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DIARRHEAL DISEASE CONTROL STUDY

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SUMMARY

From May through October 1980, the "Strengthening Rural Health Services" Project under the Rural Health Department, Ministry of Health, Arab Republic of Egypt conducted a study into prevention of child mortality from diarrheal disease through testing various modules of Oral Rehydration Therapy delivery. In a six-cell design counting a total of almost 29 thousand children between the ages of one month and 5 years of age, ORT was provided in the form of early administration of: hypotonic sodium-sucrose solution by the mother, backed by balanced electrolyte solution in the hands of the health care provider; normotonic, balanced electrolyte solution ("Oralyte") by mother and health care provider and, normotonic balanced electrolyte solution in the hands of the health care provider only, and effects on child mortality were measured. In addition, utilization and effect of ORS when made readily available at a nominal fee through commercial outlets was similarly examined. A cost-benefit analysis was performed for cost of service (process) and outcome for each of five study cells using a sixth cell, the Control, as reference.

Results showed that early rehydration with sodium/sucrose by the mothers, backed by balanced electrolyte nutrition in the hands of the health care provider is equally effective as balanced electrolyte ORT in reducing preschool child mortality by 40% and diarrhea specific mortality by 50%. This treatment modality also showed the greatest cost/benefit ratio, being half as expensive from service coverage or avertion of child deaths points of new as the treatment modality using balanced electrolyte solution in the hands of both the mothers and the health care provider.

PART 1

TECHNICAL REPORT

INTRODUCTION

In 1976 the Egyptian Ministry of Health and the United States Agency for International Development entered into an agreement to strengthen the Egyptian Rural Health Services. Following selection of a contractor and arrival of the resident consultants, the Strengthening Rural Health Services Delivery Project (SRHD) was initiated April, 1978 with the underlying goal to improve the health status of Egypt's rural population. The SRHD project is attempting to accomplish this goal by testing and demonstrating various configurations of health services and their delivery systems in ten districts of four separate governorates of Egypt.

During the first phase of the SRHD project, diarrhea and its treatment emerged as an important area of interest. Early analysis of existing health statistics supplemented by SRHD surveys indicated that children under 5 years of age, who represent about 17% of the total population, account for approximately 50% of the total deaths which occur each year in Egypt. Moreover, about 80% of these child deaths result from just two diseases: Diarrheal Disease and Lower Respiratory Tract Infection. Diarrhea is far the more important, accounting for approximately 60% of all child deaths throughout the year. Mortality followed by morbidity and disability are used in the SRHD project as indices of health status. Hence, a program aimed at the control of child deaths from diarrhea became the highest priority of the SRHD Project because of the seemingly large and positive impact it, potentially, could have on improving the health status of rural Egyptian children.

Establishing the importance of diarrhea as a serious health problem in Rural Egypt was relatively easy; however, making recommendations to the Ministry of Health as to specific services and a service mechanism for effecting the greatest reduction in diarrhea-specific mortality given the constraints imposed upon the existing rural health system was more complex. The first consideration in making program recommendations is to identify an effective, affordable prevention, or in absence of this, treatment for diarrhea. The underlying cause of diarrheal deaths is an infection, but the immediate cause of death is dehydration and electrolyte depletion.

Prevention of diarrhea at this point in time in Egypt is not a realistic way to deal with the high diarrhea-specific death rate because of the multiple sources of infection in the community. Treatment to prevent deaths, however, is straightforward: replacement of lost electrolytes and water. In this context, traditional treatment, until a few years ago consisted mainly of parenteral rehydration. More recently oral rehydration therapy (ORT) has become more popular for several reasons:

- ORT is as effective as parenteral rehydration in the treatment of established dehydration irrespective of the pathogen causing the diarrhea.

- ORT is more widely available and can be made available more quickly to a sick child than can parenteral solutions because ORT is not dependent upon the hospital setting.

- Use of ORT can be taught to paramedical personnel as well as to mothers, also facilitating wider use and earlier treatment of diarrhea.

- Oral rehydration solutions which are highly effective in preventing death are in and of themselves significantly less expensive than parenteral solutions.

Other have made a thorough review of these advantages and of the effectiveness of ORT*. Their work and results will not be reviewed here again. We will only summarize by saying that ORT has many striking and unique attributes which make it a highly suitable treatment for diarrhea; and that it is currently the accepted treatment for preventing deaths due to diarrhea and its accompanying dehyration.

With the confidence that the best treatment for averting diarrhea-specific deaths, had been found, WHO has taken the lead in an effort to combat deaths from diarrhea and is promoting ORT in the form of a standard oral rehydrant: "Oralyte". The WHO program attempts to exploit the advantages of ORT by relying upon ready availability of the pre-packaged rehydrant through existing health facilities and by promoting decentralized use of Oralyte: the use of paramedical personnel and even mothers to prepare and administer Oralyte. Administration of the solution is recommended to be initiated at the first sign of diarrheal disease and is continued until the child is well. If the child does not respond, the patient should then be referred for parenteral rehydration. In addition to administration of ORT, WHO is promoting provision of extensive health and nutrition education.

A highly efficacious treatment, however, in the absence of an efficient delivery system can lead to disappointment. Indeed despite obvious advances in medical technology coupled with an ever expanding number of medical facilities, manpower and services, diarrhea-specific mortality, worldwide, has declined only slightly. One explanation for this sistuation is that the WHO and other country programs using ORT have not had enough time to have an impact on world-wide rates. Yet, even in Egypt where an ORT program was initiated in 1977 in all governorates, preliminary survey data suggest that the impact of the Egyptian ORT program (dependent upon Oralyte) has been less successful

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* *Naomi Baumslag, et. al. Diarrheal Disease and Oral Rehydration an annotated Bibliography, U.S. Dept. HEW, O.I.H., Washington, D.C. 1979.*

than was expected. Indeed, the fact that deaths from diarrhea have not decreased as dramatically as anticipated is both disappointing and perplexing in the face of the demonstrated high efficacy of ORT in general. Several reasons, all of which pertain to delivery systems, have been identified as contributing to this situation in Egypt, but may also be generalized to other parts of the world:

- Ready availability of pre-packaged oral rehydration salts or solution (ORS) does not truly exist in Egypt due in part to the low utilization rate of health facilities by mothers with sick children. SRHD survey results from a pilot household survey conducted in 1979 indicates that about 10% of children sick with diarrhea during a 2 week period receive no care. Another 30% are treated at home by the mother or a relative through use of the village store or some other non-medical source. Only about 60% of children sick with diarrhea seek care from a health practitioner. Of these less than one fifth go to the government physician.

