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The History, Methodology and Main Findings of the Matlab Project in Bangladesh

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#### The History, Methodology and Main Findings of the Matlab Project in Bangladesh

#### Introduction

The Matlab Population is the largest population under continuous surveillance in the world. It was established in 1963 by the Pakistan-SEATO Cholera Research Laboratory (PSCRL), the predecessor of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) which was chartered in 1978 for the purpose of field testing cholera vaccines. Consequently the organization of the Matlab field operations was driven at the outset by the rigid technical and ethical requirements for the implementation of prospective double-blind controlled vaccine field trials. These high scientific standards have provided the model for field operations in Matlab ever since.

Over three hundred national and international scientists have been involved directly or indirectly in research projects in Matlab over the past three decades. The range, breadth, and depth of the research projects encompassing diarrhoeal diseases, health services, population, nutrition, and maternal and child health cannot even be simply listed in this short paper. Fortunately, in 1990 the International Centre for Diarrhoeal Disease Research produced a well indexed and abstracted "Annotated Bibliography of ICDDR,B Studies in Matlab, Bangladesh" which provides citations of the 567 papers and publications produced to date for scholars needing detailed information about the work there (Habte and Strong, 1990).

This paper will highlight major elements in the design and implementation of Matlab field operations and related data

management issues. These will be discussed in the context of the technical requirements for some of the major research projects that were carried out in the Matlab area. Major attention will be given to the establishment and evolution of the demographic surveillance system (DSS) as this provides the foundation for all other field research projects. In addition, some operational issues related to a number of specialized prospective research projects will be briefly noted, particularly those that involve intensive in-depth study of subpopulations using a variety of measuring instruments from the biomedical and social sciences. This paper will not deal with the technical issues surrounding computer management of large complex data bases being generated by the DSS. Because this is continually evolving, interested parties will need to communicate directly with the ICDDR,B for information in this area.

#### Rationale for the Initial Research Objective

The Pakistan-SEATO Cholera Research Laboratory was established in Dhaka, East Pakistan (now Bangladesh) in 1960 to develop, improve, and demonstrate measures for the prevention and eventual eradication of cholera (Habte and Strong, 1990). An essential component of this programme was the conduct of controlled field trials of cholera vaccines. At the time, it was recognized that field trials of cholera vaccines required certain conditions: cholera had to be endemic; all villages in the area had to be accessible so that long-term, follow-up studies could be undertaken; rapid treatment for cholera had to be readily available at all times; there had to be laboratory facilities for positive identification of cholera in patients with diarrhoea; and the studies had to be scientifically designed, with vaccine recipients

properly randomized. These conditions were essential as only microbiologically proven cholera cases could be considered in the protective efficacy of a vaccine.

#### Site Selection

In 1963, the Director of the CRL, Abram Benenson, together with Robert Oseasohn and M. Fahimuddin, made numerous trips by boat to find a suitable location for the planned and possible future cholera vaccine field trials (Oseasohn, Benenson, Fahimuddin, 1965). Initially some villages of Bhola, then in Barisal District, which were well known for annual cholera incidence, were thought to be a possible site of the study. Matlab got the next consideration since it was known to be the second highest cholera endemic area after Bhola. This was a low-lying area criss-crossed by several rivers and canals, facilitating access, and it was densely populated so field work could be comparatively efficient. Compared to Bhola, this area was located at a distance that would allow investigators from Dhaka to make a round trip within a day (Figure 1). In addition, there had been a census of the villages during the smallpox eradication campaign in 1961 and the household census cards were still available and easily updated.

## Research Design for Vaccine Field Trials

Because the annual incidence of cholera in an endemic population is relatively low (about 3/1000), statistical requirements mandate large populations for vaccine field trials if a protective efficacy greater than 50 per cent is to be established with any degree of confidence. Even larger populations are required if only a subgroup (e.g. children under 15) is included in the trial.

The basic design of a controlled field trial of a cholera vaccine involves taking a complete census in the villages under study and assigning an identifying census number to every individual (Table 1). The vaccine to be tested and a control vaccine (usually a typhoid vaccine or tetanus toxoid) are coded and randomly assigned to individuals in the census books. The vaccines are then administered by vaccine teams going house-to-house, locating each recipient by census number and giving the assigned vaccine. In a "double-blind" study, neither the vaccinator nor the recipient knows which is the cholera or the control vaccine. In order to detect all cholera cases, field workers must visit every household regularly to make inquiries about the occurrence of acute diarrhoeal illnesses and to obtain rectal swab cultures.

Whenever a field trial is initiated in a new population (as was the case for the first four field trials initiated between 1963 and 1968) <u>daily</u> surveillance is critical to the study design for ethical as well as scientific reasons. The acute diarrhoea of cholera can be fatal in a few hours without treatment; since death is an unacceptable outcome in any research, a field hospital in a central location with 24-hour speed boat ambulance service was essential to provide rapid treatment for all severe, acute diarrhoeal cases detected. In the early years, daily home visits were necessary, as people were not accustomed to taking cholera cases to hospitals, since in their experience severe cases were always fatal.

All records from the field, the hospital, and the laboratory are linked by the individual census number of each case. These

linked records are then analyzed to assess the protective efficacy of the vaccine.

The major cholera vaccine trials conducted in Matlab were:

**1963-64:** The first carefully controlled field trial of an injectable cholera vaccine tested a very high potency whole-cell vaccine and found that it gave significant protection for about two years (Oseasohn, Benenson, Fahimuddin, 1965);

**1964-65:** A second trial of the same vaccine showed that it was only effective for about 18 months after vaccination. Concurrently, a test of a vaccine based on the endotoxin of the Ogawa serotype produced some immunity but only for about a year (Benenson, Mosley, Fahimuddin, 1968).

**1966-69:** The effects of one and two doses of a standard cholera vaccine, given to children aged less than 14 years, were tested and showed that children aged from 0 to 4 years benefitted from two doses (Mosley, et al., 1969). Annual booster doses were also beneficial but the effects were short lived (Mosley, et al., 1972).

