A FIELD EXPERIENCE OF MASS PERCUTANEOUS BCG INOCULATION AS AN IMMUNIZING AND DIAGNOSTIC PROCEDURE: FOLLOW-UP PHASE

I. W. F. SPENCER, M.B., B.CH., D.P.H., D.T.M. & H.; M. E. E. COSTER, M.B., B.CH.; A. V. MCPHAIL, M.B., B.CH.; AND M. RICHTER, M.B., B.CH.; *City Health Department, Johannesburg*

In a previous communication[1] we described the first 3 phases of a tuberculosis control programme undertaken in the Bantu areas of Johannesburg. They were a preparatory study of 24-hour local reaction to inoculation with the vaccine, a pilot study of field application and a mass campaign of immunization and reading of local reaction used as a diagnostic procedure. The fourth and final follow-up phase of positive reactors forms the subject of this paper.

In the mass campaign described, 160,298 inoculations without previous tuberculin testing were given to all age groups in 18 working days during October 1963, 124,997 of which were to persons in the priority age group 0 - 20 years. Of the persons in this age group, in whom the local reaction to percutaneous BCG inoculation was to be assessed 24 hours later, 91,966 were traced and their reactions examined by reading teams, being 73·6% of the possible target. A total of 12,759 positive reactions were recorded.

In support of the general applicability of the methods employed, a precisely similar mass inoculation and reading procedure was subsequently undertaken in an adjacent Bantu residential complex on behalf of another local authority. Three of the 6 teams engaged in the previous campaign were put into the field. They completed their task in 10 working days in May 1964 and inoculated 63,657 persons of all age groups. A total of 46,925 was vaccinated in the priority age group 0 - 20 years, being 94% of the calculated target. Of the persons in the age group 0 - 20 years in whom the reaction to percutaneous BCG vaccination was to be assessed 24 hours later, 36,323 persons were traced and the reactions examined by reading teams. A total of 4,983 positive reactions was recorded. The follow-up of positive reactors was to be carried out by the local authority of the area.

The people of these adjacent townships were of similar socio-economic and environmental status to those of the mass campaign in the Johannesburg Bantu complex, but, unlike that community, had not been previously conditioned to rapid mass immunization procedure. Of the persons inoculated and traced in the age group 0 - 20 years in the campaign in the Johannesburg Bantu areas 13·87% presented positive reaction, while in the campaign in the adjacent areas 13·72% were positive reactors. The close correlation of these figures in separate campaigns, but in comparable communities, suggests that techniques of inoculation and reading remained constant.

OBJECTIVES OF THE FOLLOW-UP PHASE

Management of Positive Reactors

In terms of a policy directive from the State Department of Health outlined in our previous paper,[1] no further steps were to be taken in instances of negative local reaction, but the management of cases showing a positive reaction was to be as follows:

(*a*) Persons under 5 years of age were to be treated with isoniazid for 2 years as active cases.

(*b*) Those 5 - 10 years of age who showed clinical evidence of tuberculosis, or who gave a history of having been a contact of a tuberculosis case, were to be radiologically examined on 100 mm. film, and any tuberculotics thereby detected were to be treated.

(*c*) Those 11 - 20 years of age were to be radiologically examined on 70 mm. film and any tuberculotics detected were to be treated.

In addition to the positive reactors in these priority age groups, persons over 20 years of age were to be examined on 70 mm. film without any reading of reaction to inoculation, and tuberculotics detected were to be treated.

Since the Johannesburg City Health Department operates a 100 mm. mobile X-ray unit for field work, approval was obtained from the State Department of Health to use 100 mm. film for all these preliminary investigations.

Threefold Objective

The objectives of the follow-up phase were threefold:

(*i*) The investigation between the scheduled dates 1 February - 30 June 1964 of the 12,759 instances of recorded positive hypersensitivity reaction in persons aged 0 - 20 years who were vaccinated during the mass immunization phase, and control of these cases as previously directed by the State Department of Health.

(*ii*) An endeavour to persuade persons over 20 years of age to submit to X-ray examination.

(*iii*) The introduction of routine maintenance percutaneous BCG vaccination of the newborn.

As was stated,[1] Bantu members of discussion groups attended by medical field workers drew attention to the necessity not to emphasize the relationship between simple immunization, in which the people had developed trust, and subsequent follow-up of positive reactors with consequent family disruption in some instances. In accordance with their well-founded recommendation that the two procedures should not run concurrently, the follow-up phase was not begun until 3 months after completion of the immunization campaign. Though this delay increased the difficulty of tracing positive reactors it enhanced the cooperation of the people.

FIELD PROCEDURE

Assignments to attain the objectives were made to subsidiary tuberculosis clinics serving the various sectors of the Bantu areas and to an established domiciliary health visitor service. The subsidiary clinics were responsible for the tracing, investigation and treatment of positive reactors in the age group 0 - 20 years, and the persuasion of vaccinees over 20 years of age to present for X-ray and subsequent treatment where found necessary. The health visitor service was to introduce and carry out routine maintenance percutaneous BCG inoculation of the newborn with Heaf's apparatus.

Assignment to Subsidiary Clinics

Record files of inoculating teams completed during the mass campaign in October 1963 and containing the names and

addresses of positive reactors were distributed, according to the area each covered, to the tuberculosis clinic serving that area. The totals of positive reactors thus allocated is shown in Table I.