- Ready availability of ORT is affected because Oralyte distribution is restricted: it is distributed as a prescription drug on advice from a medical facility or pharmacy whose operating hours are limited. Hence, contrary to accepted medical opinion, life-saving fluid and electrolyte replacement does not begin at the earliest possible moment after recognition of the disease.

- General unfamiliarity with ORT or possibly a distrust for prepackaged ORS.

- Oralyte is simply not being distributed at a level consistant with need based on the calculated level of diarrhea which probably exists in the country. Assuming that 4 episodes of 5 days duration each occur in each child less than 5 years of age each year, then every child suffers from 20 days of diarrhea per year. For rural Egypt which has a population of about 20 million of which 17% are below 5 years of age, there are about 68 million child-days of diarrhea per year. Treatment for just rural Egypt, if done according to current recommendations, would amount to 68 million packets per year. Egypt produced or imported approximately 5 million packets of Oralyte or its equivalent in 1980.

- The logistical system for disseminating the required amount of pre-packaged ORS might eventually be possible, but currently is incapable of this task.

It was in the context of these problems that it was decided that a fresh look had to be taken at how ORT as a medical service is made available to the community before recommendations could be made to the MOH about how to strengthen rural health services and in turn improve rural Egypt's health status. Of additional interest in reducing diarrhea-specific mortality was the efficacy of a plain sugar and salt solution prepared and administered in the home by the mother early in the course of the disease. Efficacy of this alternative method of ORT was a particularly important question because of the fact that widespread distribution of Oralyte even in the shadow of an existing nationwide program seems not a realistic, achievable goal in the near future in Egypt. Further, previous experience in India provided strong empirical evidence that a sugar and salt solution could provide life-saving therapy similar to that achieved by a balanced electrolyte solution like Oralyte*.

Out of this background a diarrheal disease control study (DDCS) was initiated with the overall aim of finding an effective and eventually replicable treatment regimen for the control of deaths from diarrheal disease initially within all of the SRHD project districts covering approximately two million inhabitants or 340 thousand preschool children. Principal objectives of the program were:

- To determine utilization of oral rehydration salts (O.R.S.) by mothers and health care providers and effectiveness of ORT on reducing child mortality when O.R.S. are made readily available through various sources.

While there seems to be a general agreement, that lack of O.R.S. in either home or health facility has been a major obstacle to an effective ORT program in the past, opinions differ widely on appropriate channels for distribution of O.R.S.

- To compare the effectiveness of different methods of oral rehydration therapy administration.

Specifically, we decided to compare the extent of reduction in child mortality among three groups: one using a combination of ORT prepared from in-home ingredients (sugar and salt) administrated by the mother and balanced ORS in the hands of health care providers, one using a balanced electrolyte ORT (Oralyte) placed in the hands of the health care providers; and one using Oralyte by both mothers and health care providers.

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* *A. A. Kielmann and Colin McCord, Home Treatment of Childhood Diarrhea in Punjab Villages, Environm. Child Hlth. 23, 197 , 1977.*

METHODS

STUDY DESIGN

In keeping with the two prinicipal objectives, the study design consists of 6 "cells": two control cells and four treatment cells. "Control 1" represented no input beyond current government activity. "Control 2" input was limited to physicians' education and to ensuring a plentiful supply of oral rehydrant freely available to health facilities for use in-facility. Input into the four treatment cells comprises health personnel education, community health education, a plentiful supply of Oralyte made available for in-facility use as in "Control 2", and availability of oral rehydrant to the public through various sources.

More specifically, the inputs which were varied among the treatment and control cells are reflected in the study cell names and are described here:

Cell 1: "Control 1". In this control cell there were no inputs of any kind provided; the regular health services routinely provided by the government were allowed to continue.

Cell 2: "Control 2". In this control cell as in all treatment cells health personnel were made aware of the importance of oral rehydration as a treatment of diarrheal disease; and a plentiful supply of Oralyte was made available to all facilities.

Cell 3: "Oralyte; Home Distribution". Oralyte was distributed in the course of routine home visiting. Mothers were instructed in its use. On the initial visit the nurse left packages of Oralyte with the mother calculated against the following schedule: 4 packages for the youngest child and one more package for every additional child under 5 years of age. The mother was told to come to the facility to replenish her supply if in the course of the following month she used any or all of the packages. The nurse automatically also replenished the mother's supply of Oralyte during home-visits.

Cell 4: "Oralyte; Commercial Sources". In this study, a stock of Oralyte was provided to all shops and pharmacies, free of charge. Instruction was given to the shopkeeper or pharmacist that Oralyte was to be sold at the nominal price of 3 piasters (4.3 ¢) to mothers, and that if necessary, instructions on the use of Oralyte were to be repeated to the mother. The nurse gave health education identical to that in all other treatment cells, but instructed the mother to purchase Oralyte, when needed, from village shop or pharmacy.

Cell 5: "Sugar and Salt; Home prepared". Mothers were instructed to prepare ORS by mixing 5-6 level teaspoons of granulated sugar with half a level teaspoon of salt in one liter of water. The juice of 1/2 a lemon, if available, should be added for taste. In addition, mothers were instructed to give the child either tomato juice, orange

juice, mashed banana or tea depending upon seasonal availability, as source for increasing potassium intake. The education given by the nurse to mothers in this study cell demonstrated and stressed a properly used teaspoon: one measuring between three and six grams.