**1968-69:** Testing monovalent Inaba and Ogawa vaccines seemed to show that immunity depended on the development of serotypespecific immunity, although this was later questioned (Mosley, et al., 1970).

**1974-75:** After several years of vaccine development in the U.S. and the U.K. which resulted in an injectable cholera toxoid vaccine, the largest field trial to date was carried out involving some 93,000 recipients; unfortunately, it only gave 40 per cent protection which lasted about three months (Curlin, et al., 1978).

1985-89: Given the poor success with injectable vaccines, researchers developed an oral vaccine based on a part of the cholera toxin (B-subunit) that produces intestinal immunity but no disease. After ten years of research, two orally-administered vaccines -- one a combination of killed whole cholera cells with the B-subunit of cholera toxin, and the other the killed whole cells alone -- were ready for field testing. Over a 5-month period in 1985, some 63,000 people received three doses of one of the vaccines or a placebo. Both vaccines provided 57 per cent protection after two years; some protection extended to the third year but children aged less than 5 years had a lower rate of protection (Clemens, et al., 1988).

#### The Study Population - Demographic Landmarks

As noted above, the selection of the study area, the determination of the population size, and the structure and organization of field surveillance activities were defined by the requirements of the first four vaccine field trials between 1963 and 1968 which successively expanded the study area (Demographic Surveillance System, 1978). In subsequent years, the surveillance system was modified and the population size adjusted for demographic and other considerations. These developments are described below and summarized in Table 2.

The first of the cholera vaccine field trials of PSCRL was launched in 23 villages with a population of 27,629. In 1964 the field trial area was expanded to include an additional 35 villages with a population of 32,548. The trial area was further expanded in 1966 to cover an additional 74 villages. The total population of 111,748 in 132 villages was later referred to as the old trial

area (OTA). Beginning in May 1966 following the census, a regular registration of births, deaths, and migrations was initiated in the 132 villages (Aziz, et al., 1967) (Mosley, et al., 1967) (Demographic Surveillance System, 1978). This continuous (daily) monitoring of vital events generated data of a very high standard, as these demographic events could be independently verified by supervisory staff and thus served as a means of checking on the quality of the daily diarrhoea surveillance activities.

To have another population for a new vaccine trial, the area was further expanded in 1968 by the addition of 101 villages covering a population of over 109,402. This population was referred to as the new trial area (NTA). Daily demographic surveillance now covered 226,000 in 233 villages. In 1974, in preparation for the toxoid vaccine field trial, the entire population of the surveillance area was re-enumerated, showing 276,984 in the 233 villages (Ruzicka and Chowdhury, 1978). In October 1975, a household Contraceptive Distribution Project (CDP) was initiated in one-half of the population in 150 villages while the remaining half in 83 villages was considered as the control population (Huber and Khan, 1979) (Rahman, et al., 1980).

Economic constraints at the ICDDR,B led to a major modification in the field structure and programme activities in October 1977 with the reduction in the surveillance area. Eightyfour villages with about 105,000 population were excluded while 149 villages with 173,443 population were retained (Becker, Razzaque, Sarder, 1982). The Maternal and Child Health - Family Planning and

Health Services Project (MCH-FP)<sup>1</sup> was then launched in 70 villages with a population of 89,000, and the remaining 79 villages with 85,000 persons were considered as a comparison area (Bhatia, et al., 1980). Figure 2 shows the 233 villages covered from 1968-77, while Figure 3 shows the 149 villages divided into MCH-FP and comparison areas.

## The Demographic Surveillance System<sup>2</sup>

The demographic surveillance system (DSS) consists of registration of births, deaths, marriages, divorces in- and outmigrations and internal movements (Demographic Surveillance System, There are also periodic censuses along with socioeconomic 1978). information of the study population. The censuses were done on the basis of de jure count. The following sections describe the censuses and surveillance with reference to its changes over time. Special note is made of the numbering system since this relates to the many cohort (record linkage) studies that have been done with the Matlab data over the years. Over the years these data have been managed with increasing sophistication with frequent updating of the ICDDR, B computer facilities. In 1986 an IBM mainframe System 4361 was installed and new software is being developed to establish a relational dynamic data base.

**Census of the Old Trial Area, 1966:** Residents of each household were listed by assigning an 8-digit identification

<sup>&</sup>lt;sup>1</sup> The Maternal and Child Health - Family Planning Health Services project (MCH-FP) is referred to in some publications as the Family Planning Health Services project (FPHS). In this paper both names will be used interchangeably.

<sup>&</sup>lt;sup>2</sup> This section is taken from an unpublished paper being prepared by Abdur Razzaque (personal communication, 1991).

number. The identification number consisted of two parts: the first 3 digits identified the village and the last 5 digits identified an individual within a village, e.g. the first individual in village V12 would be V12-00001. In each village, the individual numbers started from unity and were continuous household by household until the village was covered.

At the completion of the census, three copies of typed census volumes were prepared: one for field workers, one for the Matlab office and one for the Dhaka office. After receiving the volume, field workers issued a family register for every household. Family registers of a Bari (mostly contiguously located patrilineal households around a common courtyard) were placed together in one household to use during surveillance.

## Demographic Surveillance of the Old Trial Area, 1966-70:

The demographic surveillance in this period was limited to registration of births, deaths, and migration into or out of the study area. The cause of death is based on verbal reports by relatives of the decedent which have been classified into from 9 to 27 categories at different times over the ensuing years. The cause of death reporting in Matlab is extensively reviewed by Zimicki et al., (1985).

The numbering system in the 1966 census, while satisfactory for the vaccine trial, proved deficient for demographic studies. For example, a live birth occurring after the census was given the mother's identification number followed by a letter, e.g. if the mother's number was V01-00100, the baby was assigned V01-00100/A. An identification number assigned to an in-migrant joining an existing household required adding a letter to the number of the

last member in the household. In-migrants creating new households were assigned numbers following the last identification number in the village, e.g. if the last number in the village was V01-00200, the in-migrants were assigned numbers V01-00201, V01-00202, and so on. Change of place of residence within the DSS area was not recorded as an event until 1982 but remarks were noted in the census volumes of new and old residence. A registered person changing residence always retained his/her original identification number.

