

I note this bit of history because one might assume, that for a goal such as this in which all nations would benefit so greatly and at so little cost, the global program must have received generous support from many countries — if not from the beginning, at least when it became clear that a global victory was possible. Not so. In fact, despite repeated appeals for help, field operations periodically had to be slowed or occasionally stopped because of a lack of funds.

How can one explain such a paradoxical attitude by governments? The benefit-cost ratios, after all, were overwhelmingly positive even for non-endemic countries. And I would note similar benefits could be shown for other vaccines. But other vaccination programs were little better supported than was smallpox eradication. The fact was that in all countries, for at least a generation, policy-makers and the public alike had become fixated on that component of medicine we term "sickness care" — the treatment and

rehabilitation of patients. And, indeed, over the years substantial advances were made. Increasingly, the sickness care system came to demand ever larger and more sophisticated hospitals, ever more costly pieces of apparatus for diagnosis, more elaborate operating rooms for such as transplant surgery and a proliferating array of medical specialists. The demands were insatiable and the advocates for sickness care budgets were eloquent. Conversely, those programs designed to prevent sickness — and I note immunization in particular — were seriously neglected and underfunded in every country.

Occasionally, as happened in Hong Kong, logic prevailed — where a public health officer documented that for polio, one could vaccinate the entire population several times over for the amount expended annually for surgical rehabilitation of children paralyzed by polio. Such arguments persuaded few, especially in developing countries. In fact, as recently as 15 years ago, not more than one child in 20 in the developing world was receiving such well-known vaccines as polio, measles, diphtheria, pertussis and tetanus — all diseases which are major causes of death and hospitalization in the Third World. Indeed, as I visited infectious disease hospitals during the late 1960s and 1970s, I was astonished to find entire wards, even floors of hospitals assigned specifically for patients with measles, tetanus, whooping cough and poliomyelitis — all entirely preventable illnesses. Many assumed that the dearth of immunization reflected a lack of funds for vaccine purchase. In part, this was true for some countries but for most, it reflected a decision to expend available hard currency for pharmaceuticals and surgical and diagnostic equipment rather than for vaccines — to pay for the treatment of disease rather than for its

prevention. The most pertinent question was seldom asked: How best should limited resources be expended to assure the healthiest possible population?

As the years have passed, we have come to realize that no country has anywhere near enough resources to assure the provision of all possible curative and rehabilitative services to all in the population. In short hand, no country can guarantee everyone a heart transplant. And, with an aging population, the tension between resources and demand will predictably become more acute. Recognizing that resources are finite and that, one way or another, services will have to be rationed, choices must be made and among the options is immunization.

This past year the World Bank, in its 1993 World Development Report, examined with care the interplay between human health, health policy and economic development. A multi-disciplinary study group, led by economists, endeavored to assign costs to a wide range of curative and preventive services and to estimate the benefits of each in terms of the improved quality and duration of life of the population. Among all possible interventions, immunization in particular and preventive measures more generally, ranked at the very top of the list in terms of maximum return for the investment made. In fact, it can be said of immunization, that of all procedures known to medicine it is the single, most cost-beneficial and, certainly by far, the simplest to perform.

Thus, as policy-makers increasingly begin to allocate health service resources on a rational basis, it is clear that increased funds will need to be preferentially assigned to the most cost-beneficial procedures, specifically immunization, at the expense of other, more elaborate curative and diagnostic procedures. And such decisions, indeed, are beginning to be made in both developing and industrialized countries.

In developing longer-term policy, it is important to appreciate that the potential for immunization has only begun to be realized. We can expect — and soon — many more and better vaccines. Over the past decade, we have witnessed the most incredible growth in our understanding of precisely how the body protects itself against infection and of how it deals with disease organisms. With this information and similarly detailed knowledge of each of the pathogenic organisms, molecular biologists are now designing and testing highly specific vaccines at a far more rapid pace than ever before and against many diseases for which no vaccines have heretofore been available. At the same time, new techniques in biotechnology are being exploited to improve on existing vaccines. There has been a veritable explosion of interest in vaccination research. It has been estimated that perhaps 80 to 100 new vaccines are now in various stages of development and most health officials foresee adding at least five to ten new antigens to routine immunization schedules within the next decade. There are expectations of having within the next 10 years effective vaccines against malaria, many forms of pneumonia and meningitis, cholera, bacillary dysentery, some forms of cancer and I say with less optimism — perhaps even AIDS. With new techniques for delivering vaccines, the simultaneous administration of mixtures of