Cell 6: "Sugar and Salt; Pre-packaged, Home Distribution". In this fourth and last treatment cell, a pre-packaged sugar (sucrose) and salt mixture was home delivered by the nurse during home-visiting in a fashion consistant with the Oralyte home distribution cell. Each package contained 3.5 gm salt to provide a concentration of 60 meq. of sodium per liter of water.

The health education component in the study cells was carried out in the community in general, (by both the nurse and the sanitarian), and in the individual homes (mainly by the nurse). Health education stressed five points:

- The importance of diarrhea as the most dangerous disease for pre-school children during the upcoming and every summer.
- Recognition of the signs and symptoms of diarrhea using three liquid stools per day as the criterion of disease. This definition was used, based on the previous experience of one of the investigators in India.
- Early management of diarrheal disease through preparation and administration of ORT by the mother.
- The need to continue breast feeding and usual supplemental food intake throughout the entire diarrheal episode. Mothers were instructed, however, to stop commercial supplementary milk, if used, for 24 hours.
- Recognition of the danger signs and symptoms requiring immediate referral to the health facility.

Health education was provided once every four to six weeks to all mothers with children of pre-school age by a health facility nurse through home-visiting. In addition, village men were also exposed to health education by the sanitarian of the local health facility. Health education of the men of the village was effected through a series of talks given by the sanitarian at the mosque after the prayer meeting. These talks were given on at least three Fridays per month. Handbills, appropriate to the study cell and stressing the main health education points listed above were distributed to saturation at two to three month's intervals.

Table 1

STUDY CELLS AND INPUTS OF THE DIARRHEAL DISEASE CONTROL STUDY

Study Cell	Input
Control 1	Unchanged (present) MOH system. MOH introduced ORT carried on in facilities since 1977.
Control 2	Oralyte available ad-lib at facility level. Physicians made aware of importance of ORT.
Oralyte home distributed	Oralyte distributed to all house-holds on monthly basis. Health education in homes and at mosques and other public places at regular intervals. Oralyte available ad-lib to nurses and at facilities.
Oralyte through commercial sources	Oralyte available at all village shops and pharmacies at 3 P.T. per package. Health education in homes and at mosques and other public places at regular intervals. Oralyte available ad-lib to nurses and at facilities.
Sugar/salt home prepared	S/S rehydration mixture prepared in home by mothers. Health education in homes and at mosques and other public places at regular intervals. Oralyte available ad-lib to nurses and at facilities.
Sugar/salt prepackaged; home distribution	S/S rehydration mixture prepackaged and distributed to all homes on monthly basis. Health education in homes and at mosques and other public places at regular intervals. Oralyte available ad-lib to nurses and at facilities.

In-home health education was carried out by nurses during their regular home-visits. Home visiting had been implemented as routine part of the (SRHD) revised health service delivery program in four districts earlier in 1980, hence was not set up for this study but served as a means to deliver the program. In order to accomplish a home visiting program which could reach all households with children less than 5 years of age, each nurse was assigned a sector of the village consisting of no more than 500 families, and a daily home-visit schedule quota of no more than 25 families. Nurses spent an entire day every other day visiting homes in their sectors. Nurses in the same facility took turns home-visiting so that at least one nurse was always in-facility on any given day.

During home-visits nurses instructed mothers in the preparation of the Oral Rehydration Solution (ORS). The method taught was dependent upon the study cell. In all house holds in study cells on the first home-visit, mothers were asked to provide a vessel which could be used in the future by the mother exclusively for the preparation of ORS. The vessels ranging from plastic containers to eartherware jugs, were calibrated by the nurse to measure one liter of water. The nurse first filled the vessel using a project-provided, standard one liter measure, and then marked the side of the household vessel with a sharp instrument. The etched mark was then colored. On all subsequent visits the nurse requested to see the vessel, and, if necessary, repeated the calibration procedure. Mothers were instructed to prepare ORS using the cleanest water available. Water from a tap was suggested as being the most desirable; water from the canal as least desirable. Mothers were told not to bother boiling water for the first batch of ORS so as to avoid additional delay in starting rehydration of their child. However, for subsequent batches, they were asked to boil water if it came from a source other than the tap and to cool it prior to preparing the next batch.

Mothers were then instructed in how to administer the ORS. Children were to be given as much of the ORS as they wanted over the course of the next 24 hours, but not less than one liter. Infants were to be spoon-fed ORS if necessary. Vomiting was not to deter the mother from continuing to administer ORS. Mothers were instructed to administer the solution spoon-wise between vomits. Nurses encountering a child with diarrheal disease during home-visiting were instructed to prepare ORS as used in that study cell along with the mother and to give it to the child. The mother was asked to continue to administer ORS to the child. If the physical condition of the child warranted referral to the doctor, the nurse initiated ORT using Oralyte and had the child brought to the clinic.

Mothers were instructed to refer their child immediately to the health facility under any of several circumstances:

- o Child has either of two locally, well recognized conditions:
  - "Nazla" (diarrhea and vomiting).
  - "Dysenteria" (diarrhea and blood and/or pus in stool).
- o Child looks no better or worse on the day following start of ORT.
- o Child continues to have diarrhea for more than two days after ORT starts.
- o Mother felt unsure or worried at any time.

The treatment regimen used at the health facility was identical in all treatment and "Control-2" cells irrespective of other experimental differences. The treatment was to rehydrate using ORT specifically in the form of Oralyte, and to refer severely dehydrated children or children in shock to the district or governorate hospital. In "Control-1" facilities no effort was made to influence doctors' current treatment regimen.