TABLE I. FOLLOW-UP PROCEDURE: ALLOCATION OF POSITIVE REACTORS TO CLINICS

Subsidiary tuberculosis clinics	*Positive reactors*		
	Schools and creches	*Domiciliary*	*Total for each clinic*
1 (M)	1,548	705	2,253
2 (J)	1,586	1,898	3,484
3 (O)	1,830	471	2,301
4 (S)	2,112	970	3,082
5 (P)	1,259	380	1,639
	8,335	4,424	12,759

It soon became evident as field work advanced that the totals allocated to each clinic would have to be modified (Table III). In due course it was found that at some clinics they were greater and at others less than those in Table I, while the over-all total of 12,759 positive reactors which could possibly be traced was reduced to 12,311. Various factors were responsible. Only 12,311 of the 12,759 positive reactors were found to be permanent residents of the townships and the remainder had entered from adjacent or distant areas. Their names and temporary addresses were recorded in separate files kept by the inoculating and reading teams for this purpose but, at the time of the follow-up phase, the majority of persons from these areas were not available. The totals remaining to clinics were further modified by people moving their place of residence from one part of the townships to another, and by children who had left schools and creches and were now living in sectors different from the institutions in which they had been recorded. Obviously, incorrect addresses had been intentionally given in some instances. A proportion of clerical errors could not be excluded under the conditions of pressure of the mass inoculating and reading campaign. In addition, areas assigned to inoculating and reading teams did not always precisely coincide with sectors served by individual tuberculosis clinics.

Each clinic thus amended its totals of positive reactors, and, after consultation of existing case history cards, noted in these records vaccinees found to be known tuberculosis cases. As information and statistical data on positive reactors provided the basic material for our study of the follow-up phase, it was necessary that clinical records of positive reactors brought into the orbit of the clinics be meticulously maintained and kept in coded groups to facilitate subsequent extraction of data. A case history card was made out for every such vaccinee at the time the individual was first traced, either in a domicile, school, creche or clinic, unless the person was a known tuberculotic and already had a case history recorded at a clinic. A code letter Z was entered on every case history record of any person who was vaccinated in the mass immunization phase of 7 - 31 October 1963. All these records were retained under separate filing. Clinics were required to add further coding symbols on each record to permit the submission of categorized case history records to the authors at the conclusion of the follow-up phase for analysis. The coding summary is shown in Table II.

It was decided that a Hollerith or comparable system should not be employed in this study. We considered that more was involved than grouping and compilation of statistical totals, and that a computer type of analysis would be misleading, tending to lessen medical assessment and extraction of clinical observations which would either fail to fall into punch card groupings or merely add to a statistical total without critical consideration of the observation. Detailed statistics and records were compiled from clinic case history records after completion of the follow-up phase, but weekly field statistical returns were drawn throughout the phase to control sectional and over-all progress toward the target with precise adherence to the follow-up programme.

All personnel of the various subsidiary tuberculosis clinics attended detailed preliminary briefing sessions to provide uniform compliance with determined field procedure. Fortnightly joint study groups with field staff of the subsidiary clinics were held throughout the phase to assess statistical evidence of progress, ensure adherence to the scheduled progression set between the time barriers 1 February - 30 June established for the undertaking, analyse field problems, and maintain parallel action of units to obtain effective coverage of the task assigned and to provide comparable data.

TABLE II. CODING SUMMARY

Symbol	*Representation*
Z	BCG vaccination during the mass immunization phase 7–31 October 1963.
A	Known tuberculotic diagnosed before the mass immunization phase.
B	Vaccinees who were not previously diagnosed tuberculotics.
(a)	Aged 0–4 years 11 months.
(b)	Aged 5–10 years.
(c)	Aged 11–20 years.
(d)	Aged over 20 years.
+	Positive 24-hour reaction to BCG inoculation.
−	Negative 24-hour reaction to BCG inoculation.
(×)	Vaccinees diagnosed as tuberculosis cases after completion of the mass immunization phase.

The problems of propaganda methods in relation to tuberculosis were previously considered.[1] In addition to these considerations there is frequently approval of White methods of cure of a disease but inability to accept a White man's explanation of the cause of the condition. This remains especially applicable to tuberculosis even in these areas, and constitutes a profound barrier to effective educative procedure. Incorrect relationship in the minds of the people between previous BCG vaccination and subsequently diagnosed tuberculosis would further intensely complicate the issue. For these and other similar reasons we refrained from any mass propaganda methods such as the issue of circulars to householders calling on vaccinees over 20 years of age to present for X-ray examination or any other method urging a mass response of the people. Difficulties of understanding could have held potential failure for the follow-up phase. It was considered advisable to rely entirely on the ability of our Bantu nursing services to trace positive reactors and explain the need for further investigation in a manner understood by their people.

At the outset we held little hope of any significant response by persons over 20 years of age to come forward for X-ray examination when they felt in good health. We thought that, though they had proved anxious to submit to BCG inoculation in the mass campaign, many would be unwilling to submit themselves to a procedure which could lead to detection of a condition at present causing them no trouble, with possible pressure in regard to therapy, hospitalization and family disruption. Persuasion in these matters is difficult in the Bantu with advanced disease, and they are unlikely to seek the situation voluntarily unless illness supplies the stimulus. Belief in prevention by the majority of this community has advanced firmly towards protection by immunization and other health measures, but, as with many Whites, has not yet reached the stage of searching for a potential illness before its manifestation to the individual. It is true that many Bantu believe that exposure to X-rays protects against disease, but it is unlikely that great success would be obtained in a domiciliary radiological survey in these areas. More satisfactory results would be possible among persons in schools, creches and compounds. On these grounds the persuasion of vaccinees over 20 years of age to come for X-ray examination was assigned to Bantu nursing staff to carry out during their contact with the public, in clinics, in their routine domiciliary duties and in their work of the follow-up phase in the homes of the people.