Census of New Trial Area, 1968: Because the identification numbers introduced in the 1966 census were difficult to handle during surveillance, a modified number consisting of three parts was introduced: the first 3 digits identified the village, the next 4 digits identified the household and the last 2 digits identified the individuals within a household beginning with the head. This census included relationship to household head, occupation, total times married, and the current marital status.

**Recensus of the Old Trial Area, 1970:** The census procedures and the numbering system were the same as those that followed in the NTA census in 1968. Additional socioeconomic information such as education was collected in this census.

Census of the Entire DSS Area (OTA and NTA), 1974: The census procedures and assigning identification numbers were the same as in the NTA census of 1968 and the OTA census of 1970. After the census of 1974, minor modifications were made in assigning identification numbers to newborns and in-migrants in an existing household. Registration of marriages and divorces was introduced for the first time in January, 1975. By this time the demographic

surveillance system (DSS) was put on a more systematic foundation and the first of a regular series of annual DSS Reports began to be produced.

Contraction of DSS Area and Census Update, 1978: In August 1977 the DSS area was reduced to 149 villages. At this time the population data base was again updated by verifying computer printouts of the 1974 census adjusted for births and deaths with the actual situation in the field.

Census of DSS Area, 1982: During this census dual numbering introduced for the first time. This was particularly was advantageous for tracking persons who changed residences. As noted above, the DSS census number identified the location at the time of enumeration and was nine digits: the first 3 digits for village, the middle 4 digits for household, and the last two digits for the individual in a household. The new 'registration number' was 10 digits and would be permanent for an individual. The first digit showed in what period the individual was included in the DSS. Anyone who was enumerated on or before 31 June 1982 had "1" in the first column and the remaining nine digits were the 1974 census number. Provision was made for recording both a current location and the permanent registration numbers on forms. If there was a birth or an in-migrant (new) in an existing household, he/she was assigned a current location number (village and household were identical with the other members but individual number followed the last member in the household) and his/her current number was converted to the permanent registration number by adding 2 at the beginning. If a registered individual moved from one village to another within the surveillance area, he/she would be assigned a

new current location identification number but his/her permanent registration number would be retained.

#### Field Staff Selection and Management

The administrative structure for management of the field staff was hierarchical. This structure was developed taking into account the social, cultural, and logistic conditions and constraints existing in the Matlab area. Over the 18 years that the field surveillance activities have been in existence, only one fundamental reorganization in the field activities was introduced. This occurred in 1977-78 when the Maternal and Child Health -Family Planning Operations Research project was initiated (Bhatia, et al., 1980).

Table 3 shows the staffing and organization of the field surveillance activities from the year 1968 when the population laboratory had reached 240,000. In fact, essentially this same structure existed from the inception of the project in 23 villages in 1963. As a rule, the senior supervisor has been a university graduate with a social science major, while the next level of supervision was managed by individuals with at least two years of post high school training in sanitary inspection or the equivalent. Generally these persons were experienced professionals from the Ministry of Health or the military. These senior-level staff were recruited nationally and generally did not come from the Matlab area.

The field assistants (later health assistants) were all recruited locally from the Matlab area. Persons at this level require a minimum high school graduation or equivalent and are responsible for recording all vital events and other activities in

the field area. Cultural constraints required that all of these workers be male so that they had the personal mobility required by the project. These men, however, could not go freely into any village if the women's husbands were not present because of the conservative customs of this Islamic society. Consequently, in every village at least one mature women (locally called a dai) was recruited to escort the field assistant or other field staff through her village. Typically this was a poor illiterate widow past childbearing age who had the freedom of mobility required for the work.

As noted on Table 3, up until 1977 the daily or every two-orthree-day household surveillance checking for births, deaths, and episodes of diarrhoea was carried out by the dai. Typically her work area was assigned so that she could make an inquiry in every household in about two or three hours. Acute diarrhoeal episodes were reported to the field assistant daily for examination and rectal swab culture. Up until 1974 the field assistant visited each house weekly, and from 1974-77 monthly, and registered vital events, and updated and signed the household census card. The sanitary inspector (later designated senior field assistant) had a systematic schedule to visit every household monthly (later at 4month intervals) and confirm vital events and check the visitation schedule on the household census card.

The fundamental organizational change initiated in 1977 was the replacement of the large number of illiterate dais with a smaller number of younger married women with high school education designated community health workers. This was done for three reasons: first, the design of the MCH-FP project required that

household visits to motivate mothers to practice contraception and to teach them about maternal and child care be done by young married women who themselves were practicing contraception (Simmons, et al., 1988); second, by 1977 there was a sufficient pool of educated young married women in the Matlab area available for this work to make recruitment feasible; third, over the preceding decade, the tumultuous political and economic changes, including liberation war and famine, had initiated a social transformation such that it was becoming more acceptable for young married women to take up this kind of work.

As noted on Table 3, there were 110 of these community health workers unequally divided between the two halves of the surveillance area as required by the MCH-FP project design. The 80 field workers in the MCH-FP project area carried with them a record book which had a detailed record-keeping system (RKS) for routinely monitoring the contraceptive use and reproductive status (pregnancy, breastfeeding, lactational amenorrhea, etc.) of each woman in her area (Bhatia, 1982). This specialized record-keeping system was maintained independently of the data collection by the demographic surveillance system. Noteworthy, these 80 community health workers in the MCH-FP area additionally received technical supervision from four female welfare visitors who had received two years of paramedical training following their secondary school education (Bhatia, 1981).