POPULATION SAMPLE SIZE AND SELECTION

Early in the course of the planning for the DDCS, it was decided to choose a sample size which required the SRHD project office to utilize the existing administrative structure in the field so as to avoid the potential situation of establishing a smoothly running applied research service program run by highly motivated researchers, but unable to be replicated within the existing health system infrastructure. Hence, the population size of the study was chosen to be close to that of an average district i.e. 200,000. Population size within each of the six study cells was predetermined as follows:

- o for each of the three major cells i.e. "Oralyte; home distribution", "Sugar and Salt; Home prepared", "Control-2" a population of approximately 40,000 each (approximately 7,000 children)
- o for the "Control-1" cell a population of 30,000 (approx. 5000 children).
- o for the two minor study cells, i.e. "Oralyte; commercial Sources" and "Sugar and Salt; Home distribution" populations of 15,000 each (approximately 2200 children).

Villages for the study cells were chosen randomly until the desired population size was achieved from within three districts of Dakahlia Governorate: Dekernis, Miniet-el-Nasr and Sinbellawin. Two limitations were encountered in the selection of treatment and control villages.

- All villages for the "Sugar and Salt; Home Prepared" study cell were selected from one district: Sinbellawin This was done because routine home-visiting had been instituted throughout this district in the four months prior to the onset of the study ensuring detection of excess mortality or treatment problems should those arise.

- Control villages could not be selected from among villages in Sinbellawen since home-visiting was already in progress, and hence, the routine government system no longer prevailed.

Prior to the implementation of services in villages in treatment and control cells, two types of maps were prepared. The first was drawn to show all major landmarks both man-made and natural in each village. The second type of map was a sector map corresponding to the nurse's home visiting sector of responsiblity. In each study cell village, an initial house to house visit was carried out to identify households with children of pre-school age and/or pregnant women likely to deliver during the study period. Study populations in each of the six cells were determined from updated census and household survey population distribution figures.

DATA COLLECTION

Several data collection processes were established to collect information on both intermediate (process) variables as well as on impact (outcome) variables. These included:

Household Survey. Prior to the start of the program, a household survey on demographic composition incidence and prevalence of illness and health care practice was conducted throughout the SRHD project area (January/February 1980) on randomly selected two percent of households. Three months and again nine months after begin of this program two additional special household survey rounds were held on a 10% random sample of families. These latter surveys were designed to primarily determine diarrheal disease incidence, prevalence, knowledge about and practice of management of diarrheal disease by the mother, population based mortality rates and sources of treatment, if any. The specific surveys were conducted in July of 1980 and January of 1981. The three surveys were done in all treatment villages and in the "Control 2" cell. "Control 1" villages were included only in the initial, "nonspecific" survey and in the second round of the special survey.

Ingredient and Utensil Survey. This 10% random sample survey of families was designed to determine the availability of granulated sugar, of salt, of teaspoons and their range in size, ability of mother to measure correctly one liter of water within ± 10%, and the sources of water used for preparation of beverages. This survey was conducted after three and again nine nurse home-visits in treatment and "Control 2" cells.

Home Prepared ORS Electrolyte Concentrati[illegible] lysis. This random 1% sampling of households in all trea[illegible] cells was carried out to ascertain the sodium concentration of home prepared/diluted ORS. ORS samples were obtained after three and nine (nurse), home-visits, respectively. Analysis of samples was done by the NAMRU analytical laboratory.

Mortality Survey. In all study villages, the clerk in each facility kept a regular count of the number of pre-school children who had died within the preceeding week. Age, sex, house number and father's name were reported for each death to the district health officer at the end of the week (Saturday). In addition, in treatment villages, nurses through their home-visiting routinely checked for deaths among study cell children. If a death had occurred the nurse urged the parents to register the death with the facility, and had the name of the deceased entered into the weekly mortality report prepared by the clerk. As home-visiting was not done in either control cell, nurses conducted a once-only survey of all households at the end of the study to determine previously unrecorded deaths.

Verbal Autopsy Report. In all study (treatment and control) villages, the mortality survey information (list of weekly deaths discussed above), which was subsequently forwarded to the district health officer, was in turn broken down into 5 lists. The lists were distributed to one of five specially trained physicians (called "flying doctors") for further in-depth investigation. Flying doctors rotated throughout all cells. The flying doctors verified each death and completed a "verbal autopsy" form for each death, the objective of which was to ascertain the cause of death, circumstances surrounding death, treatment information and, if a diarrhea death, specific practices used to treat the patient prior to death. Previously unregistered deaths in control villages that were detected in the final house-to-house survey at the end of the study were similarly verified by the flying doctors and, if found to be true deaths that had occurred during the study peiod, a Verbal Autopsy form was filled.

Treatment and Referral Record. Physicians in all treatment villages as well as in "Control 2" cell villages were instructed to record, regularly, the number of all preschool child patients seen for diarrheal disease in the course of their routine outpatient as well as after-hours private clinics. The treatment and referral record was designed to obtain information about presenting signs, symptoms, treatment prescribed, and referral. This survey was not done in "Control 1" villages.

STUDY ORGANIZATION

At the local level, the study was administered by a resident MOH official - the project field executive director (PFED). He was assisted by the (three) district health officers (DHO) of the districts in which the study was held. Each DHO in term was assisted by an itinerant supervisory team consisting of a physician, a senior nurse and the chief sanitarian. The PFED, DHO's and members of the supervisory teams were regular members of the governorate or district health staff.

Supervisory teams guided by the DHO were responsible for monitoring both frequency and quality of program related activities among the health staff of the study facilities: physicians, nurses and sanitarians. If and when deficiencies were found they were corrected through on-the-spot retraining. In "Control 2" health facilities, supervision covered only weekly reporting of deaths and daily completion of the "Diarrheal treatment and Referral Record" by the physicians. Supervisory visits were scheduled to occur once every month in each facility. The DHO was responsible for all activities in his district including ensuring that death reporting forms were in fact submitted to him weekly by the facility physicians, and distributing these forms to the "flying doctors" whose turn it was to work in his district during the succeeding week. The PFED, in turn assembled routinaly collected data for forwarding to the (SRHD) central office. The PFED generally coordinated study activities between the three districts and between districts and center.