ten or more antigens should be routine. Ever more purified antigens should result in a further lessening of the already near negligible risks of adverse effects. And, more vaccines will be given by mouth, or perhaps aerosol. Truly we are at the dawn of a new era in medicine.

Research and development were once the limiting factors in realizing the immense promise for vaccines. The performance of our health systems in delivering vaccines is now seen as a significant problem as well and is the source of concern in a number of countries, including my own. We should be concerned. If providers of health care are unable to effectively administer the simplest, most cost-beneficial medical intervention to at least 90% of a population, it inevitably raises questions about the quality of performance of that system with respect to the delivery of any other preventive or medical services, all of which are more complex.

From experiences which I have now had in many different countries and with many different health services, I believe it is reasonable to anticipate high levels of vaccine coverage in all countries, provided that reasonable levels of resources are available and creatively applied. Let me generalize by saying that most immunization programs, even where modestly well funded and administered, have found it possible to attain immunization levels of at least 80% for each of the different antigens by 1-2 years of age.

But immunization coverage levels of at least 90% should be the objective for every country and, indeed, such is the goal for the global immunization program. Why? Because when levels of vaccine protection reach this order of magnitude, most of the vaccine preventable infections stop spreading. There simply are not enough susceptible individuals to sustain continuing chains of infection. Those who are not successfully vaccinated — and one never succeeds in vaccinating everyone — are thus protected by high levels of protection in the community as a whole. This is called "herd immunity."

In essence, this is what was responsible for the eradication of smallpox. We did not succeed in vaccinating everyone in every country but we did succeed in vaccinating enough to stop the virus from spreading. Today, we are witnessing similarly dramatic events with regard to poliomyelitis. In 1985, a decision was made by the countries of the Americas to eradicate polio over the succeeding five years. Several events led to that decision but the most important occurred in Brazil some five years before. Brazilian health authorities had struggled for years to improve immunization levels through vaccinations given in clinics and hospitals. But coverage in the different states remained at levels of 25 to 50%, whatever encouragement and education was offered. Finally, they decided on an entirely different strategy — they decided to sponsor "national vaccination days." Health department staff joined with numerous volunteer organizations to establish some 90,000 vaccination sites all over the country. The goal was to vaccinate all children under 5 years of age on a single day — some 20 million children in all and to do this twice each year.

All manner of expert health staff assured Brazilian health authorities that they could not succeed or, if they did so on one or two occasions, they could not sustain the effort. In fact, Brazil met its goal, i.e., vaccination of 90% of the children under 5 years of age, on both national days in 1980 and have continued to do so every year since. Reported cases immediately decreased by 90% — to less than 100 cases each year.

This experience in Brazil coupled with a rapidly falling polio incidence throughout the Americas led the Pan American Health Organization to propose in 1985 a program to eradicate polio from the Western Hemisphere. That campaign, a brilliant effort, was led by Dr. Ciro de Quadros, and will be described later in this program. The last case of polio was detected in Peru in August 1991, and two months ago an international commission, after thorough evaluation, declared that polio eradication in the Western Hemisphere had been achieved.

A global polio eradication program is now in progress. The most dramatic successes are being reported from this part of the globe. As you know, it has been a number of years since polio was last detected in Australia and New Zealand. Japan and Korea are similarly without disease. The Philippines recorded its last known case more than a year ago. Of special importance is China's program — important, if for no other reason, than that it is home to one-fourth of the world's population. China's immunization program has been greatly strengthened over the past 5 years and, one year ago, China began conducting two national immunization days each year. These were similar to those conducted in Brazil, but

obviously far larger. More than 90 million children were vaccinated on each of the two days. Polio incidence plummeted and, so far this year, China has yet to confirm a single case of polio. This is not to say with certainty that there are none, as Chinese authorities also would point out, but cases are now extremely difficult to find and eradication now appears imminent.