## Changes in the Study Objectives Over Time

Up until the mid-1970s, the research agenda in the Matlab area was limited to the field testing of new technologies (e.g. vaccines) or carrying out basic research on diarrhoeal diseases,

nutrition, and the dynamics of population change. In 1975 there was a major shift in research strategy with the initiation of the Contraceptive Distribution Project (CDP) (Huber, et al., 1979). The CDP and its successor, the Family Planning Health Services project (FPHS), in 1977 moved the ICDDR, B for the first time into population-based intervention studies which required behavioral changes in the village women to produce a sustained demographic impact (Rahman, et al., 1979). At the outset the strategy with the CDP project was strictly top-down using existing field staff to make contraceptive commodities (initially pills and condoms, later, injections) available house-to-house. Subsequently the FPHS project, which took a more client-oriented approach, began offering a wider range of contraceptives (IUDs and sterilization were added) with medical backup and, over the years, additional MCH services (Phillips, et al., 1984) (DeGraff, et al., 1986). Still, as will be noted below, up to the present the programme strategy has been essentially top-down with little effort to institutionalize these programmes in the communities (Phillips, et al., 1988).

## Organization and Operation of the Contraceptive Distribution Project and the Family Planning Health Services Project

At the beginning of the Contraceptive Distribution Project (or CDP as it was called initially) there were 233 villages with an estimated population of 260,000 as of 1975 in the Matlab DSS area. The CDP involved free distribution of oral pills and condoms on a house-to-house basis to half the population of the DSS area; the other half of the DSS area served as a comparison group. One hundred fifty-four of the existing female village workers (<u>dais</u>), were briefly trained to work as distributors and depot-holders of

the two contraceptives (Rahman, et al., 1979). The initial results of the CDP were encouraging. Within three months following the initial mass distribution, the percentage of married women of reproductive age currently using contraceptives, mainly oral pills, rose from a base-line level of 1 per cent to about 18 per cent at three months; however, only about one-third of the acceptors sustained use for even one year (Rahman et al., 1980). The resulting demographic impact of the programme was only temporary and largely limited to older women (Stinson et al., 1980).

In late 1977 the modified programme, known as the FPHS project, replaced the <u>dias</u> with a cadre of 80 female village workers (FVW) who were backed up by strong supportive supervision and technical staff to provide a full range of contraceptives and selected MCH services in 70 villages (Bhatia, et al., 1980). The FVWs were locally recruited, all of them literate, young married women. They initially received two weeks' training in human reproduction and fertility control technology, followed by two weeks of closely supervised field training (Bhatia, 1981). Subsequently, in weekly sessions they were gradually given additional training in maternal and child nutrition, tetanus toxoid immunization and oral rehydration for diarrhoea.

Each FVW serves a population of about 1000 (or about 200 families) and almost all of them reside in the village or area where they work. A group of 20 FVWs is assigned to a subcentre staffed by a full-time paramedic, which provides routine maternal and child health services, IUD services, menstrual regulation services and referral support. Work routines require each FVW to visit all currently married women of reproductive age in her area

fortnightly and provide conventional contraceptives (condom and oral pill) and DMPA injections at the house of the client. The project has one lady physician who does regular rounds in the field and provides professional support to a central sterilization clinic in the Matlab headquarters. Figure 4 illustrates the staffing and pattern of supervision for the FPHS project (Phillips, et al., 1984).

The plan of the FPHS project was to incrementally assign comprehensive Maternal and Child Health-Family Planning (MCH-FP) duties to the FVW: general family planning services, comprehensive immunization services, antenatal and postnatal care, nutritional education and treatment of diarrhoeal diseases. The development of the project proceeded from general training of FVWs to a gradual introduction of all these duties.

The effect of the MCH-FP project was a prompt rise in contraceptive use-prevalence rates reaching 32 per cent in the first year. The project maintained this use-prevalence rate for five years; since 1983 the prevalence has again risen reaching almost 50 per cent in recent years. Figure 5 shows the time trend in contraceptive acceptance and the timing of introduction of other interventions from 1977-84 (DeGraff, et al., 1986).

An analysis of the demographic impact of the project showed that by 1979 fertility in the MCH-FP area was 25 per cent lower than in the comparison area (Phillips et al., 1982). Recent analysis of the DSS data suggests that the MCH-FP project is having significant impact on infant and child mortality (D'Souza, 1986) and on maternal mortality (Fauveau, et al., 1988). The demographic trends in the Matlab project from 1967-87 are illustrated in

Figure 6 which shows the impact of FPHS project since 1978 on fertility and mortality (Menken and Phillips, 1990).

#### Human Relations

The Matlab project from the outset had an unwritten understanding with the community members according to which it was ready to treat cholera patients promptly once the patients from the community were brought to the field hospital. Until the early 1970s, all diarrhoea patients were carried by project ambulance boats to the field hospital at Matlab for prompt attention by the physician. The dramatic lifesaving treatment of cholera, which is evident to everyone, has been a key factor in building and maintaining an excellent rapport between the project and the community. The Matlab Field Hospital provides free treatment to all members of the community suffering from diarrhoeal diseases, whether they occur within or outside the surveillance area. The number of in-patients served from 1963 to 1988 was 204,388 (Habte and Strong, 1990). Since entirely free service in treating a deadly disease like cholera was an unknown concept to the people of Matlab, this service amply proved the sincerity and dedication that the staff members of the project invested in saving the lives of the people.

The Matlab project has produced a change in the belief system of the people. The strikingly positive outcome of cholera treatment experienced by thousands of cholera patients over the years has effectively jolted their beliefs in the roles of the goddess <u>Ola</u> as well as <u>Kali</u> among Hindus and the role of the spirit <u>Oba</u> among Muslims, in triggering the onset of cholera leading to death. The Hindus of Matlab no longer specifically worship the

goddess Ola and give offerings (bhog) to the goddess <u>Kali</u> to spare them from attacks of cholera. Muslims also do not commission the services of the <u>Phakir</u> (religious healer) to drive away the spirit of <u>Ola</u> that brings cholera to the community. A change in deeprooted beliefs usually takes a long time with evidence demonstrating miraculous results repeated in numerous cases. Since the long-term intensive biomedical efforts were concentrated in Matlab Upazila and its neighborhood only, the changes in beliefs indicated above have remained confined to this area.

