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STUDIES OF SMALLPOX VACCINATION
BY BIFURCATED NEEDLES IN KENYA

by

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1. INTRODUCTION

The studies of Dr E. Shafa and Dr A. Rahman and the preliminary observations of the writer have shown bifurcated needles to be effective for smallpox vaccination.

The needle can pick up the reconstituted vaccine with its bifurcated point when it is dipped into the ampoule. This means that a pipette or glass rod need not be used, so that vaccine can be economized and the vaccination procedure in the field can be simplified.

To assess the value of the bifurcated needles in smallpox eradication programmes, it was proposed by the WHO Regional Office for Africa and the Smallpox Eradication unit, Geneva, to carry out a field trial of these needles. Several studies were completed between November 1967 and April 1968, designed both to assess the feasibility of performing successful smallpox vaccination by bifurcated needles and to determine the most suitable number of punctures for successful revaccination. In all these studies there were certain similarities in methodology; nevertheless, each individual series was conducted for somewhat different reasons and therefore involved somewhat different methodological approaches.

The objectives of the study were as follows:

- (a) to evaluate the take rates produced by bifurcated needle:
 - (i) when the needle is used to pick up the vaccine from an ampoule and placed on the vaccination site; and, as a control,
 - (ii) when a dropper or glass rod is used to place the vaccine on the skin.
- (b) to compare the take rates with bifurcated needles using vaccines from different countries.
- (c) to study revaccination using 15 and 30 insertions with the bifurcated needles.
- (d) to study multiple pressure and multiple puncture techniques with the bifurcated needles.

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(e) to evaluate the durability of the needles.

2. AREA OF TRIAL

A field study of the efficiency and durability of the bifurcated needles for smallpox vaccination was carried out in Kenya with the kind permission of the Ministry of Health and the co-operation of the Public Health Department of the Municipality of Mombasa. The trial took place in Bomu, Changamwe, Mtongwe and Shika-Abadu and at the vaccination clinic in Mombasa.

Vaccination was offered to all inhabitants on a voluntary basis. The population and their local leaders were very co-operative.

3. NEEDLES AND THEIR STERILIZATION

One hundred bifurcated needles received from the Smallpox Eradication unit, Geneva, were used in the trial. Sterilization of the needles was carried out by autoclaving at a temperature of 120°C for 20 minutes or boiling for 15-20 minutes.

4. VACCINES USED

The following freeze-dried smallpox vaccines were employed in the study:

- 4.1 KENYA: Medical Research Laboratory, Nairobi: Batch No. 36.
Date of expiry: January 1969.
- 4.2 RWANDA: University Medical and Veterinary Laboratory, Butare: Lot No. 3/65.
Manufactured 15 September 1966. (It is not the practice of this laboratory to indicate the date of expiry.)
- 4.3 SWISS: Serum and Vaccine Institute, Berne: Lot No. 30470.
Date of expiry: 3 September 1969.
- 4.4 THAILAND: The Government Pharmaceutical Laboratory, Bangkok: Batch No. 438.
Expiry date: 20 December 1970 (if stored below 0°C).
- 4.5 USSR: Laboratory of Smallpox Prophylaxis, Moscow: Batch No. 182.
Date of expiry: 13 November 1969.

The vaccines were reconstituted in the diluent supplied with them, and only prepared in accordance with the instructions attached by the respective laboratories. They were used within one to two hours of being resuspended in fluid.

5. VACCINATION METHODS AND READING OF THE RESULTS

The vaccination methods employed in the study are shown in Table 1, and the results were read by observing the skin reactions. The skin reactions were read on the seventh day after vaccination, both in primary vaccinees and in revaccinees. The interpretation of the results of the primary vaccination presented no problem, in that the development of a typical Jennerian vesicle - major reaction - was considered as a satisfactory response.

Reactions in revaccinees were classified in the following manner:

major reaction: presence of a typical Jennerian vesicle, a vesicular or pustular lesion, or a definite area of palpable induration or congestion surrounding a central lesion, a scab or an ulcer;

equivocal reaction: any other response to vaccination other than a major reaction (including the complete absence of any skin reaction at the vaccination site).

The same individuals were vaccinated on the opposite arms by different methods to ensure a strict comparability of the immunity level for different methods. Readings of the vaccination response were performed without knowledge of the technique employed.

