

Lessons from the Field

Enhanced disease surveillance through private health care sector cooperation in Karachi, Pakistan: experience from a vaccine trial

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Introduction In research projects such as vaccine trials, accurate and complete surveillance of all outcomes of interest is critical. In less developed countries where the private sector is the major health-care provider, the private sector must be included in surveillance systems in order to capture all disease of interest. This, however, poses enormous challenges in practice. The process and outcome of recruiting private practice clinics for surveillance in a vaccine trial are described.

Methods The project started in January 2002 in two urban squatter settlements of Karachi, Pakistan. At the suggestion of private practitioners, a phlebotomy team was formed to provide support for disease surveillance. Children who had a reported history of fever for more than three days were enrolled for a diagnosis.

Results Between May 2003 and April 2004, 5540 children younger than 16 years with fever for three days or more were enrolled in the study. Of the children, 1312 (24%) were seen first by private practitioners; the remainder presented directly to study centres. In total, 5329 blood samples were obtained for microbiology. The annual incidence of *Salmonella typhi* diagnosed by blood culture was 407 (95% confidence interval (95% CI), 368–448) per 100 000/year and for *Salmonella paratyphi A* was 198 (95% CI, 171–227) per 100 000/year. Without the contribution of private practitioners, the rates would have been 240 per 100 000/year (95% CI, 211–271) for *S. typhi* and 114 (95% CI, 94–136) per 100 000/year for *S. paratyphi A*.

Conclusion The private sector plays a major health-care role in Pakistan. Our experience from a surveillance and burden estimation study in Pakistan indicates that this objective is possible to achieve but requires considerable effort and confidence building. Nonetheless, it is essential to include private health care providers when attempting to accurately estimate the burden of disease in such settings.

Keywords Epidemiologic surveillance; Vaccination; Clinical trials; Private sector; *Salmonella typhi*; Pakistan (source: MeSH, NLM).

Mots clés Surveillance épidémiologique; Vaccination; Essai clinique; Secteur privé; *Salmonella typhi*; Pakistan (source: MeSH, INSERM).

Palabras clave Vigilancia epidemiológica; Vacunación; Ensayos clínicos; Sector privado; *Salmonella typhi*; Pakistán (fuente: DeCS, BIREME).

Arabic

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Introduction

Information about the burden of many infectious diseases in less-developed countries is sparse or not available. In Pakistan, data gathered by the government underestimate the disease burden

because only patients who use public health facilities are captured. The private health sector is the major provider of first-level health care in most of the Indian subcontinent. A study in India showed that 80% of respondents had visited a

private health care provider in the previous six months for any ailment.¹

In less-developed countries where private health care is predominant,^{2, 3} extension of disease surveillance networks to include private health care providers

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is essential for success and cost effectiveness.^{4,5} The private sector may offer the only functioning public health care system or public clinics may compete with private practitioners for patients.⁶ The inclusion of the private health care sector as a sentinel point for disease surveillance is essential but difficult to achieve, although regular contact with private practitioners and continuous feedback has been effective in some surveillance activities.⁷

In preparation for a large trial on a vaccine for typhoid fever, we conducted fever surveillance in two urban squatter settlements of Karachi, Pakistan, starting in January 2002. The study site was chosen because it had a high reported incidence of typhoid fever and no specific typhoid fever control programme had been initiated. Two study health-care centres were established to take blood samples and treat patients with a reported history of fever.

A modified passive surveillance system called "augmented passive surveillance" was adopted for the trial. Cases of reported fever at the household level were identified through weekly household visits by community health workers. Active surveillance was not possible because of the extensive logistic and resource requirements in such a setting. All cases that fulfilled the case definition were encouraged to visit the study centres or the private practitioners of their choice. The process gave the project an estimate of cases of reported fever in the community that was then compared with the number enrolled in the study to assess the surveillance's sensitivity. Household members with reported episodes of fever were encouraged to attend the study centre for treatment and recruitment into the surveillance study.

During the baseline census of the study setting, information on health-care-seeking behaviour for febrile illnesses was collected. About 60% of households stated that they visit a private health-care provider. The private practitioners in the area come from a range of backgrounds. They include dispensers, nurses, health technicians, traditional healers and people who had worked with a health-care provider in the past. The relatively lower use of study centres by residents who lived far from study centres meant that private practitioners were included systematically in surveillance activities. The participation of private practitioners was useful in establishing sentinel points that were more accessible and did not af-

fect the health-care-seeking behavior of the study population.

We report our experience of engaging private practitioners during the first year of this surveillance, the processes of working with them and their importance in assessing various estimates of disease burden in developing countries.