Electrical connection points for the mobile 100 mm. X-ray unit were available at all the subsidiary tuberculosis clinics. In addition, niphan connecting sockets were installed at 6 additional points bringing X-ray facilities within reasonable access of all parts of the townships. Vaccinees who had to be radiologically examined were required to make their own arrangements for presentation at X-ray points in accordance with a prescribed schedule. They were assisted by clinic staff wherever possible but no specific provision for transport was made. Special schedules for X-ray examination of positive reactors were drawn for each of the 160 schools and creches in the areas. When indicated by findings on 100 mm. films, vaccinees were referred to the tuberculosis master clinic for large plate investigation and any further necessary procedure.

The programme at each clinic was divided into domiciliary follow-up of positive reactors and an institutional follow-up in schools and creches. Geographical progression through the whole area followed the system employed during the mass inoculation and reading campaign. The total commitment was extended between the scheduled dates 1 February - 30 June, but the period 5 - 30 June was set aside for further attempts to trace positive reactors who had not been found, or who, though traced, had failed to present for investigation. Large detailed wall-maps of the sectors served by each clinic were provided. Each clinic abstracted and recorded the names and addresses of all positive reactors aged 0 - 20 years in their sectors from the records provided by the inoculating and reading teams. The domiciles of positive reactors were marked on the wall-maps by red pins, and schools and creches by yellow and green pins respectively. When positive reactors were traced in the field, the related pins were removed from the maps giving an indication of progress and failure. The wall-maps were photographed after all positive reactors had been marked and before tracing began. When the photographs were juxtapositioned to represent the whole of the Bantu complex, positive reactors in general appeared to be scattered fairly uniformly throughout the area, suggesting a satisfactory coverage by inoculating and reading teams. The distribution failed to show any significantly different grouping in areas considered to be of higher economic status when compared with areas of lower status. After a positive reactor was traced, procedure by the clinic services followed the stipulations according to age group of the directive from the State Department of Health.

ASSIGNMENT TO THE HEALTH VISITOR SERVICE

Following the successful introduction of a pilot project in part of the Bantu areas, a health visitor service was established covering the entire complex. In accordance with their background and training, Bantu health visitors, under the supervision of senior White staff, conduct domiciliary health education and direct their attention to all aspects of the domestic situation, namely, socio-economic factors, housing and environmental situations, marital relationship, pregnancy, the newborn, the infant, the necessity for supplementary dried milk and other preparations for individual cases of infant necessity, the pre-school child, the school child together with reactions and relationships to school activities and personnel, sibling and child-parent relationship, the adolescent, the crippled child or invalid adult, health problems of the mother and father, the aged, the family budget and spending, economy in purchase and the preparation of food, domestic hygiene and the organization of household duties. They forge liaisons with, and refer where necessary, persons and problems to ante-natal and maternity services, social workers, township superintendents, school principals and supervisors of pre-school institutions, hospital, clinic and dental services and various voluntary welfare organizations. One of their major duties is routine oral immunization of the newborn with trivalent poliomyelitis vaccine and their vaccination against smallpox. They arrange with child welfare medical officers of the service for diphtheria, whooping cough and tetanus immunization of these children.

We showed in our previous communication[1] that present knowledge indicates that protection levels remain substantial 7½ - 10 years after BCG inoculation. The mass BCG inoculation campaign conducted in these areas would be of limited value if epidemiological advantage gained was not retained by introduction of maintenance routine BCG vaccination of the newborn, with the probable necessity of recurrent mass vaccination campaigns every 7 years. Accordingly, percutaneous BCG vaccination of the newborn was introduced at the commencement of the follow-up phase and was assigned to the health visitor service. Newborn are traced from birth registration lists and notification forms usually reach the health visitor service within 10 days of births. Routine BCG inoculation with Heaf's apparatus has been carried out by Bantu health visitors as soon as practicable after receipt of birth notifications, without previous tuberculin testing or reading of 24-hour local reaction. Each health visitor was fully briefed and attended demonstrations of inoculation technique and field management of vaccine. Medical officers and White health visitors in charge of units of the service conduct recurrent inspections to obtain adherence to requirement. Full records are maintained as part of general immunizational and other data in a family folder and card system.

TRACING AND INVESTIGATION OF POSITIVE REACTORS

Sorting of Data

On account of the need in the mass immunization campaign to retain simplicity of records, to limit data to what was completely essential at that stage, to avoid unnecessary duplication and to obviate slowing of immunizing teams, totals in age groups were confined to those 0 - 20 years of age and those aged over 20 years. Knowledge of the actual age of persons in the age group 0 - 20 years was only needed when they were traced as positive reactors in the follow-up phase. Their ages were then obtained and further procedure determined in relation to the stated requirements for the age groups 0 - 4 years 11 months, 5 - 10 years and 11 - 20 years. We were thus unable to state the numbers inoculated in these age groups. It was more important that no opportunity to vaccinate any person be lost as a result of clerical delays in collecting data which were not necessary for the tracing and investigation of reactors at a later stage.

For statistical purposes a positive reactor was considered traced when the first contact was made with the vaccinee after vaccination during the immunization campaign. Positive reactors were recorded as investigated when those aged 0 - 4 years 11 months were notified as tuberculosis cases and placed on treatment, when those 5 - 10 years had presented for preliminary medical examination, and those 11 - 20 years had undergone preliminary 100 mm. radiological examination.

