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# STUDIES REGARDING THE DEVELOPMENT OF A NATIONAL EVALUATION SYSTEM FOR THE VACCINATION PROGRAMME IN EGYPT

by

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# Development of a National Evaluation System for the Program of Vaccination Against Poliomyelitis, Measles, Pertussis, Tuberculosis, Diphtheria and Tetanus

Vaccination against the six dangerous infections namely poliomyelitis, measles, pertussis, tuberculosis, diphtheria and tetanus proved to be the most effective and fundamental method available for their prevention and control in children.

In Egypt, as in other developing countries of the world, infectious diseases, including those against which immunization is available, are a major cause of morbidity and mortality among infants.

Despite the fact that poliomyelitis vaccination is compulsory for the last 10 years, it was found that among children under 10 years, evidence of typical paralysis due to poliomyelitis was detected in nearly 2/1000, a rate which is nearly the same as that in the USA in the prevaccination era (Wahdan et al., 1977).

Measles is a major public health problem with several thousand cases admitted to hospitals each year. Recognizing the fact that only severe cases, which probably represent a small percent of cases, are brought to hospital, one can imagine the extent of the problem of measles.

Tuberculous infection among children in Egypt is a great problem with a percent of positive reactors to tuberculin amounting to 11.2% among 6 years old non vaccinated children (Sallam et al., 1977).

Diphtheria is no more a main public health problem in Egypt. The number of cases decreased considerably especially after 1964 with the introduction of the booster dose at the age of 18-24 months.

Pertussis is one of the common infectious diseases of preschool children in Egypt. The available data about its incidence are very much under estimated as much of the cases and deaths are registered as bronchitis and pronchopneumonia which are among the main causes of morbidity and mortality of children in Egypt.

Neonatal tetanus is a major problem in Egypt with a rate of 3 per thousand births. Although its prevention could not be a chieved through childhood immunization, yet it indicates the importance of vaccination of those who will become mothers, in the years to come, so that their babies will be born immune.

The World Health Day (7 April 1977) focused on immunization of children selecting the slogan "Immunize and protect your child" in order to draw attention to the vital importance of childhood immunization.

The Director General of the WHO in his message for the World Health Day 1977 indicated the main reasons of the short comings of childnood vaccination in the developing world namely

the lack of appreciation of the public and the health professions of the role of vaccination in saving health and lives of infants through immunization, shortages in skills, in planning and management of vaccination programmes and lack of public co-operation.

The WHO Regional Director for the Eastern Mediterranean in his message for the World Health Day 1977 highlighted the objectives and strategies of the WHOs Expanded Program on Immunization with a look at the relevant problems of the region and indicated that the main problems facing success of immunization programmes are field operation in maintaining transport and storage and in keeping vaccines effective and in proper management.

Despite the great efforts and expenditure an immunization there is lack of insight about its effectiveness due to deficiency in evaluation which is an essential and highly needed element in National Vaccination Programmes.

Aims of the Study:

Evaluation of the compulsory vaccination against the above mentioned diseases in Egypt with the aim of determining the degree to which targets are fullfiled.

The results of the evaluation can be used for replanning and better orientation of future activities as well as to develop a built in system of evaluation.

Materials and Methods:

The field work included the following items:-

1. Collection of vaccine samples ready for distribution from the production units, and their examination in the laboratory.

2. Collection of vaccine samples ready for utilization from the field vaccinating centres, and their examination in the laboratory.

3. Application of collected vaccine samples for immunization of infants attending two health offices.

4. Assessment of the practice of immunization and public acceptance and cooperation for compulsory immunizations.

5. Follow up of vaccinees for testing induced immunity, reactions, and complications.

Results:

The following results were obtained:

1. Vaccines at production:

The potency of vaccine samples collected from the Egyptian Organization for Biological Products, and Vaccines (VACSERA), showed a potency almost within the WHO recommendations:

- The number of viable bacilli in the BCG vaccine was in the range between $10^{5.2}$ and $10^{6.8}$/ml. However it is worth mentioning that the BCG ampules were not always of dark coloured glass as recommended.

- The Schick conversion rate (SCR) of diphtheria vaccine was 95.2%.

- The virus titre in oral Poliovaccine (OPV) was between $10^{4.9}$ and $10^{5.7}$.

II. Vaccines at field units:

The potency of DPT and OPV vaccines was found almost unaffected by transportation, storage, or both:

- The Schick conversion rate (SCR) of diphtheria vaccine was 94.9%.

- The viral titre for oral poliovirus vaccine was between $10^{4.7}$ and $10^{5.6}$

However, the potency of BCG was found to be affected in some governorates, but not necessarily related to the distance from Cairo. The number of viable bacilli in the BCG vaccine was in the range between $10^{2.8}$ and $10^{6.5}$/ml.

III. Vaccination at the Health Office:

(1) As regards the BCG vaccine, post-vaccination tuberculin reactivity was found to be affected by age of vaccination and potency of the vaccine. The rate of post vaccination reactivity increases by increase in age and by increase in the count of viable bacilli in the vaccine.

A direct relation was found between the size of the BCG scar, and post-vaccination tuberculin reactivity.

The rate of post-vaccination lymphadenitis was found to be higher, (47.6%) among infants vaccinated by highly potent vaccines, when compared with those vaccinated by less potent vaccines (19.0%).

(2) As regards DPT and OPV, 63.5% of eligible infants attended the three doses. Besides, 18.5% got two doses, and 8.7% got only one dose.

IV. Assessment of the public acceptance and cooperation:

(1) Penalty was still the most frequent drive (72.6%) for parents to vaccinate their infants.

