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COMPARISON OF DIFFERENT TECHNIQUES AND TOOLS

in

SMALLPOX VACCINATION

by

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The act of vaccination in itself is so simple. It is in fact only the insertion of vaccinia virus into the epidermis of a subject, allowing for infection of the susceptible cells, which becomes evident by the appearance of a local lesion.

To this purpose, from Jenner's time, many tools have been manufactured and several techniques developed. To-day we have at hand tools as simple as ordinary pins or needles, the cost of which is only the fraction of a cent, as well as complicated gadgets such as the jet injector, which costs nearly US \$ 1 000 a piece.

We shall discuss in this paper the advantages and disadvantages of the most popular tools used in this Region for vaccination of smallpox, such as pins, needles, rotary lancet, and also introduce two rather new tools, the bifurcated needle and the jet injector, which perhaps some of us had no opportunity of using in the field yet.

Further we shall make a comparison of different vaccination techniques in usual practice, such as linear scratch, multiple pressure, rotary lancet and multiple puncture.

I. TOOLS OF VACCINATION

1. Pins and needles

These are the most popular tools ever. They have been in use for a considerable time in several countries of the Region. Cyprus, Ethiopia, Iraq, Saudi Arabia, Southern Yemen, Sudan, UAR and Yemen are currently using the needle, while Iran and Jordan are likewise using the pin, as the only means of vaccination. Over 13 million vaccinations are being performed every year with these simple tools in this Region. It is cheap, it is available everywhere, it can be provided to vaccinators in large quantities, it can be flamed in the field several times for use after use. But it can only be used for linear scratch and multiple pressure methods, and it is not possible to use it for multiple puncture, a technique which has proved better. A glass rod or a dropper is needed for transferring the vaccine from the vial to the vaccination site.

2. Rotary lancet

It is mostly used in Pakistan, in this Region. About 47 million vaccinations per year are performed by this tool. It is a presentable tool, four or five forks are provided in the vaccination end, and may give the illusion of better introduction of the vaccinia virus. But this is a relatively costly gadget, much more expensive than the ordinary needle, and as it is considered more or less a durable tool, it is used over and over (while blunt), before being discarded.

It is expected to be flamed in the field, but, if not neglected altogether, due to its bulky head, there is always the danger of overheating and slow cool-down resulting in spoilage of the vaccine.

When it looses its sharpness, in the hand of an inexperienced ordinary vaccinator, the rotary lancet may become a dreadful instrument. It is said that it is more likely to perform a biopsy than a vaccination... The reaction of a vaccination by means of this tool on the fragile arm of a new-born child is very violent, especially when as many as three insertions are given, and in fact it may cover the whole area of the forearm.

The major objection of certain groups of people to smallpox vaccination where the rotary lancet is in use, certainly finds its origin in the ill-effects of vaccination with this tool.

3. Bifurcated needle

This new device, although only recently developed, is gaining day after day more popularity. Afghanistan, Libya and Somalia are presently using the bifurcated needle. This needle is a quite simple four-inch stainless steel needle, furcated at one end. When inserted into the vial of reconstituted vaccine, one droplet, sufficient for one vaccination, is retained within the forks of the needle.

Its advantages are as follows :

- Durability : The bifurcated needle was originally intended to be used only once, and then it was to be dispensed with. However, as the quantity of needles needed during eradication programmes is considerable, hence the cost involved, studies were carried out to test the durability of the needle. In a field trial in the UAR, by Shafa, one needle was used for as many as 172 times. In this trial, flaming was used as means of sterilization. The frequency of take-rates in a group of revaccinees were observed : a greater proportion of successful takes was in fact noticed among the second half of vaccinees, thus indicating that the needle can be used effectively over and over again. In another study in the UAR, by Shafa, in a group of primary vaccinees, when boiling was used as means of sterilization, each needle was successfully used for 46 - 47 times, and would still have been good for many more vaccinations. Similar studies have been carried out in Kenya. Ladoni-reports 90 vaccinations with one single needle successfully. and still the needle could have been used more. Both autoclaving and

boiling were used for sterilization.

Metallurgical testing, carried out by the Smallpox Unit, Geneva, indicates that the needle could withstand the heat of alcohol flaming up to 50 times when exposed for 3 seconds each time, without any changes occurring in its "hardness index". EM/SEM. SE/14 page 4

<u>Saving in vaccine</u>: It is evident that the mmber of doses registered in a vial is not very meaningful unless the tool used for vaccination and the number of insertions are known. The volume of the diluent used for the reconstitution of the vaccine is also an important factor. It is not surprising to note in most cases that only 25 - 30 effective vaccinations are being performed from a vial containing 100 conventional doses. An advantage of the bifurcated needle is the amazing saving of the vaccine. Through its particular construction, it is mapable of using much less vaccine than any other vaccination tool.