6. COMPARATIVE STUDY OF TWO DIFFERENT METHODS OF APPLYING VACCINE IN THE SAME GROUP OF PRIMARY VACCINEES AND REVACCINEES USING FREEZE-DRIED VACCINES FROM DIFFERENT COUNTRIES

6.1 Primary vaccination

Seven hundred and thirty-four individuals never previously vaccinated and with no history of previous smallpox were allocated to five study groups. Each of the five groups was vaccinated with freeze-dried smallpox vaccine manufactured in different countries. The sample number in each group ranged from approximately 80 to 170 persons. Vaccine was applied at two sites on each individual, two different methods being used:

(a) The bifurcated needle was charged with vaccine by dipping it into the ampoule. The tip of the needle was held tangentially to the skin and pressed five times over an area about 3 mm in diameter.

(b) One drop of vaccine was placed on the skin of the vaccinee with a sterile dropper or glass rod. The technique thereafter was as in (a), or else one scratch of about 5 mm in length was made.

The results of the trials are summarized in Table 1. As the table shows, out of 175 primary vaccinations performed with Kenyan vaccine, 149 were read seven days after vaccination and all showed major reaction - 100 per cent. for both methods of application. Satisfactory take rates in primary vaccinees were obtained in the groups vaccinated by both methods with the USSR, Thailand and Swiss vaccines. No significant difference was found between the multiple pressure and the scratch technique in the groups.

Significantly lower take rates were observed in the group vaccinated with Rwanda vaccine. This difference is undoubtedly related to the low potency of the vaccine used, because the same persons carried out the vaccinations as in the other groups and the vaccinations were correctly performed. A dropper was employed to apply vaccine to the vaccination site.

6.2 Revaccination

Two thousand two hundred and eighty-eight individuals previously vaccinated against smallpox were allocated to five groups according to the origin of the vaccine used for their revaccination. The two methods of applying vaccine (see above) were used, but 15 strokes were performed with the bifurcated needles at each of the two vaccination sites. In groups 3 and 4 the scratch method was used as a control.

In this study, revaccinees were classified into three groups:

- (1) those vaccinated within a period of three years previously;
- (2) those vaccinated more than three years previously; and
- (3) those with an unknown vaccination history, but who showed a scar indicating successful vaccination in the past.

The results are summarized in Tables 2-6.

As will be seen from Table 2, 81.9 per cent. of those vaccinated three or more years previously and revaccinated with Kenyan vaccine with bifurcated needles developed major reactions. The take rate in the group of persons vaccinated within three years was lower - 51.7 per cent.

In contrast, only 21 per cent. of revaccinations performed with vaccine manufactured by the Butare Laboratory resulted in major reactions (see Table 6). The difference in the reaction is found also in those vaccinated within three years as well as in persons with an unknown vaccination history. Tables 3, 4 and 5 give the results of revaccination with the USSR, Swiss and Thailand vaccines by the two methods. The results are self-explanatory.

It can be concluded that the application of vaccine with bifurcated needles produces results as good as those produced when using a dropper or glass rod.

From Tables 1-6 it can also be concluded that the USSR, Swiss and Thailand vaccines compare favourably with the Kenyan freeze-dried vaccine in primary vaccination, but that, for unknown reasons, a difference exists between these vaccines when used for revaccination.

7. COMPARISON OF THE MULTIPLE PRESSURE AND THE MULTIPLE PUNCTURE TECHNIQUE WITH BIFURCATED NEEDLES IN REVACCINATION

The results of a trial employing the bifurcated needles and freeze-dried vaccine in the multiple pressure and the multiple puncture technique are summarized in Table 7.

A comparison was made between the multiple pressure and the multiple puncture technique employing 15 strokes with the bifurcated needle. In both techniques the vaccine was picked up with the needle and applied to both arms. Revaccination was carried out in a primary school in Mombasa, Kenya, 278 children of both sexes being revaccinated, most of whom had undergone vaccination about three years previously. Two hundred and seventy-one revaccinees were checked on the seventh day. One hundred and sixty-five major reactions (60.8 per cent.) were observed with the multiple puncture method and 159 (58.7 per cent.) with the multiple pressure method.

8. COMPARISON BETWEEN 15 AND 30 INSERTIONS WITH THE BIFURCATED NEEDLES IN THE SAME GROUP OF REVACCINEES

Table 8 shows a comparison of the take rates when 15 and 30 strokes were used in the multiple puncture technique. Fifteen and 30 strokes were applied simultaneously to both arms. The proportion of major reactions among those vaccinated three years previously or more was approximately the same, whether 15 or 30 strokes were used. However, for those vaccinated less than three years before, a higher proportion of takes was observed among those receiving 30 strokes.