(2) Knowledge of the parents as regards vaccines administered revealed that 73.8% knew about OPV. Meanwhile, DPT and BCG vaccines, were only recognized by 25.1, and 1.5% respectively.

(3) In relation to compulsory vaccination, 89.6% of interviewed parents showed that they are willing to immunize their infants against measles; which is voluntary.

(4) As regards post-vaccination complications, the interviewed parents mentioned most of the common reactions and complications. Fever, and irritability were mentioned by 68.2 and 36.6% respectively. Meanwhile, ulcers, and abscesses were mentioned by only 2.7 and 0.2% respectively.

(5) As regards complaints from the Health Office, it was found that 56.3% had no complaints. Delayness was mentioned by 23.7% and unorganized cues was the complaint of 13.4%. Improper sterilization of the syringes were mentioned by only 0.2%, while post-vaccination complications were the complaint of 4.8%.

(6) As much as 31.7% of the parents preferred an after-noon session for vaccination.

Conclusions:

From the results, it could be concluded that:-

(1) The vaccine samples collected from VACSERA stores showed a potency almost within the international standards.

(2) The vaccines were found to be potent in most of the governorates. However, the potency of the BCG vaccine, was found to be affected in some governorates not necessarily related to the distance from Cairo.

(3) The rate of attendance for vaccination was high and almost within the recommended levels that keep the disease under control. However, some weak aspects in execution, such as; recording, training of personnel, supervision, and control were identified.

(4) The knowledge of parents as regards vaccines and vaccinations is very superficial and far from the standard at which acceptance and cooperation of the public is beneficial.

Recommendations:

Vaccine production and distribution:

(1) Active move towards lyophilization for the BCG vaccine. Besides achieving better keeping qualities, it can help establishment of the ability to test the BCG batches in-vitro before their release.
(2) The 2 ml. ampoules of BCG have to be issued in dark brown glass.

(3) Every vaccine container should be properly labelled using water insoluble adhesives.

(4) The administrative principle; "External auditing is better than internal auditing" has to be applied on the control of vaccine production. It is unlogic that the vaccine control laboratories are under the supervision of the production administration. An independant national control system should be established. However, for the time being, if it is not practical to establish such an organization, the assistance of local organization as University Laboratories, and International Bodies like the WHO, is recommended for control.

(5) To ensure the continuation of the cold chain in the transportation and storage of the vaccines, the following is recommended:

i. Distribution of the vaccines from VACSERA to the different governorates by prope ly equiped car refrigerators in weekly journeys. Whenever possible, planes can be used in order to achieve the quickest possible route of transportation of the vaccines from VACSERA to the governorates.

ii. Vaccines are better to be distributed by the higher administrative levels which have better facilities, to the lower administrative levels, instead of the present system where the field work personnel are responsible for receiving the vaccines from the central stores.

iii. Better maintenance of refregirators at the field units especially the rural ones.

(6) Vaccinating centres have to be supplied with vaccines in quantities exceeding the number of doses administered. Otherwise, too strict formalities may result in administering expired vaccines in order to escape penalty.

Legislations:

(7) In view of the fact that many parents who are penalized for not vaccinating their infants, abstain from bringing them for vaccination, as well as the observed results of lower complications and higher take rates among those delayed than the vaccination schedule; it is worth considering another approach than imposing penality in case of any delay. This suggested approach is to try to find the reason for delay and to persuade parents to bring their infant for vaccination. In the case of failure to respond, penalty could be imposed if vaccinations were not completed during the first year of life. This approach may also reflect its effect on the quality of recording in the Health Office as regards vaccination data because reliable data are dependable for proper planning.

(8) To avoid too frequent alterations in the vaccination schedule. This can be reflected on the coverage of vaccination, public knowledge, and opinion.

(9) Some of the instructions need revision, such as those dealing with the vaccinator. In the present regulations, the trained assistant nurse, midwife, or health visitor is the responsible to give the intradermal BCG vaccination and the physician to give the OPV vaccine. The reverse may be considered.

Execution:

(10) Ensuring utilization of vaccination cards for all infants for recording all vaccinations administered to them.

(11) The after-noon sessions for vaccination have to be practiced, by the Health Office.

(12) A yearly meeting on immunization is recommended, in order to discuss any new scientific information, the problems in execution, and seek solutions. This should be attended by assistant directors responsible for immunization in the different governorates.

(13) Proper pre- and in-service training of the personnel as regards the values and benefits of the different vaccines, and the proper techniques to be applied. The interest of the personnel must be encouraged, and any misconception corrected, to avoid being reflected on the standard of their performance and on the public cooperation.

(14) Legislation is not the only garantee for maximal coverage of vaccination. Organized health education programme as regards vaccines and vaccinations is indispensible. Skilled health educators are needed to study the best ways and means for realising public cooperation.

(15) The evaluation programme:

An immunization programme must be subjected to frequent check up, the development of a programme for evaluation of the present immunization programme in Egypt is cardinal.

Independant evaluation teams, entirely separate from the remainder of the operational staff, should be involved. They may be especially employed for this task in the programme, or they may be staff of the epidemiological unit of the Ministry of Health. Consultants who are not normally part of the programme are useful in providing independant evaluation periodically:

1. Evaluation of the vaccine potency by wise, frequent, and periodical sampling.

2. Evaluation of programme management and operation, by means of investigating various administrative, and technical operations included in the programme of immunization.

3. Evaluation of vaccination coverage, through reliable records or through marks of vaccination as in the case of BCG.

4. Surveillance of the target diseases and their present dynamics; through morbidity and mortality data analysis.

The feedback aspect of evaluation (recommendations), is to be derived from the evaluation process that may serve to improve the immunization programme through replanning.

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