Statistical Results

The follow-up of positive reactors was completed between the scheduled dates 1 February - 30 June 1964. A statistical analysis is summarized in Table III. Of the total of 12,311 positive reactors 9,655 (78·4%) were traced and 8,694 (70·6%) were investigated and placed on treatment when necessary. In vaccinees aged 0 - 4 years 11 months (among whom, in accordance with the directive from the State Department of Health, all positive reactors were considered active cases) 1,495 children were traced and 1,469 were notified as tuberculosis cases and placed on treatment. In the group aged 5 - 10 years 3,287 children were traced and 2,840 were investigated and placed on treatment where necessary. In those aged 11 - 20 years 4,873 were traced and 4,385 were investigated and treated where necessary.

TABLE III. TRACING AND INVESTIGATION, 1 FEBRUARY—30 JUNE 1964

Clinic	Target 0–20 years			Tracing and investigation								Percentage of target 0–20 years						Over 20 yrs
	Over-all	Schools and creches	Domiciliary	0–4 yrs 11 months		5–10 years		11–20 years		Total 0–20 years		Over-all		Schools and creches		Domiciliary		
				Traced	Investigated	Traced	Investigated	Traced	Investigated	Traced	Investigated	Traced	Investigated	Traced	Investigated	Traced	Investigated	
1 (M)	2,327	1,554	773	250	237	723	666	921	822	1,894	1,725	81·4	74·1	85·6	78·0	73·0	66·5	103
2 (J)	3,385	1,637	1,748	596	592	916	734	796	641	2,308	1,967	68·2	58·1	62·0	52·8	74·0	63·0	68
3 (O)	2,468	1,748	720	225	220	594	491	1,207	1,155	2,026	1,866	82·1	75·6	81·4	78·0	83·8	69·9	46
4 (S)	2,503	1,755	748	303	300	600	529	1,114	1,042	2,017	1,871	80·6	74·8	79·2	75·3	83·8	73·5	30
5 (P)	1,628	1,237	391	121	120	454	420	835	725	1,410	1,265	86·6	77·7	94·3	83·8	62·4	58·6	85
Total	12,311	7,931	4,380	1,495	1,469	3,287	2,840	4,873	4,385	9,655	8,694	78·4	70·6	79·7	73·0	76·0	66·2	332

Traced = first contact with vaccinee since vaccination in immunization campaign.
Investigated: 0–4 years 11 months = notified and placed on treatment.
5–10 years = preliminary medical examination.
11–20 years = preliminary X-ray examination.

In support of our previous contention and the reasons advanced therefor, despite every effort, only 332 vaccinees over 20 years of age came forward for X-ray examination. It was especially significant since 35,321 persons in this age group had been vaccinated in the mass campaign.

A purpose of the fortnightly study groups with field personnel was not only to obtain parallel and uniform action by the subsidiary clinics, but to secure adherence to the schedule set for them. No additional staff was available for any part of this tuberculosis control programme, and if staff had been allowed to concentrate to excess at any period on the follow-up phase, the heavy load of routine tuberculosis duties would have suffered unduly with detrimental results to those under care. A steady, scheduled application to their task and retention of an equal division of effort between tracing and investigation of positive reactors is reflected in Fig. 1, and the decreasing numbers of persons traced and investigated in the 'mopping-up' period in June indicated that there was

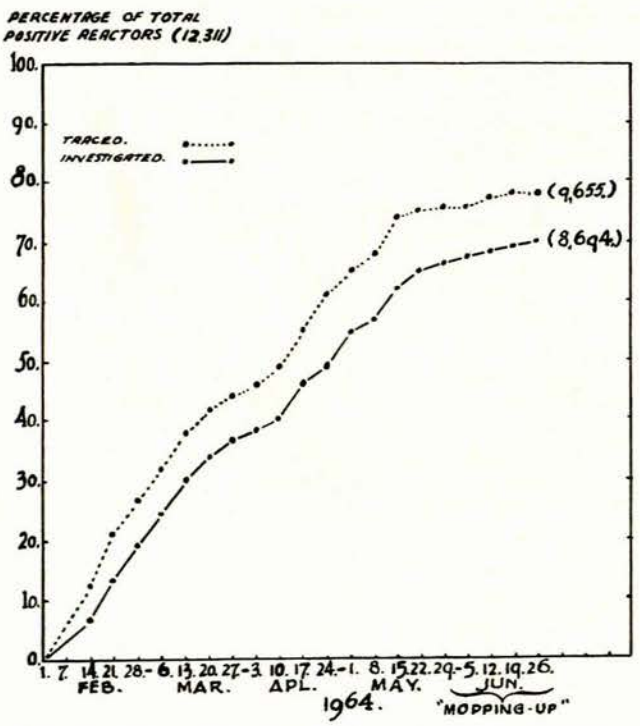

Fig. 1. Tracing and investigation of positive reactors 0 - 20 years—weekly progress.

little more that could be achieved in these directions. Neither was marked effort at this stage able to increase the numbers traced nor narrow the gap between the numbers traced and those investigated. Whenever possible additional visits and persuasion had been brought to persons traced but who failed to present for investigation. It was realized that there was often nobody at home during the day to bring little children for investigation, but even with increased attention in the 'mopping-up' period, there was nothing further to be gained.

Varying success rates at the different clinics were evident. Staff aptitudes and motivations at the clinics were judged to be fairly similar, while personnel complement was proportionate to the population served. It was anticipated that the tracing and investigation of positive reactors would have been simpler and more effective in schools and creches than in the homes, yet the unexpectedly high success rate of the domiciliary work resulted in a greater percentage in domiciliary tracing than in schools and creches in 3 of the 5 subsidiary tuberculosis clinics—2(J), 3(O), 4(S). This could not be attributed to any specific factor, but suggested that the difficult assignment of domiciliary follow-up had been well met. In the case of clinic 5(P), which covers the last remaining slum area in the Bantu complex, the high and shifting population concentration, living under poor conditions of housing and sub-tenancy, would have accounted for the lower domiciliary success rate when compared with the other clinics. However, better results were obtained in the schools and creches of this area than in any other sector. Further, the over-all percentages of persons traced and investigated were the highest. Broadly, success achieved appeared to be related to problems of distance, which was supported by the lower over-all percentage result obtained by clinic 2(J) which covered the largest area. We were unable to relate varying success rates in the different areas to the diversity of transcultural development, socio-economic status, attitudes, motivations or cultural backgrounds existing in this complex.