It is hoped that global eradication will be able to be attained by the year 2000, just 6 years hence. Should that occur, it would be possible to stop all polio vaccination just as we have done with smallpox. To eliminate for all time, the threat of two major human diseases portrays vividly the potential inherent in vaccination. But even as these efforts proceed, recent experiences in the Americas portray the possibility for attacking measles in a similar manner. Measles, like smallpox and polio, has no natural reservoir other than man. Thus, if we are able to stop the virus from spreading from one person to another — i.e., to break the chains of transmission — measles will disappear. Once again, the challenge is that of inducing and sustaining sufficiently high levels of immunity — but higher levels than were required for polio or smallpox. In the Caribbean countries, a joint and concerted effort by those countries now appears to have interrupted transmission nearly 3 years ago. Special, repeat vaccination programs will be required at periodic intervals to sustain protective levels. How often these will be needed and for what ages is under study. In the U.S., we introduced several years ago a routine two-dose measles immunization policy and in the past two years coverage increased from around 70% to 85%. Meanwhile, surveillance has been greatly strengthened. From the surveillance data and laboratory characterization of

strains, it appears that last autumn the transmission of indigenous strains was stopped and that the 800 plus cases in 1994 derive from importations. Once again, this autumn, transmission appears to have ceased. However, with measles able to spread so readily and rapidly, active vigilance will be critical.

This is a far cry from the situation in the United States only four years ago. The deficiencies of our health care system were then forcefully brought home to us when in 1989-1990 large-scale measles epidemics occurred. In all, some 55,000 cases were reported; 11,000 children were admitted to hospital; 132 died. The medical care costs were more than U.S. \$150 million, far more than the costs of vaccinating all children against measles. Given a vaccine which protects 95% with a single inoculation and nearly 100% with two doses, not one of these cases should have occurred. Countless studies have now been conducted in an effort to determine the causes of failure and to offer solutions. Indeed, from the quantity of literature which has been so far generated, it has seemed to me that the conduct of such studies is fast becoming an established cottage industry. We find immunization levels plotted against family income, mother's education, race, sex, age, religion, source of primary care, frequency of consuming fast foods, belief in Santa Claus, and perhaps 20 to 30 other variables. Given the propensity of researchers to analyze each of the variables separately and then in combinations with each of others, one can grasp how weighty and opaque some of these treatises have been. This is not to suggest that there are not a variety of factors associated with lower levels of vaccination immunity. There are. But, as I have discovered, many of these very weighty reports do not offer a great deal of

practical help in answering the very fundamental question — what practically can be done to improve levels of vaccination immunity? It is interesting to know, for example, that vaccine coverage varies inversely with the mother's years of education and inversely with the rent paid by the family. But I do not believe that the authors intend to imply that those responsible for the vaccination program should plan to open schools for mothers or to offer subsidies for rent.

Our keenest insights as to what needed to be done in the U.S. came from our colleagues in Britain. Interestingly, Britain does not now have, nor has it ever had, compulsory vaccination requirements. From the 1950s, immunization levels in Britain customarily hovered in the range of 60 to 70% for most antigens. As health officials always explained to me, British parents are well informed by their physicians and the health department about the benefits and risks of immunization and thus make thoughtful and fully informed decisions as to whether or not to have their children vaccinated. Given this well-informed populace, officials considered compulsory immunization at school entry, or at any other time, to be wholly inappropriate and unacceptable. They viewed with tolerance our U.S. policy of compulsory immunization at school entry and in day care centers. Implied, of course, was that American parents were much less well-informed than British parents and so the U.S. was required to take such expedient measures.

During the 1980s, the British Health Service introduced a national vaccine registry so that the names of all children were entered into a computerized record at birth and their

vaccination status regularly updated. With this system, it became possible by 1988 to determine immunization levels by District, by school and, indeed, to measure immunization coverage of children registered on the panels of individual practitioners. Beginning some six years ago, health authorities decided to offer to each health practitioner a modest bonus approximating U.S. \$1000 each year for physicians attaining 70% coverage of their panel of children. Later, a sum which is three times this amount was offered for those reaching 90% coverage. Many physicians argued for exceptions to be made to recognize that some children could not be vaccinated because of religious objections, contraindications, etc., but health authorities were firm. All children would be counted in the denominator population.