The support of the field hospital to the diarrhoea-stricken community members led to a lasting bond of friendship between the project and the people which over the years enabled researchers to successfully undertake many investigations. These include cholera vaccine trials, research on oral rehydration therapy (ORT), clinical research which included studies on drug trials, search for pathogens, and bringing diagnostic tools closer to the field, and in-depth epidemiological and population studies. This is not to say that difficulties were not encountered from time to time. Some of these will be highlighted below.

Management Problems Encountered: A major source of low morale among the field staff is insecurity about their jobs because they are always working on time-limited projects and lack of information on future activities. In general, field staff are not aware of projects under development where they have an opportunity for involvement. Coupled with this, lack of communication between different levels of workers and worry of the continuation of the Matlab project can lead to breakdown of morale. Staff awaiting with uncertainty for project assignments may express jealousy

toward staff members who are assigned in well-funded projects. And then selection for long-term versus short-term assignments can create tensions among staff. Finally, as with any organization offering opportunities for employment, relatives and others can create pressure on the project administration for positions.

Public Relations Problems: Popular magazines and newspapers often published stories about the Matlab project. This provided information throughout Bangladesh to medical professionals, teachers, students, and other elites. Unfortunately, at times these reports criticized or misrepresented the activities of the ICDDR,B based on local sources of information about what was happening in the various field programmes. Frequently this involved misinterpretation of what was actually going on in the field research projects where the activities impacted on large numbers of people. This included such activities as administering injectable and oral vaccines; mass (finger stick) blood collections; sample surveys collecting such specimens as rectal swab cultures, urines, or breastmilk; and contraceptive field studies involving injectables, IUDs, different oral contraceptives or surgical sterilization. In the early years of the project, too often insufficient attention was given to the press until some misleading story had already been published. Presently, far more attention is given to effective public relations to communicate the programs and activities of the ICDDR, B.

**Community Relations:** Many project activities created misunderstandings among the villagers in the Matlab area that considerably hampered the field work and often required extensive effort to rectify the situation. The implementation of the vaccine

trials, because they involved such a massive direct intervention into these conservative communities, typically generated many rumors that had to be countered. The adverse reactions in the village were undoubtedly compounded by the fact that the vaccine teams used sophisticated jet injectors rather than more familiar syringes and needles to administer vaccines. Furthermore, the minor side effects related to the immunization procedure (fainting, local pain, low-grade fever) at times created a sense of panic in the communities. Examples of rumors were that the vaccine was actually a family planning injection or that the population was being used as guinea pigs for experimentation with a completely new drug only to be tried on animals.

Many studies involved the collection of blood specimens, typically a single drop by finger prick but in some studies intravenous blood collection. (For example, see McCormack, et al., 1969.) Because blood is considered a highly valuable item, when IV blood collections were done many people believed that the project was selling their blood in Dhaka. Even finger prick blood collections would create concern among many individuals as the prevailing belief was that the amount of blood in the body was fixed and even the loss of one drop could result in a permanent loss of strength. Because there was insufficient feedback to the community about the reasons for taking blood samples repeatedly, there was tension on a continuing basis.

Over the years there were multiple in-depth longitudinal studies of communities involving repeated questioning and specimen collection to study the epidemiology of diarrhoeal diseases or the dynamics of birth intervals. Not surprisingly, many of the

questions were considered sensitive by the community which led to embarrassment and reluctance to respond. For example, the epidemiological studies pursued questions on personal habits including defecation practices, personal hygiene, and food preparation which were considered private (Spira, et al., 1980) The intensive routine demographic data (Black, et al, 1982). collection often created suspicions when questions were asked about fetal wastage, stillbirths, conceptions among unmarried women, induced abortion, self-arranged marriages, and divorce (Demographic Surveillance System, 1978) (Aziz, 1978). Studies of the dynamics of fertility required monthly urine collection which would detect extramarital pregnancy and induced abortion which were socially 1983) sensitive (Becker and Chowdhury, (Fauveau, 1989). Furthermore, there was reluctance in providing information on matters considered very private like menstrual cycles and sexual behavior (Huffman, et al., 1987) (Ruzicka and Bhatia, 1982).

The in-depth investigations referred to above were only undertaken after the project had been in operation for five or ten years or more. By that time the field staff had gained a great deal of rapport and credibility with the people. This was facilitated by the interpersonal skills that the project staff gained over the years in interpersonal communication, typically building up a 'fictive' kinship relationship with individuals so that it would be appropriate to engage in personal discussions about sensitive issues (Aziz, 1979).

Noteworthy, it was not until the development of the MCH-FP project in 1977, which employed young married contracepting women from the community to counsel women about family planning and child

care, that the project actually selected and developed a cadre of field staff for the explicit purpose of effective communication with the community in order to implement a social intervention (Bhatia, et al., 1980) (Phillips, et al., 1988) (Simmons, et al., 1988). The design of this project followed an in-depth analysis of the preceding CDP project which had been implemented in 1975 by the pre-existing field staff. That analysis revealed, in particular, that the dais who were asked to distribute oral contraceptives house-to-house had no credibility in the community for this purpose both because they lacked any personal experience with contraception and because they were typically poor and from the low social classes (Rahman, et al., 1978) (Rahman, et al., 1980).

Government Relationships: From 1966 to 1989, the headquarters of the Matlab project was located on the premises of the Matlab Government Rural Health Centre. Occasionally, the sharing of space within the same building created some tension between the project and Government staff members because of lack of sufficient space in the buildings for both parties. To minimize this problem, special administrative contacts were sometimes required between the Matlab project and the Health Ministry officials of the Government of Bangladesh. In February 1990, the Matlab project, now named the Matlab Health and Research Centre, was moved from the Government Upazila Health Complex to a newly constructed two-story Health Complex building of its own located only several hundred yards away from the existing building.

In 1982 the MCH-FP Extension Project was established to test the ways in which the successful components of Matlab could be transferred to the government services programme (Phillips, et al.,

1984). In addition to working in Matlab, the Extension Project has field sites in two other upazilas in rural Bangladesh; Sirajgonj in Sirajgonj District and Abhoynagar in Jessore District. Service delivery in these areas remains the responsibility of the government, with the role of Matlab project staff limited to research and counterpart support.