This corresponds to the results of Dr Ataur Rahman, Institute of Public Health, Dacca, East Pakistan, who also used the bifurcated needles in multiple puncture vaccination employing 15 and 30 strokes.

9. A COMPARISON OF THE MULTIPLE PUNCTURE AND SCRATCH TECHNIQUES EMPLOYING ONLY ONE METHOD ON THE SAME INDIVIDUAL

As stated above, in each group each individual was vaccinated once on each arm, and different methods of applying the vaccine and different methods of vaccination were employed. It was decided to carry out an additional study in which only one method was employed on the same individual. One hundred and twelve primo vaccinations and 324 revaccinations were performed with bifurcated needles using the multiple puncture method only. At the same time, another group of persons (102 primo vaccinees and 294 revaccinees) were vaccinated employing

the scratch technique and using the same batch number of vaccine (USSR Batch 182) and the same diluent. Table 9 sets out the vaccination status of each study group and expresses the results of the observations made on the seventh day after vaccination. As it shows, the take rate was higher in the group of people vaccinated with bifurcated needles employing the multiple puncture technique.

10. AMOUNT OF RECONSTITUTED VACCINE PICKED UP BY THE BIFURCATED NEEDLE

In a trial carried out by Dr Arita, WHO, the amount of reconstituted vaccine picked up by the bifurcated needle ranged from 0.0017 ml to 0.0019 ml. However, it has been found that in field conditions the amount of vaccine taken up by the bifurcated needles ranges from 0.0017 ml to 0.0029 ml. The difference is probably due to the viscosity of the vaccine, which varies according to atmospheric conditions and temperature.

As can be seen from Table 10, our observations show that an ordinary single dose of vaccine can be utilized from four to 10 times.

11. DURABILITY OF THE BIFURCATED NEEDLE

One hundred needles were used during the trial. It is estimated that each needle was used 90 times at least for multiple pressure or multiple puncture vaccination, and the needles are still in good condition. Both autoclaving and boiling were used for their sterilization.

CONCLUSIONS

1. The quantity of reconstituted vaccine that can be picked up by the bifurcated needle by being dipped into an ampoule is sufficient for successful primary vaccination and revaccination against smallpox.
2. An ordinary single dose of freeze-dried vaccine can be utilized roughly 4-10 times when a bifurcated needle is used to pick up the vaccine from an ampoule and place it on the vaccination site.
3. Five strokes are sufficient with a bifurcated needle for a primary vaccination and 15 for a revaccination if the potency of the vaccine comes up to WHO requirements.
4. Each needle in our study was used at least 90 times and the needles are still in good condition.
5. Bifurcated needles were found to be highly effective, both with the multiple pressure and with the multiple puncture method.

QUANTITY OF RECONSTITUTED VACCINE PICKED UP BY BIFURCATED NEEDLES

Origin and batch No. of vaccine	Doses labelled	Amount of diluent*	Number of vaccinations with bifurcated needles	Estimated average amount of vaccine taken up by needle	No. of ampoule checked
Kenya, B.No. 36	25	0.34 ml.	180-204	0.0019-0.0017	6
Swiss, L.No. 30470	50	0.60 ml.	207-226	0.0029-0.0026	5
Thailand, B.No. 438	25	0.45 ml.	201-225	0.0022-0.0020	3
Rwanda, L.No. 3/65	100	1.00 ml.	396	0.0025	1
USSR B.No. 182	20	0.30 ml.	161-176	0.0019-0.0017	6

* The amount of diluent was measured with a tuberculin syringe (record type).

TABLE 1. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION IN PRIMARY VACCINATION

No. of Study Group	Origin & batch No. of vaccine	Number of persons vaccinated	Number of persons observed	Method of application of vaccine and method of vaccination	Number of major reactions	Take rate
1.	Nairobi B. 36	175	149	With bifurcated needle: M.P.M.*	149	100%
				With pipette: M.P.M.	149	100%
2.	USSR B. 182	163	134	With bifurcated needle: M.P.M.	131	97.8%
				With glass rod: M.P.M.	132	98.5%
3.	Thailand B. 438	143	117	With bifurcated needle: M.P.M.	114	97.4%
				With pipette: Scratch	112	95.7%
4.	Swiss B. 30470	165	153	With bifurcated needle: M.P.M.	146	95.4%
				With pipette: Scratch	145	94.7%
5.	Butare B. 3/65	88	85	With bifurcated needle: M.P.M.	61	71.8%
				With pipette: M.P.M.	64	75.3%

* M.P.M. = Multiple pressure method.