The Household Survey, Utensil and Ingredient Survey, and sampling of diarrhea mixtures for the home prepared ORS electrolyte concentration analysis were carried out under the direction of the regular MOH social scientist from Dakahleia governorate. Interviewers were hired from among (Mansourah) university students as well as chosen from among existing health personnel staff. All interviewers received special training for each type of survey from central (SRHD) staff together with the social scientist.

Carrying out study activities required work beyond that carried out routinely by MOH employees resulting in longer working hours. For this reason it was decided by the MOH to provide on a monthly basis the following monetary incentives provided program activities were carried out according to preset performance criteria:

- Health facility nurses and sanitarians (treatment villages only) L.E. 5.- ($ 7.-) per month.

- Health facility physicians in treatment villages: L.E. 7.- ($ 10.-); in control villages L.E. 5.- ($ 7.-) per month.

- Supervisory team members: physician L.E. 15.- ($ 21.40) Sanitarian L.E. 12.- ($ 17.10), nurse L.E. 10.- ($ 14.30) per month.

o D.H.O.'s and PFED L.E. 30.- ($ 42.90) per month.

In addition to these,clerks (3 district, 1 governorate and 1 central) and survey team personnel received special remuneration. Since their work was, however, entirely research-related and would not be encountered in a pure service program their remunerations shall not be detailed here.

STUDY IMPLEMENTATION

The study was launched May 1, 1980 in 29 villages spread over the three districts with a total child population of alomst 29.000 children belwo five years of age. Eleven villages (total population approximately 64.000) were, in Sinbellawin district, ten villages (total population approximately 74.000) were in Dekernis and eight villages (total population approximately 48,000) were in the smallest of the three district, Miniet-el-Nasr.

RESULTS

PROCESS

In Tables 2 through 5 results from the Ingredient and Utensil survey are presended. In both rounds, households were selected randomly, hence households in rounds I and II are not the same unless by chance. As expected, granulated sugar and salt were readily available. Use of the correct size of teaspoon in the "Sugar/Salt Home Prepared" cell rose from 74% to 96% ($P < .005$) and the ability to measure one liter of water within ± 10% rose from 85% to 97% ($P < .005$) in all treatment cells as shown also in Figures I and II, respectively.

In Table 5, sources of water used to prepare beverages (tea and/or ORS) are shown as determined during the initial and repeat surveys. Overall, the proportion of mothers using canal water was highest in the "Sugar/Salt Home Prepared" cell, less in the "Oralyte Home Distributed" cell and non-existant in the other three study cells.

Although there was a numeric decline in the proportion of mothers using the canal in the two cells where canal water was being used from 19% to 12% this shift is statistically not significant. Neither did any of the other changes in the source of water between the initial and final surveys reach or approach statistical significance.

Table 2

AVAILABILITY OF GRANULATED SUGAR AND SALT ON INITIAL (I) AND REPEAT (II) SURVEYS

Study Cell	Survey No.	Granulated Sugar				Salt				Total No. of households surveyed
		Yes		No		Yes		No		
		No.	%	No.	%	No.	%	No.	%	
Control (2)	I	66	97.1	2	2.9	68	100	0	0	68
	II	68	100.0	0	0	68	100	0	0	68
Oralyte; home distribution	I	59	100	0	0	59	100	0	0	59
	II	74	100	0	0	73	99	1	1	74
Oralyte; through commercial services	I	27	100	0	0	27	100	0	0	27
	II	32	100	0	0	32	100	0	0	32
S/S; home prepared	I	75	97.4	2	2.6	77	100	0	0	77
	II	67	97.1	2	2.9	69	100	-	-	69
S/S; prepackaged; home-distr.	I	26	100	0	0	26	100	0	0	26
	II	28	100	-	-	28	100	-	-	28
ALL	I	253	98.4	4	1.6	257	100	0	0	257
	II	269	99.3	2	0.7	270	99.6	1	0.4	272

Table 3

DISTRIBUTION OF SIZES OF "TEA SPOONS" PRESENTED

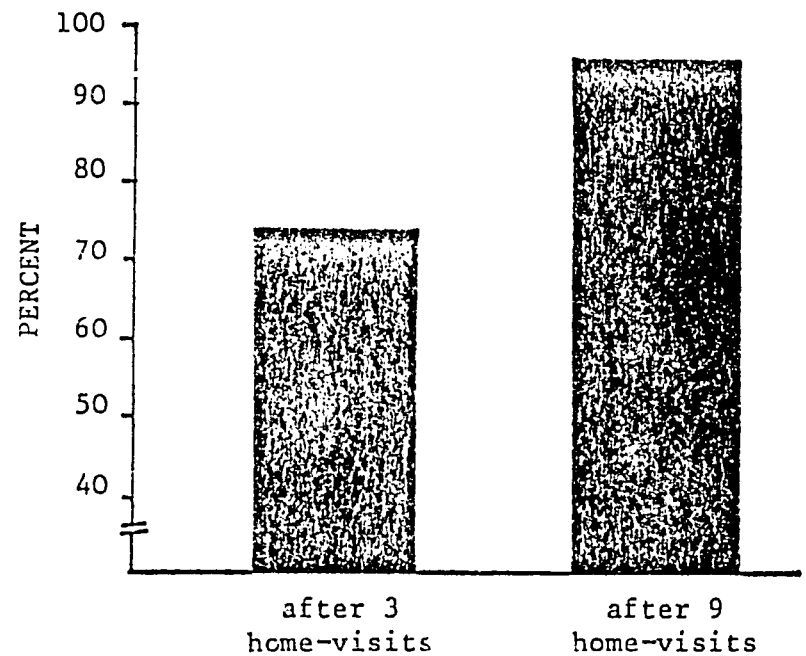
ON REQUEST IN INITIAL (I) SURVEY IN ALL AND IN REPEAT (II) SURVEY IN THE

"SUGAR AND SALT HOME PREPARED" CELL

STUDY CELL	Survey No.	SIZE 1 Mean=1.9 gr.		2 Mean=2.9 g.		3 Mean=4.7 gr.		4 Mean=6.2 gr.		5 Mean=9.8 gr.		NO SPOON AVAIL.		ALL
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.
Control (2)	I	0	0	0	0	56	82.3	7	10.3	2	2.9	3	4.4	68
Oralyte; home-distributed	I	0	0	5	8.5	46	78.0	7	11.9	1	3.4	0	0	59
Oralyte; through Commercial sources	I	0	0	0	0	22	81.5	5	18.5	0	0	0	0	27
S/S; home-prepared	I	10	13.0	21	27.3	18	23.4	18	23.4	9	11.7	1	1.3	77
	II	3	4.3	18	26.1	47	68.1	1	1.4	0	0	0	0	69
S/S; prepackaged; home-distr.	I	0	0	0	0	18	69.2	7	26.9	1	3.9	0	0	26