#### Legacy

Population surveillance is continuing in Matlab; the last chapter is not yet written, thus the impact of Matlab is continuing to be made. Any attempt to capture the past contributions of Matlab to advancements in science, policy, and programmes in health and population in a brief summary will surely neglect important areas, but a few broad generalizations with selected studies noted for illustration are appropriate.

Work in Matlab has had a profound impact on health and population policy worldwide. While the results of the cholera vaccine trials in the 1960s and 1970s failed to produce an effective vaccine, they did lead to a recognition that the international quarantine requirements of the WHO for cholera vaccine were ineffective (Mosley, et al., 1973). Consequently these requirements were eliminated, saving millions of people around the world the inconvenience, pain and cost of a useless procedure. In terms of demonstrating the practical utility of oral rehydration therapy, the first large-scale hospital-based study was carried out in the Matlab treatment centre in 1968 while the first major investigation of alternative approaches to home-based therapy was tested in the field in the mid-1970s (Cash, et al., 1970) (Chen, et al., 1980). In the area of family planning, the

Contraceptive Distribution Project and its successor, the Family Planning - Health Services project initiated in 1977, provided conclusive documentation of the effectiveness of household distribution of contraceptives in impoverished populations (Phillips, et al., 1982). At the same time, it demonstrated the standards of service delivery required to sustain a demographic impact (Simmons, Phillips, Rahman, 1984) (Phillips, et al., 1988).

The scientific contributions of the Matlab project to our basic understanding of the complex interrelationships between biological and social factors in determining the levels of health fertility in poor developing country populations and are incalculable. In the area of diarrhoeal diseases, field work in Matlab has tremendously expanded our knowledge of the multiple etiologic agents of these diseases, the spectrum of illness they produce, the biological and social factors underpinning their transmission in households and communities, their consequences for survival, growth and development, and the relative effectiveness of alternative intervention strategies (Black, et al., 1982a) (Black, et al., 1982b) (Black, et al., 1982c) (Black, et al., 1984). In the case of fertility, longitudinal studies in Matlab have provided detailed knowledge on the determinants of natural fertility and birth intervals including the biological and social factors related to breastfeeding, lactational amenorrhoea, coital frequency, fecundity, and fetal wastage (Chowdhury and Becker, 1981) (Huffman, et al., 1987) (Ford, et al., 1989) (John, et al., 1987).

The maintenance of a demographic surveillance system for almost three decades has permitted an extraordinary range of studies that would otherwise have been practically impossible

through any other approach. For example, studies in Matlab have documented the demographic impact of natural and man-made disasters including famine and war (Chen and Chowdhury, 1987) (Razzaque, 1989) (Bairagi, 1986). High quality nutrition studies require knowledge of the exact chronological age of the study subjects which can only reliably be obtained through an on-going registration system. The work in Matlab has not only contributed fundamentally to our knowledge of the determinants of growth of infants and children but more recently researchers have begun to look at the interrelationships between adolescent growth, nutrition, menarche, and child bearing (Bairagi, 1986) (Riley, Huffman, Chowdhury, 1989).

The design of the demographic surveillance system permitting record linkage of vital events provides multiple opportunities for long-term cohort studies. This system has been exploited to answer many questions including the interrelationships between infant mortality and fertility, the social and economic determinants of child survival, the levels and determinants of maternal mortality, and the demographic impact of immunization programmes (Swenson, 1978) (D'Souza, Bhuiya, 1982) (Koenig, et al., 1988) (Koenig, Fauveau, Wojtyniak, 1989). The Matlab Demographic Surveillance System, with its data base, has also provided the opportunity for the development and validation of methodologies for demographic data collection (Chowdhury, 1977) (Becker, Mahmud, 1984).

There is another important contribution of the Matlab project that should not be overlooked. This is its role in training scores of scientists in Bangladesh and around the world. This training has not only been in the field in Matlab but also through the

availability of data from the DSS to many leading universities around the world. This contribution to the development of a pool of scientists with critical skills in studying developing country health and population problems is perhaps one of the most important contributions of the ICDDR,B in general and the Matlab project in particular.

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## TABLE 1

## Elements in the Design and Implementation of a Cholera Vaccine Field Trial

## A. Preconditions

Endemic cholera must be present.

Study population size must be large enough to detect a significant effect of a cholera vaccine in reducing the incidence of cholera associated diarrhoea episodes.

## B. Elements in the Design and Implementation

Baseline census - to assign individual identifying numbers.

Provision of each individual and household with census record card.

Random allocation of cholera vaccine(s) and control vaccine (by code letter) to individuals listed in census books.

"Double-blind" administration of assigned vaccines and recording in census book.

<u>Daily</u> house-to-house surveillance for all severe diarrhoeal episodes. (Home visits recorded daily on household census card.)

Rectal swab culture of all moderate diarrhoea at home with daily shipment to laboratory.

Immediate rapid transport (speed boats) of severe diarrhoea cases to research treatment center.

All field surveillance, clinical and laboratory records identified by individual census number to link records for data analysis.

Vaccine code broken at end of study to analyze per cent reduction in cholera case rate among cholera vaccine recipients as compared to control group.

#### TABLE 2

Year	Event	No. of Villages	Population		overed by old Surveillance <sup>b</sup> Populations	
1963ª	New Census	23	27,629	( 23	28,000)°	
1964ª	New Census	+ 35	32,548	( 58	62,000) <sup>c</sup>	
1966ª	Recensus 1963/64 pop New Census	58) +74}	111,748	132	112,000	
1968ª	New Census	+101	109,402	233	226,000	
1970	Update 1966 Census	132	<b>~124,642</b>	233	245,000	
1974ª	Recensus All	233	274,979	233	277,000	
1975	Contraceptive Distribution I Treatment Villages	150	140,000			
1977	Control Villages Reduce study area	83 (-84	<i>136,000</i> -105,000)	149	174,000	
1977	Family Planning - Health Service Project <sup>d</sup>					
	Treatment Villages Control Villages	70 79	89,000 85,000			
1978	Update 1974 Census	149	174,443	149	174,500	
1982	Update 1978 Census	149	~187,574	149	188,000	
1984ª	Population Estimate			149	193,000	
1988	Population Estimate			149	200,000	

#### Demographic Landmarks in Matlab, Bangladesh 1963 - 1988

<sup>a</sup> Years Cholera Vaccine Trials were initiated.