The amount taken up, by the furcated end of this needle is less than 0,0025 ml., in comparison to any other conven-, tional methods which would employ much more than 0.01 ml. of vaccine per vaccination.

In an experiment in the UAR, a vial of 50 doses of vaccine (from the Swiss Sera and Vaccine Institute, Bern) with 0.5 mL. fill, as diluent, was used by Shafa for over 500 vaccinations. Similar observations were reported by investigators in India also.

This in fact represents a saving of 10 times in the amount of vaccine used. To be on the safe side, let us say that the bifurcated needle will use five times less vaccine when compared with other vaccination tools.

- Satisfactory take-rates : In all field trial as well as smallpox eradication programmes, where bifurcated needles were used, satisfactory take-rates were observed. In a few planned studies carried out by several investigators (Millar, Zikmund, Ladnyi, Huisman, Meyer and Shafa), with freeze-dried vaccine of standard potency, take-rates of 98 to 100% in primary vaccinations and 56 to 76% in revaccinations; were reported in vaccinations performed by this needle. Other tools have shown invariably lower take-rates. In these studies, linear scratch, multiple pressure, and multiple puncture methods were used.

- <u>Simplicity in field use</u> : Simplicity obviously plays an important role in vaccination practices especially in field mass campaigns. Vaccinators are always subject to carry bulky things along with them. The use of bifurcated needles practically simplified this matter. It has eliminated the carrying of another binstrument, a dropper, a glass rod or a pipette, normally used for transfer of the vaccine from the vial to the vaccination site. Simple dipping of the bifurcated needle into the vial of vaccine will permit adherence of a small amount of vaccine between the two forks of the needle, sufficient for vaccination.

Furthermore, a sufficient number of clean needles can be provided to each vaccinator every day; allowing the use of one needle for each individual vaccinee, thus saving the time and equipment required for sterilization in the field.

Special capsule containers designed for the bifurcated needles allow easy carrying of over 200 needles in a compact practical form, sufficient for the day's work of a single vaccinator in the field. The used needles of each day are an indication of the number of vaccinations performed, where and when, recording of the number of vaccinations is necessary. This capsule container also permits easy sterilization of all used needles after work in the field is accomplished. It requires only the boiling of this capsule containing the used needles in any available pot or heat facilities any place in the field. This in fact will eliminate also the danger of using a hot needle, which is always a risk in vaccination practices. Furthermore, it eliminates the heavy load for vaccinators to carry with them troublesome means of sterilization facilities such as sterilizers, spirit lamps, alcohol, matches, etc... It is thus obvious that with this new tool and its container,

the bulk which the vaccinator is to carry with him in house to house vaccination method is reduced to practically two containers, one with a sufficient number of needles for his day's work, and the other for collecting the used needles plus a vial of diluted freeze-dried vaccine.

- <u>Number of insertions</u>: This may be a minor point, but a fact, that, with bifurcated needles, due to the furcated end, when used for multiple puncture or multiple pressure methods, fifteen strokes mean practically thirty strokes, and when used for linear scratch technique, one insertion means two insertions, thus increasing the probability of successful takes.

<u>Cost</u>: One thousand of these needles cost only \$ 5,-. When considering that over 100 vaccinations can be successfully performed by each single needle, the depreciation cost would be about one US cent for each 200 vaccinations, quite a reasonable price when compared with any other tools presently in practice.

Due to these many advantages, WHO has recommended the use of bifurcated needles in all its smallpox eradication assisted programmes throughout the world and I hope that this effective new tool, the simplicity, utility and efficacy of which are well established, will replace other vaccination instruments in all the countries of this Region for any sort of vaccination.

4. Jet injector

Jet injectors are rather new tools which have been introduced for smallpox vaccination; so far, several models have been developed and subjected to field tests to ascertain their usefulness in smallpox eradication activities. Some have proved to be cumbersome and difficult to operate; others failed to produce take-rates of acceptable level; some depend on electric power, thus limiting their use; some are heavy; some have the disadvantage of frequent clogging and breaking.

One of the promising models is the dermo-jet, a hand-operated jet injector which has shown good results in a few planned field studies; they still, have to be assessed for practical use under difficult field conditions.

Amongst jet injectors, the <u>Ped-O-Jet</u> is the only one in wide use giving excellent results, and which has been sufficiently evaluated under field conditions. It is powered by an hydraulic system operated by foot. It injects the vaccine through a very small orifice into the superficial skin layers. It has been in wide use in West African programmes, in Brazil and elsewhere, and excellent results have been obtained.

