

In this appendix we offer a set of questions we think useful in reviewing influenza prospects and programs. They are intended to elaborate the assumptions underlying initial decisions and to lay a base for program review. The questions deal with the magnitude of the potential influenza threat, the desirability, feasibility and scope of a responsive program, and its implementation. Detailed questions on implementation become increasingly important the larger the contemplated Federal role and the wider the program's scope.

We doubt that anyone would want to ask all questions of any single expert group, no matter what its expertise. We do think the last question should be asked of every group, regardless of expertise.

A. The threat of influenza in the United States

1. How likely is the new influenza strain to spread in the United States? What do you consider the likelihood of no outbreak, of sporadic outbreaks only, of an epidemic? Within what time?
2. What number of people (grouped according to age, medical condition or socioeconomic class) are likely to get influenza? What number are likely to die from it? On what assumptions? What protection already exists in the population? What protection, if any, would be retained from previous vaccination?
3. What additional surveillance, if any, should be undertaken to identify the appearance and magnitude of influenza outbreaks?

B. Vaccination and alternative interventions

1. Would you recommend any substitutes or supplements to vaccination with killed virus vaccine (e.g., live vaccine, amantadine, other agents)? In what circumstances would you advocate their use at present? Air assumptions.
2. Against what viral strains should the production of vaccine be contemplated? What do you consider the relative advantages and disadvantages of whole and split virus vaccines? Is there a role for both? Under what assumptions?

C. *Availability and testing vaccine*

1. What vaccines are already available? What is known about their possible usefulness?
2. Is manufacture of new vaccines feasible, and how long will it take to produce what quantities? What are your assumptions about facilities, final dosage and yield at each stage of production? Which steps limit the volume and rate of production? How readily changed, if at all, is each rate-limiting step? What are the trade-offs (e.g., cost, reactivity)?
3. What quality control and other testing must be done at each stage of production?
4. What field trials should be conducted, with what dosages and types of vaccine, what number of doses, and in which population groups?

D. *Vaccine benefits, risks and costs*

1. What efficacy in terms of disease prevention and decreased mortality do you expect from the new vaccine, for which age groups? How long will it take for inoculation to confer protection, and how long-lasting will it be. Air assumptions.
3. What side effects, of what type and severity, and in what frequency, do you foresee?
4. What additional surveillance will be required to detect different types and frequencies of side effects?
5. What do you estimate as the dollar cost of vaccine production and administration? What are the components of your estimate? Are there additional, indirect costs, as from litigation, which you anticipate? Air your assumptions.

E. *Program objectives, organization, implementation*

1. What vaccination objectives would you recommend in terms of total numbers to be vaccinated, dosages and schedules in different age groups, reaching what socioeconomic levels, over what time span, completed by when? State what you would like ideally. Then state what you would regard as satisfactory. Air your assumptions.
2. Given these aims, what alternatives do you see for administration of the following tasks as among federal, state and local agencies, private manufacturers, insurers, medical practitioners, voluntary agencies, other (specify in each case)?
 - Preparing recombinant and seed strains
 - Producing and distributing vaccine
 - Purchase of vaccine
 - Testing vaccine at different stages
 - Storage of vaccine

- Design and conduct of field trials
- Surveillance of disease, vaccinations and side-effects
- Intergovernmental consultation (among whom?)
- Advising doctors and professional societies
- Informing public interest groups and voluntary agencies (whom do you think relevant?)
- Assuming liability (for what?)
- Preparing consent forms
- Operational planning (e.g., ensuring local availability of consent forms, obtaining supplies, securing staff and space, giving injections)
- Explaining coincidences
- Statistical reporting
- Periodic program review

Do you foresee other tasks? Add them on.

3. Under each set of alternatives you give for handling these tasks, how many people do you expect will actually be inoculated? With what biases in terms of age, race, socioeconomic class and health risk? Air your assumptions.
4. What combinations of tasks and agencies do you recommend? Explain your reasons.
5. Who should be consulted in Congress? In what sequence? At what stages? By whom? Given the projected cost and program organization, what would be specifically required by way of legislative authorization and appropriations?
6. Working step-by-step backward from inoculation, what is required of each implementing agency? What are the weak links? Is there a hint of any issue just beneath the surface which could rise to haunt, slow or stop your preferred program (as liability did in 1976)?
7. How should HEW be organized internally to play its part? How linked to Department of Defense? Domestic Policy Staff? Veterans Administration? World Health Organization? Who has to do what, specifically? How minimize Congressional or press confusion about "who's in charge here," as occurred at times in 1976?
8. With what other top managements, public or private, should HEW prepare to deal directly, so as to avoid surprises like insurance company decision-making in 1976? Specifically, who should deal with whom, where and how?
9. What is expected of, by, from the media? On what premises? What steps should be taken to anticipate and relate technical contingencies, such as temporally linked deaths, to prospective media coverage?

10. How do you think the program you prefer should be presented to Congress, states, the medical community and media? As "available," "desirable" or "imperative"? For whom? Air assumptions.

F. Preparation for program review

1. List perceived deadlines for decision and action. When must what be done? Why? Which deadlines may be movable? Which not? Air assumptions.
2. When and how should the above questions and answers be reviewed? What should be the mechanism for review, given perceived deadlines and the development of additional information, whether anticipated or unexpected?
3. What new information would cause you to change some or all of the recommendations you have made? Which recommendations? In what ways changed? Air your assumptions.