Methods

Surveillance for infection with *Salmonella typhi* was carried out in two urban squatter settlements (Sultanabad and Hijrat Colony) of Karachi, Pakistan. The study population of 46 273 people lives in about 7000 households and consists mostly of immigrants from elsewhere in Pakistan, especially the north. Domiciliary surveillance was conducted through a team of community health workers. They visited each household weekly and asked whether any child in the household currently suffered from fever or had done so during the past week. A study health-care centre was established in each settlement for disease surveillance activities and provided consultation and free treatment. The working hours of the study centre were 10:00 to 22:30. The target group for the trial was children aged 2–16 years, but consultation and treatment was provided to all children. The population seeks health care for mild illnesses from private health care providers (professionals and non-professionals) in the study area, whereas for more serious illnesses, tertiary hospitals of the city are preferred. Because residents were known to obtain most health care from private health care providers, we decided to integrate private practitioners into the study

as sentinel points for disease surveillance. Regardless of qualification, each health-care provider in this study was considered a private practitioner.

Aga Khan University, Karachi, previously has conducted studies of enteric fever in the study area but had limited success in collaborating with local private practitioners to detect cases of enteric fever. In our study, staff visited health-care providers at regular intervals to discuss strategies to optimize patient referral. Initially, microbiology results were provided to private practitioners free of charge in return for referring patients, but these efforts resulted in few referrals. We therefore explored alternative approaches to increase the referral of children with prolonged episodes of fever. Basic information was collected about all private practitioners in the study area, including staffing and hours of operation. In December 2002, an invitation letter was distributed to all private practitioners to introduce the study's aims, objectives and processes. During meetings with private practitioners in January and February 2003, the private practitioners were given the case definition for the project, and various options for case referral were discussed.

After suggestions from private practitioners for case referrals, a two-person phlebotomy team comprising a research medical officer and a phlebotomist was formed. The team was given a cellular phone for communication. The working hours of the phlebotomy team matched the clinic hours of private practitioners. Private practitioners also received a cash incentive for the cases referred to compensate them for the time they spent

Table 1. Characteristics of population in study settings (Sultanabad and Hijrat Colony, Pakistan) based on project census data from January 2003

Characteristic	Study setting		
	Sultanabad	Hijrat Colony	Total
Total households	3191 (46) ^a	3823 (54)	7014
Total population	21 133 (46)	25 140 (54)	46 273
Sex			
Male	12 005 (46)	14 185 (54)	26 190
Female	9128 (54)	10 955 (46)	20 083
Age (years)			
<2	1251 (05)	1257 (05)	2508
2–16	8693 (41)	10 468 (42)	19 161
>16	11 189 (53)	13 415 (53)	24 604
Average monthly household income (rupees) ^b	5452	5730	5591

^a Numbers in parentheses are percentages.

^b US\$ 1 = 59 Pakistani rupees.

referring cases to the project. The project paid 50 rupees (US\$ 1 = 59 rupees) for each referral, 100 rupees for serology-positive cases and 300 rupees for culture-proved cases. This graded payment system was chosen to limit inappropriate referrals.

Referral process

When private practitioners were visited by a child who had a reported history of fever for three or more days, the phlebotomy team was contacted by the private practitioner. Variations in the clinical expertise and qualification of private practitioners meant that only reported history of fever was set as a criterion for enrolment to reduce subjectivity. Private practitioners, however, were encouraged to refer cases who did not have localizing signs, such as sore throat, otitis media, etc. The other rationale for keeping our case definition simple was to ensure that qualified and unqualified practitioners understood fever in the same way. Informed verbal consent for participation in the study, including consent for blood sampling, was taken from each patient. After consent was given, the phlebotomy team drew blood at the private practitioner's clinic for laboratory investigation. Blood samples then were brought to the microbiology laboratory for serological and microbiological diagnosis of infection with *S. typhi*. The most preferred way for taking blood samples from children was at private practitioners' clinics; however, some of the samples were collected at study centres.

Results of all investigations were distributed to the private practitioner concerned as soon as these were received from Aga Khan University's laboratory. We visited all private practitioners in the study setting weekly to distribute a report on burden of prolonged fever in the community and number of patients who sought health care from the private health care sector and study treatment centre, as well as the patients' serology and microbiology results. Before the study started, a research medical officer visited each practitioner to explain the objectives of the study and how to refer a case. To keep the private practitioners motivated towards the referral process, individual meetings were held with them at regular intervals. We compared our weekly surveillance data with the number of patients referred by private practitioners to assess the completeness of referrals by private practitioners.