In terms of the directive by the State Department of Health, positive reactors traced in the age group 0 - 4 years 11 months were placed on isoniazid therapy as active cases. Argument supporting the evaluation of these children as active cases is that positive reactions indicate infection with the tubercle bacillus, and in children in this age group it is thought virtually impossible to determine whether the disease is active or quiescent. As healing may take up to 3 years after infection, and many children

become infected within the first 2 years of life, they are therefore considered to be in an active stage if found to have a positive hypersensitivity skin reaction during the first 5 years of life even if there is no clinical or radiological evidence of tuberculosis. Accordingly, positive reactors in this age group who were traced and placed on isoniazid therapy were all notified as tuberculosis cases. Being notified, they became subject to routine medical surveillance and supplementary feeding schedules provided by the tuberculosis services for notified cases. During the course of the follow-up phase 1,469 in this age group were thus notified as tuberculosis cases on the grounds of positive hypersensitivity skin reactions without supporting clinical or radiological evidence. A number may have been converted by BCG vaccination before the mass immunization campaign. There will be a marked increase in the number of cases of tuberculosis notified in the age group 0 - 20 years in these areas as a result of the follow-up phase and which will not be related to an increased incidence of the disease. The particular circumstances of notification in the age group 0 - 4 years 11 months will require consideration.*

An attempt was made, in study groups held during the follow-up phase, to assess whether there were factors influencing notifications of disease and statistics compiled therefrom. It had been our experience that notification of diseases like diphtheria or typhoid was generally accurate, especially since confirmation of diagnosis depended on laboratory findings. In kwashiorkor, on the other hand, notification depended on a clinical syndrome which introduced a variable of individual opinion. In a recent assessment it became evident that, despite clear clinical criteria for the diagnosis of kwashiorkor, variation of interpretation was considerable. This, and other factors, often led to notification of pre-kwashiorkor and various nutritional states as kwashiorkor by practitioners both in institutional and private practice. Even though tuberculosis fell into the first category where confirmation by radiological and laboratory findings was available, a tendency to a different approach, often subconscious, to notification of tuberculosis in Bantu was detectable in our services.

Where a calcified apical lesion in a White would possibly be retained under observation, the same lesion in Bantu would frequently be notified and the patient treated and given supportive supplementary feeding. The tendency was produced by the socio-economic circumstances of the Bantu. In the follow-up phase an influence culminating in notification of cases which would otherwise have been viewed with circumspection was the co-existent finding of a positive hypersensitivity reaction.

A CONTROL OF RADIOLOGICAL INTERPRETATION

The necessity and efficacy of BCG immunization in the control programme was accepted. The extent of BCG inoculation offered opportunity for large-scale assessment of the value of 24-hour hypersensitivity skin reaction to percutaneous BCG inoculation as a preliminary diagnostic procedure under the field conditions and available medical facilities of a large urban Bantu population, broadly representative of similar communities and conditions elsewhere in this country. Diagnostic application of the skin reaction, though secondary to the basic aim of raising immunity levels by vaccination, was nevertheless of considerable significance in view of the loss of the tuberculin test as a preliminary diagnostic tool following mass conversion by extensive BCG inoculation in this programme. The advantage of simultaneous immunization and skin testing in a single procedure added to the need to appraise the usefulness of the skin reaction under existing field circumstances. Though many positive reactions would be due to exposure to the tubercle bacillus without other detectable manifestation, or to conversion by previous BCG inoculation in a small number, the appraisal of the value of the skin reaction would primarily depend on radiological examination of the positive reactors. A critical estimation of the standard of interpretation of radiograms in relation to pulmonary tubercular pathology was considered necessary. Specialist radiological facilities are not available in the Bantu complex except in exceptional circumstances. Interpretation of 100 mm. films and large plates of cases subsequently referred for X-ray to the master tuberculosis clinic are read as a routine procedure by medical officers of general practitioner status. Positive reactors of the follow-up phase who were traced and who required radiological investigation were referred in the usual manner to these established services.

We decided that estimation of levels of radiological interpretation would best be accomplished by comparison against specialist standards, but accepted that the assessment would be hypercritical since the reasonable skill demanded of medical officers should not be expected to approach specialist attainment. However, it would indicate the extent to which the hypersensitivity skin reaction could be evaluated by the routine radiological facilities provided.

Method

One of us was a member of the routine tuberculosis services and was actively involved in the clinical and radiological work of the follow-up phase. Because of inevitable bias he was excluded from any participation in this control, or in the later collation and analysis of data described in this paper. Films for the control were drawn after completion of the follow-up phase.

A median sample was represented by medical officers who read 100 mm. films of positive reactors. One had long and extensive experience in the tuberculosis services, one an intermediate experience and the other had recently joined. A median sample was taken of 100 mm. films of positive reactors read by these medical officers according to the population groups from which the reactors came and included the remaining slum area, an intermediate area and an area of higher socio-economic status. The sample further included a median selection of age through the group X-rayed, i.e. 5 - 10 years, 11 - 20 years and over 20 years. Finally it was composed of an equal number of readings of films where pathology was reported and where nothing abnormal was demonstrated. Within the limits of these median selections a random sample of 1,044 films was drawn with an equal division of 348 films reported on by each medical officer.