TABLE 2. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION
IN REVACCINATION WITH KENYAN VACCINE (BATCH NO. 36)

(Study group No. 1)

Interval since last vaccination in years	Number of revaccinees observed on 7th day	Method of Vaccine Application			
		By Bifurcated Needle		By Pipette	
		Major Reactions	Take Rate	Major Reactions	Take Rate
0-3 years	87	45	51.7%	46	52.9%
More than 3 years	261	214	81.9%	211	80.8%
Unknown vaccination history	67	48	71.6%	48	71.6%

TABLE 3. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION
IN REVACCINATION WITH USSR VACCINE (BATCH NO. 182)

(Study group No. 2)

Interval since last vaccination in years	Number of revaccinees observed on 7th day	Method of Vaccine Application			
		By Bifurcated Needle		By Glass Rod	
		Major Reactions	Take Rate	Major Reactions	Take Rate
0-3 years	88	42	47.7%	41	46.6%
More than 3 years	172	105	61.0%	103	59.9%
Unknown vaccination history	47	28	59.6%	26	55.3%

TABLE 4. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION
IN REVACCINATION WITH THAILAND VACCINE (BATCH NO. 438)
(Study group No. 3)

Interval since last vaccination in years	Number of revaccinees observed on 7th day	Method of vaccine application			
		By bifurcated needle		By pipette	
		Major reactions	Take rate	Major reactions	Take rate
0-3 years	71	26	36.6%	27	38%
More than 3 years	211	130	61.6%	132	62.5%
Unknown vaccination history	106	58	54.7%	58	54.7%

TABLE 5. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION
IN REVACCINATION WITH SWISS VACCINE (BATCH NO. 30470)
(Study group No. 4)

Interval since last vaccination in years	Number of revaccinees observed on 7th day	Method of vaccine application			
		By bifurcated needle		By pipette	
		Major reactions	Take rate	Major reactions	Take rate
0-3 years	158	68	43.0%	70	44.3%
More than 3 years	329	214	65%	219	66.6%
Unknown vaccination history	52	31	59.6%	31	59.6%

TABLE 6. COMPARISON OF THE TWO METHODS OF VACCINE APPLICATION
IN REVACCINATION WITH RWANDA VACCINE (BATCH NO. 3/65)

(Study group No. 5)

Interval since last vaccination in years	Number of revaccinees observed on 7th day	Method of vaccine application			
		By bifurcated needle		By pipette	
		Major reactions	Take rate	Major reactions	Take rate
0-3 years	89	10	11.2%	12	13.5%
More than 3 years	114	24	21%	26	22.8%
Unknown vaccination history	48	9	18.7%	12	25%

TABLE 7. COMPARISON OF TWO METHODS OF VACCINATION
(KENYAN VACCINE B NO. 36)

(Study group No. 6)

Method of vaccination	Number of persons vaccinated	Number of persons observed	Major reactions	Take rate
Multiple puncture	278	271	165	60.8%
Multiple pressure			159	58.7%

TABLE 8. COMPARISON BETWEEN 15 AND 30 INSERTIONS BY MULTIPLE PUNCTURE TECHNIQUE WITH BIFURCATED NEEDLES IN THE SAME GROUP OF REVACCINEES (KENYAN VACCINE B NO. 36)

(Study group No. 7)

Interval since last vaccinated in years	Number of persons observed	15 strokes		30 strokes	
		Major reactions	Take rate	Major reactions	Take rate
0-3 years	189	92	48.7%	108	57.1%
More than 3 years	144	102	70.8%	104	72.2%
Unknown vaccination history	nil	-	-	-	-

TABLE 9. COMPARISON OF MULTIPLE PUNCTURE AND LINEAR SCRATCH METHOD OF VACCINATION (USSR VACCINE B NO. 182)

Method of vaccination	Status of vaccination	Number of people vaccinated	Number of people observed	Number of major reactions	Take rate
Multiple pressure method	Primary vac.	112	98	98	100%
	Revaccination	334	302	184	60.9%
Scratch method	Primary vac.	102	99	97	98%
	Revaccination		269	156	57.9%