What happened next, astonished everyone. The number of physicians achieving bonus targets rose dramatically. However independent and well-informed British parents had been about the benefits and risks of vaccination, it was apparent that interested health care providers could be remarkably persuasive in providing them with a new appreciation of the importance of immunization. National levels of immunization climbed steadily. The goal of 90% coverage for each of the antigens was exceeded two years ago; the goal was raised to 95% and that should be met for all antigens by April next year.

In 1992, a decision was made by the United Kingdom to recommend that hemophilus influenzae vaccine be routinely administered to all young children. This was fully discussed and agreed with professional organizations and appropriate information disseminated. More important, a carefully planned and sophisticated educational program

was launched through television, radio, the print media and through contact with community groups. In public health, such activities are now collectively referred to as social marketing, basically similar techniques to those used by Walt Disney or Nike or Coca-Cola to market and merchandise products. And — why not? Within a year, the mothers had become remarkably well-informed about hemophilus; most important, by the end of the year immunization coverage had exceeded 90%!

From our distillation of the blizzard of U.S. studies documenting reasons for our failure to do a better job, we concluded that a primary problem was our health care providers — physicians, nurses, clinics, hospitals — most of whom no longer saw immunization as a priority. Complacency prevailed but there were, of course, reasons for complacency. The vaccine-preventable diseases had declined to such low levels that, to many younger physicians, diseases such as polio, measles, mumps, diphtheria, tetanus and rubella were all but textbook entities. It was seen as less urgent that the child be vaccinated at the appropriate time and — so what if he did not get vaccinated as an infant — he would be vaccinated at school entry. The resurgence of measles served to dramatize the fact that we could never lower our guard.

We discovered that a great many children were regularly seen in clinics on many different occasions for various complaints but were not vaccinated. Immunization records were seldom reviewed; immunization was mistakenly denied because of supposed

contraindications; some were refused vaccination until after receiving complete physicals. Interestingly, those rejecting vaccination because of fear of adverse reactions or because of religious reasons accounted for less than one percent of those failing to be vaccinated. Initially we assumed that health maintenance organizations, with their emphasis on quality control and prevention, would record satisfactory coverage levels. Not so. When we contacted two of the largest and best, we discovered that neither had been monitoring this very simple and obvious indicator of quality performance. When they did tabulate the information, they discovered, to their embarrassment, that only 70% of the children were being vaccinated.

Redirection of our own national program began just two years ago with strategies and tactics which draw heavily on the experience of the United Kingdom and social mobilization efforts which have proved so successful in immunization programs in Latin America. It is directed essentially to four elements:

1. The Health Care Providers — The single, most critical element in the immunization strategy is to change the norm of professional behavior for health care providers to recognize that immunization is our most important health care measure and that to delay, discourage or deny vaccination is unacceptable.

The U.S. association of health maintenance organizations has now launched a program to assure that all members routinely monitor immunization performance as

a quality assurance measure. Techniques to do this in the larger pediatric practices are also being developed.

The registry system, as used in Britain, represents an ideal method for measurement and a useful mechanism to remind parents when immunizations are due. The bonus payment system has clearly yielded remarkable dividends for the U.K. Pilot registry systems have begun in the U.S. and some are being used to routinely notify parents when immunizations are due, although, in fact, comparatively few yet do so. As one somewhat sheepish Baltimore pediatrician pointed out to me, it is difficult to find a veterinarian in the entire city who does not mail out cards to remind pet owners when their animals need rabies shots and fast service lubrication centers do the same for cars. However, almost no pediatricians yet send out such notices for children.