Films were received in folders on each of which was recorded a routine serial number, the coding of the follow-up phase, personal particulars and age of the patient, whether a contact of a tuberculosis case, sputum examination results and therapy if applicable, date of the X-ray examination and the report of the medical officer who read the film. Films were removed from their folders and placed in similar folders which had recorded on them all data on the original except the medical officer's report. The films in these folders were then submitted to a specialist radiologist of standing who recorded his report on each film on the relevant folder. The radiologist was aware of the meaning of the code symbols on the folders and therefore had precisely the same information and reading conditions as the medical officers. After

*In a recent communication received from the Secretary for Health, subsequent to submission of this paper for publication, we were informed that notification in respect of this age group should be amended. Accordingly only those vaccinees subsequently clinically confirmed as tuberculotics will be notified in the age group 0 - 4 years 11 months.

return by the radiologist each film had attached to it the original folder and the folder from the radiologist. We made a comparative analysis as far as was possible of the reports of the medical officers and the radiologist.

Extensive comparative criteria were drawn to show the extent of agreement between the reports of the radiologist and the medical officers, and whether the degree of disagreement was of significant consequence. It was directed toward the recognition of active and quiescent tubercular pathology, ability to detect and exclude non-tubercular abnormality and awareness of unsatisfactory elementary technique by the radiographer, e.g. poor patient positioning and resultant problems of assessment of hilar glandular involvement, or the taking of expiratory films and consequently increased reading difficulty.

Analysis

Wide differences in nomenclature were encountered but analysis was made in terms of fundamental intention of meaning. Reasonable latitude of interpretation was accepted.

A total of 617 or 59% of reports by medical officers were in agreement with those of the radiologist.

Of the 427 in varying degrees of disagreement, which included a small proportion of non-tubercular conditions such as muscular cysticercosis, cardiac pathology, osseous abnormality and other lesions, it was found that in 5·17% of non-tubercular conditions medical officers made no comment, while they omitted to report in 2·77% of instances of significantly unsatisfactory radiological technique. In 31·77% of films in which medical officers considered tubercular pathology present, the radiologist did not. In the group of films which in the opinion of the radiologist showed quiescent tuberculosis the medical officers differed in 38·6%. Of 83 cases of active tuberculosis diagnosed by the radiologist, 35 or 42·2% were not considered active tuberculosis by the medical officers. They judged 16 of them to be quiescent tuberculosis and in 19 they failed to demonstrate any abnormality. Nineteen cases of tuberculosis (22·9%) in this group of active pathology were therefore missed by the medical officers.

In instances of active tuberculotic disease the medical officers predominantly differed from the radiologist in regard to hilar glandular involvement, active primary complexes and pulmonary infiltration, while in quiescent cases variance was similarly centred on healed primary complexes, hilar presentations and fibrotic lesions. Again in instances where medical officers reported on the presence of tubercular pathology which was not present in the opinion of the radiologist, differences were chiefly related to hilar involvement and fibro-infiltration. In general there was a tendency by medical officers to over-diagnose hilar fibrosis and under-diagnose fibrosis in lesions other than at the hilum. There was a lack of consistency in terminology of reporting and a more uniform format would have been advantageous.

Evaluation

The findings were perturbing. According to our experience we thought that interpretation in these services was representative of any institution where reading of radiograms is, in the main, conducted by officers who are not specialist radiologists. The control has shown the need to reassess the structure of the service, which must contribute largely to the ceiling of medical officer standard in this field. Infallability in a medical skill is not attainable at general practitioner nor specialist level, and therefore a margin of error at both levels must be co-existent. At both levels a degree of skill in accordance with the training and experience of the reader is the optimum expectation. Nevertheless the level of medical officer reading requires adjustment to a higher level. The attitudes and application to the over-all work situation by the medical officer sample in this study was of impeccable and consistently high order. Clearly they were limited in radiological interpretation by circumstances beyond their control and inherent in the structure of the service. The need is apparent to provide improved guidance and correlation of accumulated experience, and a standard of interpretation against which they could recurrently measure their ability. Without such a standard, medical officers have tended to develop variants of interpretation which eventually became embodied in routine practice, and were conveyed to newcomers to the medical officer complement. The pressure of other duties made it difficult for officers to improve and reorientate radiological ability, unlike the radiologist, whose work, contact with colleagues, and medical reading is largely confined to one field.

Arising from this study we advise it necessary to create a post approved by the State Department of Health for a specialist radiologist in the tuberculosis services in these Bantu areas, whose duties would include the control of the X-ray services, the coordination of reporting, the maintenance of medical officer reading ability against an acceptable standard which he must set, the conduct of study groups with medical officers to maintain interest, awareness of progress and for presentation and discussion of selected problems, being available to medical officers for consultation, interpreting radiograms of complexity and taking recurrent random sample surveys of reports by medical officers.

Similar problems may be found to exist in similar services of parallel magnitude in other areas.

We reaffirm that the control analysis was critical and extensive, and consider that, though it gave grounds for concern and reconsideration, it still permitted a reasonable expression of opinion in regard to the follow-up of positive hypersensitivity skin reactors. However, the study also showed that, apart from the 1,044 films already reported upon by a radiologist, all the remaining films of positive reactors will have to be submitted forthwith for specialist reassessment and, in any additional instances of tubercular pathology discovered, the reactors be re-traced and treated.

A REVIEW OF FINDINGS

On completion of the follow-up phase, 11,720 Z-coded patient records were submitted to 3 of us for extraction and study of relevant material from each. The number was greater than the total of positive reactors traced because other vaccinees who subsequently came to the tuberculosis services were included.