 <sup>b</sup> Frequency of household surveillance: 1963-70 Daily 1970-71 Irregular (war) 1972-74 Every 1-2 days (?) 1974-78 Every 2-3 days 1978- Fortnightly

<sup>c</sup> From 1963-65, only diarrhoea/cholera surveillance was carried out. Demographic surveillance began in 1966.

<sup>d</sup> In some publications this project is referred to as the Maternal and Child Health - Family Planning project (MCH-FP).

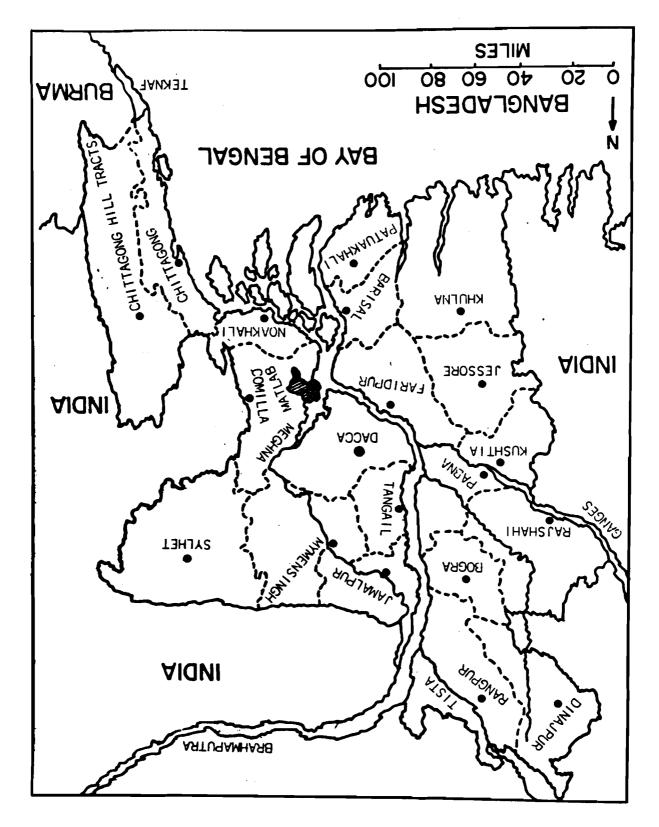
## TABLE 3

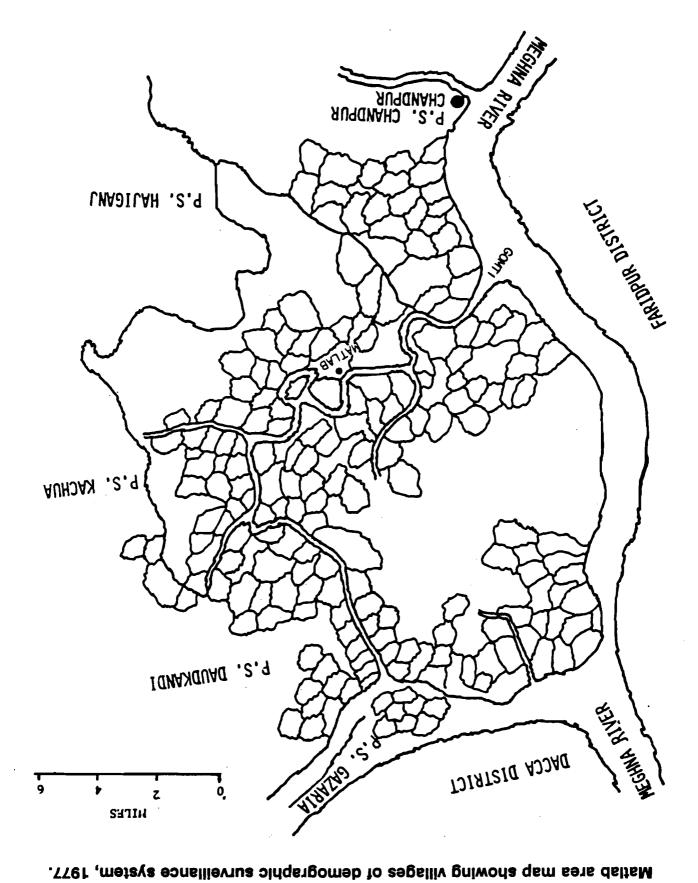
Surveillance Worker	Number	Average Population Per Worker	Visitation Cycle
	a. 1968-74		
Field Surveillance Supervisor	2	120,000	random
Sanitary Inspector	14	17,000	monthly
Field Assistant	50	4,800	weekly
Dai (female worker)	300	800	daily
	b. 1974- 77		
Supervisor	1	280,000	random
Field Surveillance Assistant	3	93,000	random
Senior Field Assistant	4	70,000	4 months
Field Assistant	16	17,500	1 month
Dai	290	900	2-3 days
	c. 1978-		
Senior Field Research Officer	1	159,000	random
Field Research Officer	3	53,200	random
Senior Health Assistant	6	26,600	2-3 months
Health Assistant	12	13,300	monthly
Community Health Worker	80/30 <sup>ª</sup>	1000/2700 <sup>a</sup>	weekly

## Staffing and Administrative Organization of Field Surveillance Activities Matlab 1968 to Present

<sup>a</sup> From 1978 the area was divided into the Family Planning - Health Service Area with 80 Community Health Workers (CHWs) and the control area with 30 CHWs. The populations were similar, but intensity of coverage was very different. (See text).