Figure I

USE OF CORRECT (3-6 gm) TEASPOON SIZE
AFTER THREE AND NINE HOME VISITS



$P_{\Delta} < .005$

Table 4

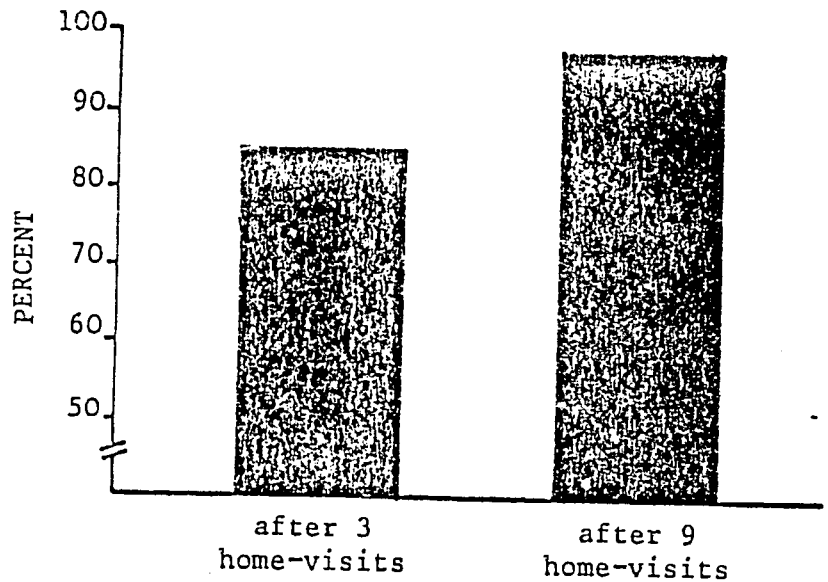
ABILITY TO MEASURE CORRECTLY ONE LITER OF WATER ON INITIAL (I) AND REPEAT (II) SURVEYS

Study Cell	Survey No.	ABLE		UNABLE		ALL
		No.	%	No.	%	Number
Control (2)	I	1	1.5	67	98.5	68
	II	1	1.5	67	98.5	68
Oralyte; home distributed	I	53	89.8	6	10.2	59
	II	72	97.3	2	2.7	74
Oralyte; through commercial sources	I	27	100	0	0	27
	II	31	96.9	1	3.1	32
S/S; home prepared	I	55	71.4	22	28.6	77
	II	60	87.0	3	13.0	69
S/S; prepackaged; home-distr.	I	25	96.2	1	3.8	26
	II	28	100	-	-	28
ALL *	I	160	84.7	29	15.3	189
	II	191	97.0	6	3.0	197

* excluding control

Figure II

ABILITY TO MEASURE CORRECTLY
ONE LITER OF WATER
AFTER THREE AND NINE HOME VISITS



$P_{\Delta} < .005$

Table 5

SOURCES OF WATER FOR HUMAN CONSUMPTION ON INITIAL (I) AND REPEAT (II) SURVEYS

Study Cell	Survey No.	Tap in Home		Public Tap		Pumps		Canal		TOTAL No. OF HOUSEHOLDS
		No.	%	No.	%	No.	%	No.	%	
Control (2)	I	40	58.8	28	41.2	0	0	0	0	68
	II	45	66.1	23	33.8	0	0	0	0	68
Oralyte; home distributed	I	20	33.9	22	37.3	9	15.3	8	13.6	59
	II	35	47.3	22	29.7	10	13.5	7	9.5	74
Oralyte; through commercial sources	I	14	51.8	13	48.2	0	0	0	0	27
	II	15	46.9	17	53.1	0	0	0	0	32
S/S; home prepared	I	7	9.1	22	28.6	30	40.0	18	23.4	77
	II	3	4.8	30	47.6	20	31.7	10	15.9	63
S/S; Prepackaged; home-distrib.	I	14	53.9	12	46.2	0	0	0	0	26
	II	13	46.4	15	53.6	0	0	0	0	28
All Cells	I	95	37.0	97	37.7	39	15.2	26	10.1	257
	II	111	41.8	107	40.4	30	11.3	17	6.4	265

In Table 6 the sodium concentrations of randomly collected, home-prepared ORS in initial and repeat surveys are shown. In the initial survey, mean soldium concentrations tended to be considerably higher than expected suggesting that mothers, in general, tended to use too little water. On repeat survey, the mean and mode of the sodium concentration in all treatment cells closely approximated expected concentrations as shown in Figure III.

In Table 7 the consumption of pre-packaged oral rehydration salts (Oralyte and pre-packaged Sugar/Salt) by source and study cell is shown. Total use ranged from 1/25 of a package per child per six months in the "Control 1" cell to almost 5½ packages per child in the "Sugar and Salt; Pre-packaged; Home distribution" cell as shown in Figure IV. The majority of pre-packaged ORS used came through home distribution, 94% in the "Oralyte: Home Distribution" cell, 95% in the "Sugar and Salt Prepackaged; Home Distribution" cell. The next highest utilization occured in the "Oralyte Commercial sources" cell with 1.3 packages per child per six months, of which 81% was purchased by mothers. In health facilities Oralyte use ranged from the previously mentioned 1/25 of a package per child in the "Control 1" cell to almost half a package per child per six months in the "Sugar and Salt; Home Prepared" cell with the other cells taking intermediate postions.

