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Challenges in Vaccination
Consultation Group on Vaccine Development
Bethesda, October 26 1992

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Importance of immuniz. to global health is unquestioned by ^mostly all participants
Clearly, vaccines represent by far the most cost-effective hlth. interventions in ~~third~~ ~~world~~ health care. Need not elaborate.
Moreover, the potential of immunization is only beginning to be realized.
Biomedical advances, specially in biotechnology, offer enormous promise.
Finally, ~~immunization~~ savings from immunization represent ^true ~~real~~ potential savings in health care — one of few medical tech. which do.

But How ~~many~~ ~~of us~~ ^we view this intervention and how our medical colleagues, — let alone the ^broader development community — is quite another matter.
~~[illegible]~~
Development community generally sees this as only one in a host of targetted programs — ~~[illegible]~~ only one of a ~~[illegible]~~ ^vital spectrum of medical interventions — albeit a remarkably successful one — by any standards.
Which are funded and which provided now depend largely on interest groups — and the prevention-public health group has been neither especially influential nor notably articulate.
WHO — which could advise on priorities — has ~~[illegible]~~ ^played an essentially a laissez-faire role.
World Bank happily has begun to take a leadership role ^in policy development (for health strategies) where WHO has not and I believe this will be apparent in its 1993 World Development Report.

+ IOM Report
New + Emerg. V.
BW capacity

Meanwhile, resources for vaccine research, ^and development, &c.) production and distribution of products; and for their delivery has ^grown but, by any standards ~~remains~~ seriously deficient — ~~altho I hasten to point out that~~ The U.S. has played and is playing a singularly important ~~role~~ supportive role in the efforts to date.
What more should be done and how, however, is not entirely clear.
~~Today~~ ~~[illegible]~~ I personally see an enormous number of needs and opportunities /
I don't ^yet see a blueprint

A brief retrospective of the past and how we proceeded to this point is helpful in endeavoring to understand the present and to shape the future.

Let us deal only with 3rd world issues for the moment

Until mid 1970's global immunization programs were essentially limited to two antigens – BCG and smallpox.

BCG – procured (by UNICEF) and distributed to countries on request.

Some countries produced their own but w little quality control.

Different strains were in use but no comparative studies of their efficacy or safety were being done. In fact, as you know, basic questions of vaccine efficacy, if any, remain a controversial topic today.

Smallpox – vaccine was widespread use – SE began. All countries vac. / Vaccine of ? quality. Countries paid for their own.

- WHO SE Unit rapidly assumed responsibility for all aspects of the program – precisely sited in different units of WHO
  - Vaccine production and quality control of vaccines –
  - Research on vaccines, vaccine production and smallpox itself
  - Vaccine distribution
- Integrated program permitted planning re: resources needed for the field
  - International quality control and improved nat'l standards
    - Two labs.
  - Development of production capacity in 3rd world –
    - e.g. 5 yrs. – >80% being produced in endemic countries
  - Coordinated research prog. involving manufacturers and academia.

EPI – launched in 1974 –

Remarkably – incredibly successful – as a vaccine delivery program.

To reach 80% of world's pop !

Vaccine, when not produced locally, purchased by UNICEF / Rotary / bilateral agencies

- ~~Only~~ In the Americas ~~was~~ ~~an~~ efforts ~~made~~ was intrinsic to the plan as well as to promote ~~...~~ national self-sufficiency in vaccines ~~and~~ to assure that all vaccine in use met accepted standards. This effort was not replicated globally.

- CVI was decided upon in 1990 —
  "Children's vaccine", was the 1° thrust but, as it became apparent that a strengthened research and development was ~~perhaps~~ only part of the challenge, its mission has ~~...~~ broadened.

Last ~~two~~ few years, it has steadily become apparent that we are challenged ~~...~~ by incredible opportunities for the future — but we now discover that the foundation to sustain what we have so far accomplished has been built on sand.

Vaccine donors — bilaterals, UNICEF, Rotary — argue that they cannot supply existing vaccine, ~~...~~ let alone new ones, indefinitely and ask for a long-term plan re: global vaccine production. There is none as yet. Meanwhile polio vaccine is in such short supply that eradication in WPRO is seriously compromised.

We discover that a surprising number of countries are producing DPT, and some polio vaccine. However, unless they want to sell them to UNICEF, there is no assurance of vaccine quality and, as yet, no global plan to assure quality.

Global CVI has developed its first task forces to pursue developmental goals with regard to improvement of existing vaccines and ~~...~~ to develop new ones. An R+D plan is needed but ~~...~~ far from completion.

~~As~~ As we have dealt with this problem, it has become ~~...~~ ~~...~~ apparent to us all that vaccines are unique beasts —
Of limited interest to the private sector
Profit, regulatory issues, liability all contribute

To develop public-private sector partnerships is a necessity if we are to bring to bear the best of expertise in R, D, production. Not at all clear how this can be accomplished.

For this field, in particular, a need as in no other in medicine to ~~deal~~ take into account the totality of issues needed for development of ~~to develop~~ a vaccine, ~~to produce it, to identify [illegible] assure quality, to identify dangers [illegible] financing issues and~~ to deliver ~~it~~.

We have little experience in tackling a problem of this complexity.
∴ ? White House/FCCSET Task Force + plan
∴ CVI

I believe we can overcome problems — with one antigen we were successful in so doing — but it requires a unique well-considered complex of activities and players.

Simply, we can't ~~argue~~ present the case for added resources or even utilize those we have without a far better vision of what we want to achieve, ~~and~~ how we are to get there, ~~how~~ who are to be the principal players and how much it will cost.