Laboratory methods

Blood samples from consenting patients were tested. If 6 ml of venous blood had been obtained, it was inoculated into Bactec bottles (Bactec, Becton Dickinson, Franklin Lakes, NJ, USA). Blood volumes of ≤ 3 ml were inoculated into Bactec Peds Plus blood culture bottles. One ml of blood was put in a plain tube with no anticoagulant for Widal serological diagnostic tests (BioRad, Raymond Poincaré, Marnes-la-Coquette, France). An additional 1 ml was used to assess complete blood counts. Culture identification of *S. typhi* and *S. paratyphi* included biochemical and serological (agglutination) procedures. Results of complete blood counts and typhoid serology were shared with each patient one day after the blood sample was collected. For blood culture and antimicrobial sensitivity, the results were shared on day 2 or 3 if any growth was noticed, and the final report was delivered to the patient on day 7. An episode of fever in which *S. typhi* or *S. paratyphi* was isolated from blood cultures was considered positive for enteric fever.

Data collection and management

Patient information was collected through structured questionnaires by trained research medical officers at the health centres. For private practitioners, a modified shorter version of the case report form was filled in by the referring person or the phlebotomy team. All forms were reviewed by the in-charge research medical officer before they transferred them to the data management unit. Log books were maintained to ensure that no valuable information was lost. The forms were double entered into visual FoxPro 6 (a database management system). The system included data

entry, editing, reporting of errors and data documentation. Means (standard deviation) and proportions were calculated for variables, wherever applicable, with SPSS software.

Ethical considerations

The study was approved by the International Vaccine Institute's institutional review board, the Aga Khan University of Pakistan's ethical review committee and WHO's Secretariat Committee on Research Involving Human Subjects.

Results

The study setting consisted of 46 270 people, of whom 21 669 (47%) were younger than 16 years. The characteristics of the study population are shown in Table 1. About half (25/52) of the private practitioners in the area were licensed physicians; the remaining 27 were trained paramedics who worked in public hospitals, traditional healers or unqualified practitioners (Table 2).

Between May 2003 and April 2004, 5540 children with prolonged fever were enrolled in the disease surveillance study and 5329 blood samples were taken. In all, 211 (4%) children or their parents refused permission for blood sampling. A mean of 461 children were registered monthly (353 per month from study health centres). On average, private practitioners referred 109 cases each month. In total, 56 private practitioners referred cases to the project in one year's surveillance. Fifty-three per cent of referrals were from 5/56 (9%) practitioners, 30% from 13/56 (23%) practitioners and the remaining 17% from 38/56 (67%) practitioners. Five practitioners referred cases every month, six referred 9–11, seven referred 6–8, 18 referred 3–5 and

Table 2. Distribution of health-care facilities and providers in the study setting

Health care providers	Study setting		
	Sultanabad	Hijrat Colony	Total
Total	33	29	62
Public	6	4	10
Government dispensaries	1	1	2
Maternal and child health centres	2	1	3
Expanded programme of immunization centres	3	2	5
Private	27	25	52
Qualified ^a	12	13	25
Not qualified	15	12	27

^a Had formal training from a medical university.

19 referred cases only once or twice during the surveillance period. The median age of study participants was seven years, and the median duration of fever was four days. No statistically significant differences in age or sex were seen between children enrolled at study centres and those referred by private practitioners. Blood cultures identified 116 organisms: 78 *S. typhi*, 36 *S. paratyphi* A and two *S. paratyphi* B. Of these, 32 *S. typhi*, 15 *S. paratyphi* A and 1 *S. paratyphi* B were from blood samples of children referred by private practitioners (Table 3).

On the basis of disease surveillance system findings, the annual incidence in children aged 2–16 years was estimated to be 407 (95% confidence interval (95% CI), 368–488) per 100 000/year for *S. typhi* and 198 (95% CI, 171–227) per 100 000/year for *S. paratyphi* A. Overall, the results of cultures showed an incidence of 605 cases of enteric fever per 100 000/year in Karachi's squatter settlements. Without the patients referred by private practitioners, the rates would have been 240 per 100 000/year for *S. typhi* and 114 per 100 000/year for *S. paratyphi* (Table 4).

Discussion

The results showed an incidence of enteric fever in two Karachi squatter settlements of 605 per 100 000 population. Private practitioners referred 23% of the patients who had fever and 41% of the culture-proved cases of *S. typhi*. Without these referrals, the incidences of culture-proved *S. typhi* and enteric fever would have been 240 per 100 000 and 354 per 100 000, respectively. In this study, therefore, the private health sector played an important role in determining the burden of disease.