Ita advantages are :

- <u>Speedy vaccination</u> : One is capable to perform 500 vaccinations per hour. Three to four thousand vaccinations per day have been reported in some eradication programmes. However, our experiment in the Dacca Municipality mass vaccination campaign showed a much lower number of vaccinations per day, probably because of administrative and cultural problems on account of this new gadget.
- The injected dose of waccine is 0.1 ml and normally 25 cc or 50 cc. vials are sufficient for 250 to 500 vaccinations in a row without change of vials.

- As no needle is used, and vaccine is injected by pressure into the skin, there is no hazard of infection being transmitted from one individual to another.
- High take-rates were invariably observed throughout field operations and as evaluated through concurrent assessment in West-African programmes.

Unfortunately, there are a few problems :

- Contrary to needles, the proper use of which can be taught to ordinary vaccinators, the handling of the jet injector demands rather special skill and understanding. One should be somewhat mechanic-minded to handle the machine and perform minor repairs when and where necessary.

- Maintenance of the machine requires special care; spare parts should be available in sufficient quantities. These are rather expensive , not easily available, and have to be ordered well in advance.

- Major repairs cannot be performed under field conditions, and more elaborate tools, as well as higher skilled mechanics should be within reach.

- It is an expensive machine. With the price of only one jet injector, one can purchase 200 000 bifurcated needles, capable of performing 20 million vaccinations.

- The use of the Ped-O-Jet is only justifiable in static vaccination centres, where and when vaccinees can be gathered in an orderly manner and in large numbers. It is ideal for schools, institutions, army camps, etc... Its use in the house-to-house operations is neither economical nor practical. Consequently, the use of the jet injector should be limited to specific programmes where a supply of special vaccine could be managed. Training of vaccinators and field supervision carried out effectively; where spare parts would be available and repair of machines manageable.

The use of jet injectors in this Region is being limited to vaccinate the population of big towns, market places, institutions, and in containment of epidemics.

II, COMPARISON OF DIFFERENT TECHNIQUES OF VACCINATION

When considering the expenses involved for sending a field vaccinator to far-away villages, one just cannot afford to accept low take-rates.

It is now quite evident that the technique used in the vaccination has a lot to do with the result of a successful takerate. Better take-rates can be obtained where a good technique of vaccination has been used. It is imperative that this technique could easily be taught to vaccinators, and at the same time, it should be unanimously accepted by the public.

In this Region, Iran, Iraq, Jordan, Saudi Arabia, Southern Yemen, Sudan, UAR and Yemen are using the linear scratch technique; Ethiopia and Libya are using the multiple pressure technique and Afghanistan, Cyprus and Somalia are using the multiple puncture method. Although the multiple puncture technique is much preferred and almost always gives the better take-rates, in comparison with other vaccination techniques, in fact very little is actually in practice. In 1968, about 1,5 million vaccinations by this method were performed in this Region, while 14 million vaccinations were done by scratch technique and 47 million employing the rotary lancet. EM/SEM.9E/14 page 10

The multi-puncture technique has been field-tested and better results have been observed. In a comparison study in a group of revaccinees, by means of rotary lancet method and multiple puncture in India, carried out by Nath and Rao, 75% positive reactions were observed with multiple puncture against 42% with rotary lancet technique. As both techniques were performed in the same group of 153 subjects, the results showed 59 subjects with positive reactions resulting from their multiple puncture vaccination, whereas the same subjects' reaction was negative as far as rotary lancet was concerned. Contrarily, there were only 7 negative reactions with multiple puncture method where the reaction for rotary lancet were positive.

In a study by Ladnyi in Kenya, 112 primary vaccinations were performed with the multiple puncture method and scratch technique. The results read after 7 days showed that where 100% take-rates were observed in multiple puncture technique, for scratch technique 98% were recorded. In 334 revaccinees, the take-rates for,multiple puncture and scratch were 60.9% and 57.9% respectively.

Multiple pressure method was also compared against the scratch linear technique in the UAR, by Shafa, in a group of revaccinees. 75 to 77% take-rates were observed for multiple pressure as compared to 65 to 70% for scratch technique.

The multiple puncture technique was not previously recommended nor recommendeble because of the danger represented by possible deep penetration of the skin by the normal needles; with the bifurcated needle, this danger vanishes : the structure of the needle prevents deep penetration.

To-day, based on available information, the multiple puncture technique performed by means of bifurcated needles is a method of choice, and this is highly recommended by WHO.