Tables 8 through 10 show the results of the Diarrhea Treatment and Referral survey. In total 2760 children (12.1%) were seen in the course of outpatient clinics during the six months of the program. Of these, the vast majority (94%) were seen during regular working hours, the remainder (6%) after hours as "private" patients. In table 8 a breakdown of these children is given by study cell and age groups.

Overall, the majority of children seen (5.1%) were between one and 12 months of age, the least (3%) above two years and below 5 years of age. The rate of facility treatment ranged from 6% in the "Oralyte commercial sources" cell to 18% in the "Sugar/Salt pre-packaged; home distribution" cell, with the other three cells taking intermediate positions. Results from both the S/S prepackaged home-distribution "and" "Oralyte; commercial sources" cells are statistically significantly different from each other as well as from the results in the other three cells ($P < .01$). The differences in the rates of facility use between these latter cells are statistically not significant.

In table 9 a distribution of presenting signs and symptoms on arrival to the facility is shown. Ninety-eight percent of those coming to the facility for treatment come with the chief complaint of diarrhea. Almost half were vomiting and/or were febrile. Twelve per cent showed signs of dehydration; and eleven per cent also had blood and/or pus in their stools. One percent showed periorbital edema, half a per cent generalized edema and almost one per cent come with the history of convulsions.

Vomiting, dehydration and fever were most frequent among children seeking care from the "Control-2" villages. Vomiting, as presenting sign, occurred also rather frequently (62%) among children from the "Sugar/Salt prepackaged; home distribution" cell villages, least among those from the "Oralyte home distribution" cell. Signs of dehydration were seen frequently among pediatric outpatients from the "Oralyte; commercial sources" (23%), somewhat less frequent from among the "Oralyte; home distribution" and "Sugar/Salt; home preparation" (11%) cells and least (2%) from among those of the "Sugar/Salt; prepackaged; home distribtion" cell villages.

Periorbital edema and/or generalized edema were most frequently seen among outpatient children from the "Oralyte; commercial sources" villages (4%), somewhat less frequent (2.4%) in the "Oralyte; home distribution" villages, and were least among children seen from the "Sugar/Salt; home preparation" villages (0.7%).

Table 10 shows the treatment provided by the physician. Overall, Oralyte-ORT per os was given to 86% of the patients, Oralyte through nasogastric tube to 2%. Four per cent were rehydrated parenterally and two per cent were refered directly to the hospital, Six percent received no O.R.T. Of those seen, almost half (48%) were given antibiotics, almost three quarter (73%) received intestinal antiseptics and a third (31%) antiemetics.

Referral to the hospital was highest among "Control-2" children (7.5%), intermediate (1.7%) among children in "Oralyte" villages, and least (0.1%) among children in Sugar/Salt ORT villages.

By dividing the number of pediatric outpatients seen for diarrheal disease (2760) into the total number of O.R.S. packages used in the individual facilities (6348), an average of 2.3 packages of Oralyte per diarrheal episode results.

PROBLEMS

Rumours. Several rumours arose early on in the study. All arose in areas where prepackaged electrolytes - Oralyte or prepackaged Sugar/Salt were used. In several villages rumours circulated to the effect that the content of the packages killed children. One of the origins of this rumour was traced to a pharmacist (who probably worried about a decline in sale of antibiotics and intestinal antiseptics during the summer diarrhea season). The District Health Officer (DHO) as well as the physician supervisor from the district discouraged further spread of the rumour by talking to the pharmacist concerned, to the persons known to have spread the rumour as well as to the villagers in general, after the Friday prayer meeting at the mosque. Another was traced to a family whose child had been suffering from severe

diarrhea, was treated with oral therapy and had died. The supervisory team explained to the family and to the village community that even with "good treatment" there are occasionally failures and that probably the treatment had come too late. In another group of villages where Oralyte was distributed on a house-to-house basis a rumour spread to the effect that Oralyte permanently sterilized children. As previously, source and focus of the rumour were identified by the supervisory team and were found to be limited to one village. The supervisory personnel as well as the nursing staff in that village defused the rumour by giving dissolved Oralyte to their own children in front of village persons at a meeting specially arranged for the village community.

Secondary treatment sources. Physicians were advised to directly refer cases of moderate to severe dehydration to the pediatric departments of either district and/or governorate hospital, hence a visit to each of the "rehydration centers" in the pediatric wing of the governorate (referral) hospital as well as in one of the district hospitals was made. The district rehydration center was found to be non-operative. The center in the governorate hospital was deficient both with respect to quality of care and available equipment.

Lastly, since in an earlier sample survey we had found that 17% of mothers went directly to the pharmacist for medical care if their child had diarrhea, a survey was carried out in nine pharmacies, three of which were in the governorate capital (Mansoura) and six in the diarrhea study area. The objective was to determine the treatment pharmacists commonly advise (and sell) for uncomplicated childhood diarrhea. A medical anthropologist and visitor to the project posed as mother whose 8 month old baby allegedly was suffering from diarrhea since one day.

Drugs advised (and sold) were: Chloramphenicol, Pentrax (Ampicillin), Nimarol, Enteroquin and Enteroquin with Streptocillin. Not one pharmacist advised Oralyte or Rehydran*. Only when specifically asked for, was oral rehydration salt sold. All pharmacists indicated that O.R.T. was only for severe diarrhea when there was dehydration. The dose recommended ranged from 1 teaspoon of the diluted mixture every ten minutes to one every 15 minutes. Two pharmacists from within the "Oralyte; commercial sources" cell claimed, contrary to our records, not to have any Oralyte left and further added that it had a bad reputation among villagers because it reportedly killed children. One of them stated that when he used to sell it, he dissolved 3 packages in ½ liter of water for those mothers who asked for it. One pharmacy in one of the study districts sold one liter of 5% Glucose solution to the interviewer as rehydration mixture.