Extensively categorized sheets and cross-references were compiled covering any apparently significant type of information which could be obtained from these records. Trial runs of data extraction were made and summarizing and breakdown sheets amended until it was thought that they were adequately designed to carry all information which might contribute to the drawing of conclusions.

In the final analysis it became obvious that it would not be possible to draw valid conclusions regarding many of the questions to which answers were sought. This undertaking was primarily a mass field application of percutaneous BCG inoculation to a community shown to be in priority need of rapid raising of immunity levels to tuberculosis.[1] Secondary procedures of associated reading of hypersensitivity reaction, and application as a case finding method with assessment of its value, could not be permitted to deviate the basic purpose of essential immunization. Controlled studies especially designed for the specific purpose of evaluating defined aspects of these secondary procedures will be necessary if additional knowledge is required.

The community reaction to the follow-up programme was cooperative and satisfactory in regard to the tracing and investigation of positive reactors in the age group 0 - 20 years, among whom 90·04% of persons traced subsequently presented for investigation. The fact that a positive reaction was explained as an indication of exposure to infection was a contributing stimulus. In vac-

cinees over 20 years of age, in whom reading of the skin reaction was not required, this stimulus was lacking. For this and other more significant reasons previously described, vaccinees over 20 years of age generally failed to respond to persuasion to present themselves for X-ray investigation. Field staff frequently found on visiting the recorded addresses of positive reactors that they refused to admit to their identities. Positive reactors among school children sometimes endeavoured to change their names, fearing confirmatory diagnosis of tuberculosis. They were especially anxious because of possible interruption to their schooling. Fear of diagnosis increased with age and responsibility. Analysis showed that, apart from first visits in tracing positive reactors, nursing staff revisited 1,612 vaccinees a total of 2,334 times, individual vaccinees being revisited 1 - 6 times.

The follow-up phase resulted in the notification of 1,856 new cases of tuberculosis; 1,626 were notified as the result of tracing and investigation of positive reactors, and a further 230 were discovered as a result of the follow-up of vaccinees who were found to be contacts of these cases. However, of the total of 1,856 new cases notified, 1,331 were in the age group 0 - 4 years 11 months and were therefore notified on the grounds of a positive hypersensitivity reaction alone. This group thus included both actual and potential tuberculotics, and in terms of our assignment were all placed on treatment without investigation to determine the presence of overt tuberculosis. A total of 525 clinically confirmed tuberculotics were discovered in persons over 4 years 11 months of age as a result of this campaign. Three positive reactors were found to have extrapulmonary tuberculosis; one arthritic and 2 glandular. As the radiological control showed under-diagnosis in interpretation of films of positive reactors by the routine services, it can be assumed that additional new cases could have been found among these reactors. This aspect will receive attention during the proposed reassessment of films by a specialist radiologist. It was evident in the age group 5 - 10 years—in which positive reactors who showed clinical evidence of tuberculosis, or who gave a history of being a contact of a tuberculosis case, were X-rayed—that, since medical examinations were conducted during the winter months, the prevalence of respiratory infections led to increased occurrence of abnormal sounds on auscultation. Thus a greater number was sent for X-ray examination than would have been the case in the summer months.

An unevaluated opinion arose in the minds of some workers that evanescent hilar lymphatic reaction to BCG inoculation may lead to the radiological diagnosis of a 'hilar flare', when, in fact, no true tubercular infection was present. A controlled study would be valuable if conducted along the lines of selecting persons shown to have normal pulmonary radiograms who had not been previously inoculated with BCG vaccine, and then, after inoculation with BCG, have serial X-ray examinations made to determine the possible occurrence of demonstrable hilar reaction and, if present, the period of persistence.

346 previously known tuberculotics happened to present to immunizing teams and were inoculated with BCG vaccine. We were unable to attribute any adverse effect in these cases to BCG vaccination. In this group of vaccinees 31·1% were found to have negative skin reactions. Possibly, a few might have had anergic skin responses, but it was more likely that a majority were on drug therapy and that negative responses arose from drug sensitivity of the organism of the vaccinee. These findings do not therefore reflect on the value of the hypersensitivity skin reaction, but emphasize the need for drug-resistant percutaneous BCG vaccine for use in persons on prophylactic therapy.

122 negative reactors aged 0 - 20 years were found to have tuberculosis after the inoculation campaign. In 3 of these cases reactions were ascribed to anergic response due to advanced tuberculosis. We could not ascertain the negative reactions which might have arisen from other causes of anergic response, e.g. recent parturition, exposure to roentgen radiation or corticosteroid therapy. Moreover some of these negative reactions might have resulted from errors of inoculation or reading technique under the conditions of pressure of 160,298 vaccinations administered in 18 days. Apart from low protective levels from vaccination in some individuals, inadequate protection levels could be anticipated in instances of exposure to infection about the time of vaccination.

Scarring

Residual scarring at the inoculation site is of value to the clinician as an indication of previous BCG inoculation. A study was completed to determine the extent of residual scarring persisting 9 months after inoculation, and was conducted among 1,027 vaccinees who were school pupils aged 5 - 20 years, all of whom had skin reactions recorded 24 hours after inoculation. No evidence of scarring could be detected in 60·9%, while 36·4% showed some cicatrical signs of inoculation. In 2·7% scarring was considered excessive, and in 2 older subjects keloid formation was present. A greater proportion of scarring occurred in the higher age group 10 - 20 years. Broadly, positive reactors had a greater tendency to scarring than did negative reactors. The absence of scarring was no indication that the person had not been vaccinated with percutaneous BCG vaccine.