Some diagnoses of enteric fever were missed because the patient or guardian

Table 3. Characteristics of children with fever who enrolled in the study in Karachi, Pakistan, May 2003–April 2004

Characteristic	Source of referral		Total
	Study health-care centre	Private practitioner	
Total cases registered	4236 (76) ^a	1312 (24)	5540
Monthly average registration	353	109	461
Total blood samples taken	4027	1303	5329
Age (years)			
<5	1506 (43)	319 (31)	2247 (40)
5–10	1741 (33)	462 (28)	1765 (32)
>10	989 (24)	531 (41)	1528 (28)
Sex			
Male	2075 (49)	818 (63)	2897 (52)
Female	2161 (51)	494 (37)	2643 (48)
Duration of fever (days)			
<4	2643 (62)	857 (65)	3495 (63)
5–7	1161 (27)	310 (24)	1469 (27)
8–14	248 (06)	93 (07)	340 (06)
>14	184 (04)	52 (04)	236 (04)
Total culture-positive cases			
<i>Salmonella typhi</i>	46 (68)	32 (65)	78 (67)
<i>S. paratyphi</i> A	21 (31)	15 (33)	36 (31)
<i>S. paratyphi</i> B	1 (1)	1 (2)	2 (2)

^a Values in parentheses are percentages.

refused to have blood drawn. Patients who visit private practitioners usually look for a quick recovery at a low price and may be reluctant to spend additional time involved in study procedures. All patients referred from private practitioners agreed to phlebotomy, which perhaps indicates that patients who refused or were reluctant to take part in the study were not referred. It also is possible that a proportion of febrile patients visited health-care providers who did not participate in the surveillance and therefore were missed by the disease surveillance system. Furthermore, not all private practitioners referred cases of prolonged fever to the project health centre: some run

busy clinics and have no time for enrolment procedures. As these potential cases of enteric fever could not be evaluated, our estimates of incidences are likely to be underestimates. Some private practitioners may have feared losing patients to the project health facility. Competition with private practitioners for relevant cases is likely to be futile and ultimately not in the interest of the study population. Studies tend to be limited in time, and services provided by the study are not sustainable. If the study replaced private practitioners, the community might be left with an inferior health care system once the study is closed.

Information on cases of fever at the household level and health-care-seeking behaviour for the particular case was collected through the domiciliary surveillance component of the project. This information was compared regularly with the number of cases referred by private practitioners. This gave the project staff an idea of the quality of the referral procedure. As the private practitioners were not bound to refer all patients, referral of children with fever could not be enforced on private practitioners.

The project staff worked hard to integrate private clinics without competing for patients, but in the densely

Table 4. Influence of case referral by private practitioners on the incidence of typhoid fever in the study setting of Karachi, Pakistan, May 2003–April 2004

Culture findings	Total cases		Incidence per 100 000/year	
	Without private practitioners	Total	Without private practitioners	Total
<i>Salmonella typhi</i>	46	78	240 (211–271) ^a	407 (368–448)
<i>S. paratyphi</i>	22	38	114 (94–136)	198 (171–227)
Culture-proved enteric fever	68	116	354 (318–392)	605 (558–654)

^a Values in parentheses are 95% confidence intervals.

populated squatter settlements, news of free treatment for febrile episodes spread quickly. At the start of the study, health-care clinics may have reduced the patient load of individual private practitioners and consequently reduced their income. To create a fair partnership, the project team made every effort to transfer patients back to private practitioners after treatment for the disease episode was complete.

Our results suggest that cooperation of private practitioners is essential for complete detection of cases of typhoid

fever in the study area. The results are encouraging, as elsewhere,⁸ and replication may be possible in other parts of Pakistan and perhaps in other low-income countries. ■

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Résumé

Amélioration de la surveillance des maladies grâce à la collaboration du secteur privé des soins de santé de Karachi, Pakistan : expérience tirée d'un essai vaccinal

Introduction Pour les projets de recherche tels que les essais vaccinaux, une surveillance précise et exhaustive de l'ensemble des résultats intéressants revêt une importance critique. Dans les pays moins développés, où le secteur privé est le principal prestataire de soins de santé, il faut faire collaborer ce secteur à l'activité des systèmes de surveillance afin de bien prendre en compte toutes les maladies à suivre. Dans la pratique cependant, la mise en place de cette collaboration pose d'énormes difficultés. L'article décrit le processus de recrutement des établissements privés en vue de leur participation à la surveillance dans le cadre d'un essai vaccinal et les résultats de ce processus.