2. The Public — Across the world, programs of immunization and family planning have discovered that health messages can be most effectively communicated through community groups by broad community involvement and by modern methods of marketing and merchandising, employing effectively such as television, radio and the print media. Unfortunately, most of our health programs have relied on very traditional and very stuffy health education messages and approaches. Contemporary approaches in social marketing are now playing a major role in the United Kingdom and Latin America and are likewise a central strategy for the U.S. program. In

doing so, we have found unexpected, indeed, overwhelming interest and support from all manner of private sector groups — including Rotary, McDonald's, Walt Disney, church organizations, Kiwanis, Gerber Baby Foods, Major League baseball and many more. The concept of providing support to programs intended to help young children has enormous appeal.

3. Vaccine Coverage — It would seem obvious that if one is to measure progress in a national program and to evaluate different strategies in achieving specific goals, one needs objective measurements. This is a primary deficit in many health programs and was no less in the U.S., which decided in 1985 to terminate surveys of vaccination coverage. Such surveys have now been reinstated. Sample surveys monitor vaccination coverage nationally and by states, and special simplified survey techniques permit assessments in cities and other defined areas. Some form of computer registry system extending across the country, such as in the U.K., is a longer-term objective.

4. Surveillance Systems — Of all the activities associated with immunization programs, surveillance systems (which include disease reporting) are, in general, the least adequately developed and yet the most important guarantor of long-term success. Indeed, the ultimate objective of all immunization programs is disease prevention, not the vaccination of some percentage of all children. An immunization program cannot be considered satisfactory if the disease in question is not being successfully

prevented. This would appear obvious but there are now on record any number of programs which have mistakenly proclaimed success based solely on satisfactory levels of vaccination coverage. In such programs, when surveillance was begun, so many cases were recorded that it became apparent that something was amiss. In certain countries, it was discovered that the vaccine was not being refrigerated and so was rendered useless; in others, vaccine was used which did not meet standards and, in some cases, lower level health officials falsified data about coverage.

The foundation of a surveillance system is a national network of clinics and hospitals which report either monthly, or preferably weekly, all cases they have seen of the disease under surveillance. In Latin America, for example, the surveillance network for poliomyelitis includes 20,000 reporting sites which are expected to report weekly whether or not they have seen cases — and, indeed, more than 90% of reports are received, and on time. Every suspect case is immediately investigated by a trained epidemiologist who evaluates the case and obtains specimens. Similar surveillance measures for polio are now being implemented in Asia, Europe and some parts of Africa.

Should other diseases be placed under surveillance? If we are serious about effective disease control, this is a necessity and, in ever growing numbers of countries, neonatal tetanus and measles are now being placed under special surveillance programs.

In the smallpox program, and now in the polio program, we accepted the premise that every case which occurred represented, in some manner, a failure of the program. Given the fact that we had the tools and the means to prevent every case, no cases should occur if programs were properly run. By analyzing the characteristics of those cases which continued to occur, it was possible to identify particular groups and geographic areas for which special measures were needed. This served to focus resources on areas and groups at highest risk.

For the United States, our ultimate immunization goals are now specifically identified not in terms of coverage but in terms of numbers of cases of the vaccine-preventable diseases. Specifically, in 1996, we anticipate reaching a nil incidence for polio, measles, diphtheria, rubella, mumps and hemophilus influenzae cases under five years of age and these have been so identified as national goals by the President. This implies the need to greatly strengthen our U.S. national surveillance system, and this is being done. It means that we will need better tools for more rapid and specific laboratory diagnosis, and such research is under way.

Finally, with the promise of what vaccination might achieve, we believe it is necessary to augment our national investment in basic research — and this we are doing. It is important that we work closely with the private sector in the cooperative development and application of products — and this we are doing.

If there is one important lesson which successful immunization programs have provided, it is quite simply that this important, indeed critical, area of medicine demands uniquely a highly collaborative, well-integrated strategy extending from the basic scientist at the bench to the vaccine manufacturer, to the community organizations who can promote immunization, to the physician and nurse administering the vaccines — from university research centers to national laboratories to international organizations such as WHO and UNICEF. As much as anything, it requires a few unique individuals who fully grasp and understand the importance of the totality of this effort, who can work effectively and imaginatively at all levels and who do so because of the respect they have earned. In brief, we desperately need more Frank Fenners.