Local, regional, and occasionally general complications, were apt to occur with the previous use of intradermal BCG liquid vaccine. Though usually minor, ulceration, lymphadenitis and suppuration were often difficult and protracted. As stated, 2 cases of keloid formation were discovered during the study of residual scarring. Three minor tuberculoid reactions were reported. Apart from these instances, no ulceration, regional adenitis, suppuration, general or any other type of complication has been brought to notice following the immunization campaign with percutaneous freeze-dried vaccine. Further, no observed or reported complications have arisen from percutaneous vaccination of the newborn introduced at the beginning of this follow-up phase.

Parenteral therapy can be maintained and controlled by medical services, but oral therapy is a greater problem. Even in tuberculosis hospitals, some Bantu patients, if opportunity presents, avoid taking pills issued. Default and unsatisfactory maintenance of therapy is virtually

impossible to assess under field conditions of domiciliary treatment, particularly in Bantu areas, and is significant in regard to the development of drug resistance.[1] Though pills may be issued at regular intervals, it is impossible to know with certainty whether they have been taken regularly or at all. In ambulant cases supplementary feeding rations and oral drug issues are often drawn concurrently, and the issue of the latter is accepted by many to obtain the former. Domiciliary injection therapy by nursing services has advantages in these areas, and where persons are on combined drug regimes of oral and parenteral therapy, part of the treatment is assured. We were anxious to have some assessment of the situation in regard to the age group 0 - 4 years 11 months in which the positive reactors were placed on isoniazid therapy, but were unable to obtain valid conclusions. We thought that in all age groups default and unsatisfactory maintenance of therapy was not inconsiderable, but that the greatest number of defaulters was in the youngest age group, especially for one-month periods. Resulting from the follow-up phase, 62 vaccinees were admitted to hospital as tuberculosis cases, 25 of whom were aged 0 - 4 years 11 months, 16 were 5 - 10 years of age, 12 were 11 - 20 years of age and 9 were over 20 years of age.

During the first 5 months (February - June) of maintenance vaccination of the newborn by the health visitor service 6,694 births were notified, of whom 4,520 (67·5%) had been traced and vaccinated. In only 3 instances during this period was parental consent for vaccination refused.

The degree of protection offered by the mass immunization campaign and subsequent introduction of routine maintenance immunization of the newborn cannot be judged at this stage. The efficacy, conversion rate, duration of conversion and similar factors regarding the vaccine have been established by various workers and were surveyed in our previous communication.[1] The final elucidation will be the effect on the incidence of tuberculosis in these areas in the next decade studied after subsidence of the inevitable incidental increase due to notification of cases found during the follow-up phase and of those positive reactors in the age group 0 - 4 years 11 months. Possible effects arising from any parallel improvement in socio-economic circumstances of this community during the decade will require joint consideration in determining whether these methods have raised immunity levels and succeeded in greater prevention of entry into the infector pool.

CONCLUSIONS

Percutaneous freeze-dried BCG vaccine inoculated with Heaf's apparatus, and concurrent reading of 24-hour local hypersensitivity reaction as a preliminary diagnostic procedure, proved eminently suitable to mass, rapid field application.

The absence of local or general complications following 160,298 inoculations in the mass campaign, and 2,100 in the pilot study, represented a significant advantage over previous vaccines and their techniques of administration.

The hypersensitivity skin reaction proved a satisfactory indicator of exposure to infection with the tubercle bacillus.

The loss of the tuberculin test as a result of mass vaccination campaigns, in communities where socio-economic factors and a high incidence of tuberculosis indicate the need for rapid raising of immunity levels, is far outweighed by the advantage of vaccination and skin testing being combined in a single operation, and by the suitability of the hypersensitivity skin reaction to percutaneous BCG vaccination as an indicator of exposure to infection.

Routine percutaneous BCG vaccination of the newborn is essential to maintain and extend epidemiological advantage gained by mass immunization campaigns. Further, recurrent mass campaigns would appear necessary at 7-year intervals.

According to the reasoning and experience of this study, radiological surveys undertaken on a domiciliary basis are unlikely to achieve satisfactory results in the adult population of these Bantu areas. However, better results could be anticipated in schools, creches and compounds.

The need for motivating and including the community in preparing for undertakings of this pattern and magnitude was shown in the planning and application of the field propaganda methods employed. It is inadvisable to press any form of compulsion for BCG vaccination upon Bantu communities of this structure, and the principle of obtaining consent at all levels contributed toward the evolving of considerable trust in the immunization facilities provided.

Epidemiological circumstances in these areas have recently compelled the introduction of extensive mass immunization campaigns against smallpox, diphtheria, whooping cough, tetanus, measles, poliomyelitis and tuberculosis. Since these circumstances are probably common in varying degree to other Bantu urban communities, it would seem that legislation has become necessary specifically permitting local authorities to carry out immunization procedures and campaigns, and to incur expenditure therewith.

SUMMARY

1. The follow-up phase of a tuberculosis control programme in the Bantu areas of Johannesburg is described.
2. The study involved an assignment to trace, investigate and treat 12,759 persons who presented 24-hour positive hypersensitivity skin reactions to percutaneous BCG freeze-dried vaccine inoculated in a mass immunization campaign in which 160,298 persons were vaccinated.
3. The procedure, statistical results, a control of radiological interpretation and the collation and analysis of data are outlined.
4. A review of findings and field experience is submitted.

The views of the authors do not necessarily reflect the opinion of the State Health Department or the Johannesburg City Health Department.

We are indebted to Dr. H. I. Osler for assistance with the radiological control, and to Prof. A. H. Smith, Medical Officer of Health, Johannesburg, for permission to publish this paper.

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