Méthodes Le projet a débuté en janvier 2002 dans deux lotissements urbains spontanés de Karachi (Pakistan). À l'initiative de praticiens privés, une équipe spécialisée dans les prélèvements veineux a été constituée pour apporter un appui à la surveillance des maladies. Les enfants ayant des antécédents signalés de fièvre pendant plus de trois jours ont été recrutés dans l'étude pour faire l'objet d'un diagnostic.

Résultats Entre mai 2003 et avril 2004, 5540 enfants de moins de 16 ans ayant présenté de la fièvre pendant trois jours ou plus ont été recrutés dans l'étude. Parmi ces enfants, 1312 (24 %) ont été vus d'abord par des praticiens privés, les autres ayant été présentés

directement aux centres d'étude. Au total, 5329 échantillons de sang ont été prélevés pour examen microbiologique. L'hémoculture a permis d'évaluer l'incidence annuelle de *Salmonella typhi* à 407 cas [intervalle de confiance (IC) à 95 % : 368-448] pour 100 000 enfants appartenant à la tranche d'âges considérée et celle de *Salmonella paratyphi A* à 198 (CI à 95 % : 171-227) pour 100 000 enfants appartenant à la tranche d'âges considérée par an. Sans la contribution des praticiens privés, ces taux auraient été évalués à 240 pour 100 000 enfants de l'âge considéré et par an (CI à 95 % : 211 - 271) pour *S. typhi* et à 114 (CI à 95 % : 94-136) pour 100 000 enfants appartenant à la tranche d'âges considérée et par an pour *S. paratyphi A*.

Conclusion Le secteur privé joue un rôle majeur dans la dispensation de soins de santé au Pakistan. L'expérience tirée de cette étude de surveillance et d'estimation de la charge de morbidité au Pakistan indique qu'il serait possible d'atteindre l'objectif d'amélioration de la surveillance grâce à la collaboration du secteur privé, mais que cela nécessiterait des efforts considérables et un renforcement de la confiance. Quoi qu'il en soit, il est essentiel de prendre en compte les dispensateurs de soins privés lorsqu'on tente d'estimer avec précision la charge de morbidité dans de tels pays.

Resumen

Mejora de la vigilancia de la morbilidad mediante la cooperación con el sector sanitario privado en Karachi, Pakistán: experiencia de ensayo de una vacuna

Introducción En proyectos de investigación como los ensayos de vacunas, es fundamental aplicar una vigilancia exhaustiva de todos los resultados de interés. En los países poco desarrollados donde el sector privado constituye el principal proveedor de atención sanitaria, dicho sector debe formar parte de los sistemas de vigilancia si se desea detectar todas las enfermedades pertinentes. Sin embargo, en la práctica esto plantea grandes retos. Se describen aquí los procedimientos y los resultados de la contratación de consultorios privados con fines de vigilancia en el ensayo de una vacuna.

Métodos El proyecto comenzó en enero de 2002 en dos asentamientos ilegales urbanos de Karachi, Pakistán. Por sugerencia de algunos médicos privados, se formó a un equipo de flebotomía para que apoyara las actividades de vigilancia de la morbilidad. Se reclutó para diagnóstico a los niños que presentaban

una historia de fiebre de más de tres días.

Resultados Entre mayo de 2003 y abril de 2004 se reclutó para el estudio a 5540 niños menores de 16 años con una historia de fiebre de al menos tres días de duración. De ellos, 1312 (24%) fueron examinados por primera vez por médicos privados; los otros acudieron directamente a los centros de estudio. En total se obtuvieron 5329 muestras de sangre para análisis microbiológico. La incidencia anual de *Salmonella typhi* diagnosticada mediante hemocultivo fue de 407 (intervalo de confianza del 95% (IC95%): 368 - 448) por 100 000/año, y la de *Salmonella paratyphi A*, de 198 (IC95%: 171 - 227) por 100 000/año. Sin la ayuda de los médicos privados, las tasas habrían sido de 240 (IC95%: 211 - 271) por 100 000/año para *S. typhi* y de 114 (IC95%: 94 - 136) por 100 000 /año para *S. paratyphi A*.

Conclusión El sector privado cumple una importante función de atención sanitaria en el Pakistán. La experiencia de nuestro estudio de vigilancia y estimación de la morbilidad en el país indica que el objetivo planteado se puede lograr pero requiere un

considerable esfuerzo y medidas que estimulen la confianza. No obstante, si se desea estimar con precisión la carga de morbilidad en esas circunstancias, la participación de proveedores de salud privados es fundamental.

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