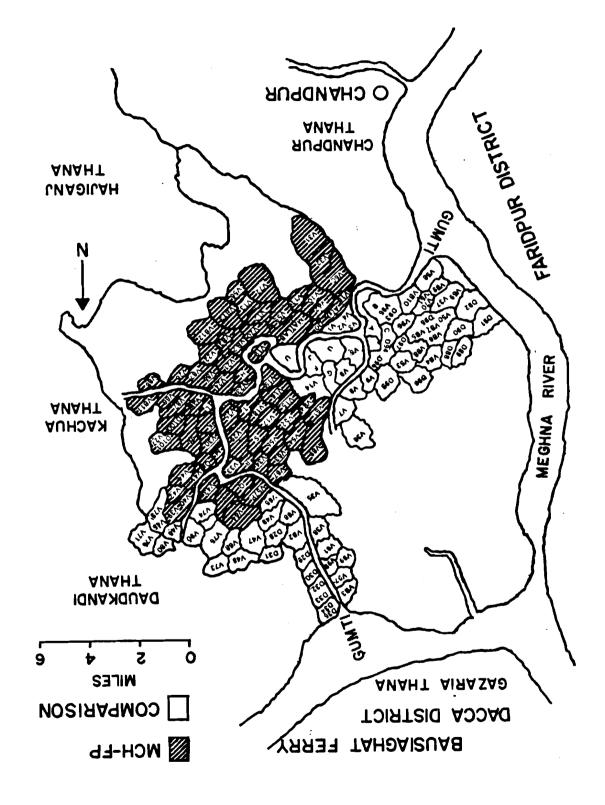
# Map of Bangladesh showing the study area





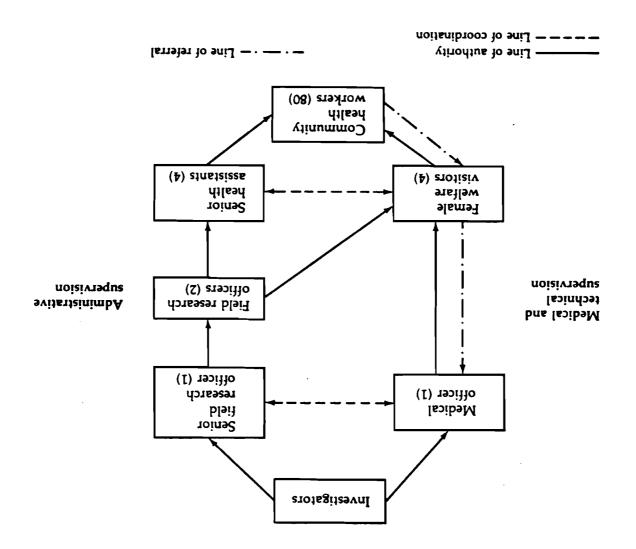




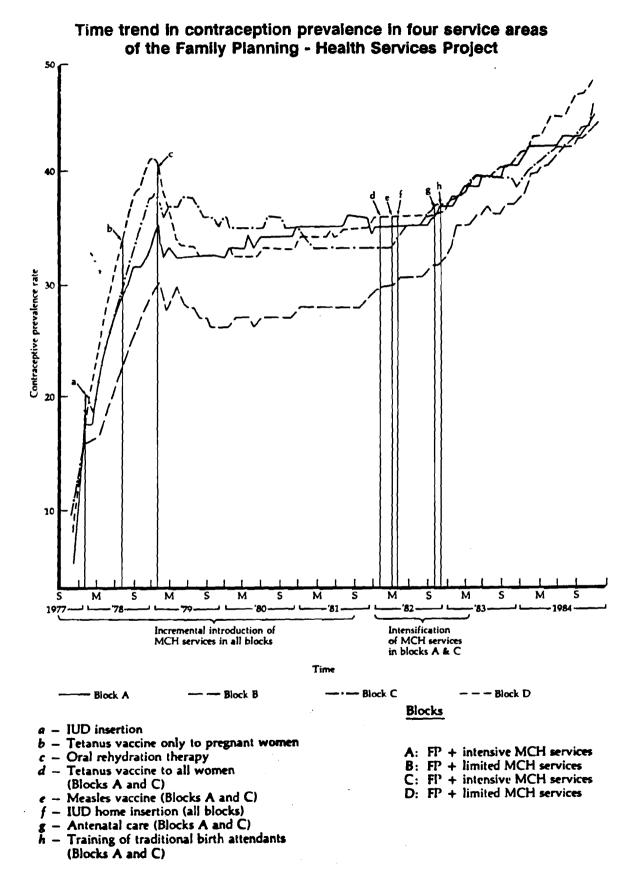


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## Organization of the Matlab Family Planning - Health Services Project

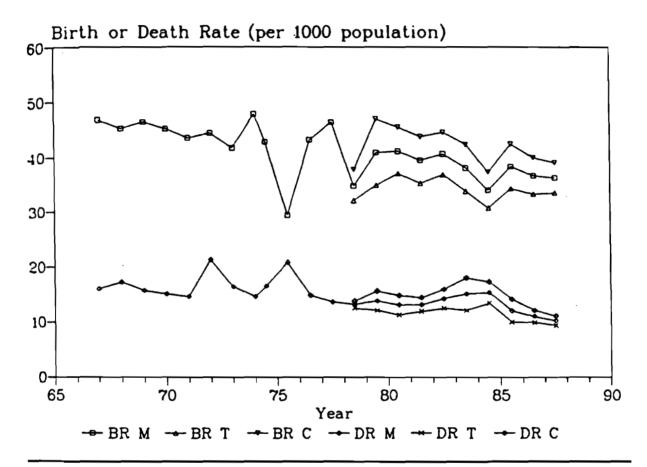


Source: Phillips, et al., 1984.



Source: DeGraff et al., 1986.

Birth (BR) and death (DR) rates: Matlab (M) 1967-87; Treatment (T) and comparison (C) areas, 1978-87



SOURCES: Publications of the Demographic Surveillance System for the various years; annual reports of the International Centre for Diarrhoeal Disease Research, Bangladesh.

Source: Menken and Phillips, 1990.

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