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* *Rehydration salt prepared by a commercial drug company in Egypt of identical composition as Oralyte but packaged for dilution in 200 cc.*

OUTCOME

Table 11 shows the total and diarrhea-specific death rates for children one month to five years of age in the six study cells. Deaths below one month of age were not included in the analysis as there is strong evidence to support that deaths below that age are under-reported.

The differences in total mortality and diarrhea specific mortality between "Control 1", "Control 2" and the "Oralyte; Commercial Sources" cell are statistically not significant. Similarly, the differences in total child mortality and diarrhea-specific mortality between the "Oralyte Home Distribution", "Sugar and Salt; Home Prepared" and "Sugar and Salt Pre-Packaged; Home Distribution" cells are statistically not significant. The differences in mortality between these two groups are around 40% in total mortality and 50% in diarrhea specific mortality and are statistically, highly significant ($P < .005$). Differences in child mortality between each of the three study cells where ORS was made either at home (from sugar and salt) or where ORS was delivered in high quantities to the home and each of the other three cells, "Control 1", "Control 2" and "Oralyte Commercial Sources" are similarly statistically highly significant ($P < .005$). Figure V shows the percentage reduction in total child mortality and diarrhea-specific mortality between 1 month and 5 years of age in all treatment cells as compared to the mortality mean of the two control cells.

In Table 12 mean mortality by study cell is shown over the four years preceeding the study, as well as in 1980. Observed differences in mortality rates between the two time periods are statistically insignificant for the two control cells as well as the "Oralyte: commercial sources" cell. They are highly significant ($P < .005$) for the three other treatment cells. Overall, it seems that from an initial level of around 22 per 1000 children per six months (May through October) in 1976/77, mortality dropped significantly ($P < .005$) to a mean of 17.5/1000 in 1978/79 and to a mean of 10.5 ($P < .005$) by 1980 in the three treatment cells (excluding the "Oralyte; Commercial Sources" cell). This drop in total child mortality is shown graphically in Figure VI. Interestingly the MOH introduced nation-wide measles vaccination as well as an oral rehydration program in September 1977 similarly seemed to have brought about a 20% decline in child mortality.

There were no significant differences in the proportion of male and female deaths in control or treatment cells. In control cells the one month to less than five year mortality rate for males in these six months was 99/5115 = 19.4, among females it was 91/5303 = 17.2. In treatment cells it was 106/9348 = 11.3 for males and 102/9160 = 11.1 for females

Twenty per cent (80) of all Verbal autopsy record forms (394) were selected by random process. Blinding labels were placed over the study cell identification and final diagnosis, and the reports were then photocopied. These copies were sent to an un-biased investigator* for independent assignment of most probable causes of death. Among the 80 cases, 60 (75%) were assigned to diarrheal disease, 18/80 (23%) were due to other causes and for 2/80 (3%) no exact cause could be assigned.

Our and the un-biased observer's diagnoses as to cause of death was in agreement on all diarrheal deaths and on 17/20 (85%) of deaths due to other causes. Two deaths among the three with differing diagnoses were ascribed by us to "Lower Respiratory Tract Infection", and to "Unknown fever" and "neonatal sepsis" by the outside observers. In the third case our and the outside observer's diagnosis were "congenital anomaly" and "failure to thrive" respectively.

Scrutiny of this randomly selected twenty percent sample of verbal autopsy forms suggests that even though the majority of fatal cases were seen by private physicians (50/60 = 83%), only in the minority (25/60 = 42%) were fluids part of the prescribed treatment. Among those that received O.R.T. 76% (19/25) received too small a quantity of it so that 90% (54/60) received either no ORT or in inadequate amounts. In the majority of cases, treatment consisted of one or several antibiotics, intestinal antiseptics and tonics with little, if any, follow-up. Mothers not infrequently consulted two and more private practitioners for the same illness episode.

COST BENEFIT ANALYSIS

Table 13 summarizes the cost for the delivery of the services components of the program up to and beyond routine expenses incurred in the "Control I" cell. Of the total cost 51% was due to salary supplements, 34% to the cost of pre-packaged ORS, 8% to increased transport needs (mainly for supervision), 1% for health education posters and less than half a percent for training. By dividing the costs of the program up to and beyond that encountered in the "Control-1" cell by the total number of children affected by the program, a cost per child was obtained. This cost ranged from L.E. 0.16 ($ 0.23) in "Control-2" villages to L.E. 0.61 ($ 0.87) in the "Sugar/Salt; Prepackaged; home-distribution" villages. In the "Sugar/Salt; home prepared" villages it was L.E. 0.30 ($ 0.43). Lastly, by multiplying the number of the study population in each cell other than "Control-1" by the diarrhea-specific mortality rate in the "Control-1" cell and subtracting the total number of diarrhea-specific deaths observed during the study period in these cells from the product, the number of "averted deaths" was determined to come to 134.

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* *N. Hirschhorn, The John Snow Public Health Group, Inc.*

Table 6

SODIUM CONCENTRATION OF RANDOMLY COLLECTED SAMPLES OF REHYDRATION MIXTURE ON INITIAL (I) AND REPEAT (II) SURVEYS

Study Cell	No. of Samples		Expected sodium conc.	Obtained Na concentration (mmols)						Percent of samples with > 120 mmols	
				mean		S.D.		range			
	I	II		I	II	I	II	I	II	I	II
"Oralyte" home distribution	74	74	90	103	90	8.2	11.4	81-125	63-124	1	1
"Oralyte" through commercial sources	24	22	90	112	101	22.7	15.0	96-173	78-123	21	23
Sugar/Salt mixt; home-prepared	76	69	40	59	48	34.7	16.0	13-250	21-106	4	0
Sugar/Salt mixt. prepackaged; home-distr.	27	28	60	79	64	19.8	10.4	52-121	18-73	4	0

I : Samples taken after 3 home visits
II: Samples taken after 9 home visits

Figure III

SODIUM CONCENTRATION IN HOME PREPARED/DILUTED ELECTROLYTE SOLUTIONS ON INITIAL (I) AND REPEAT (II) SURVEYS

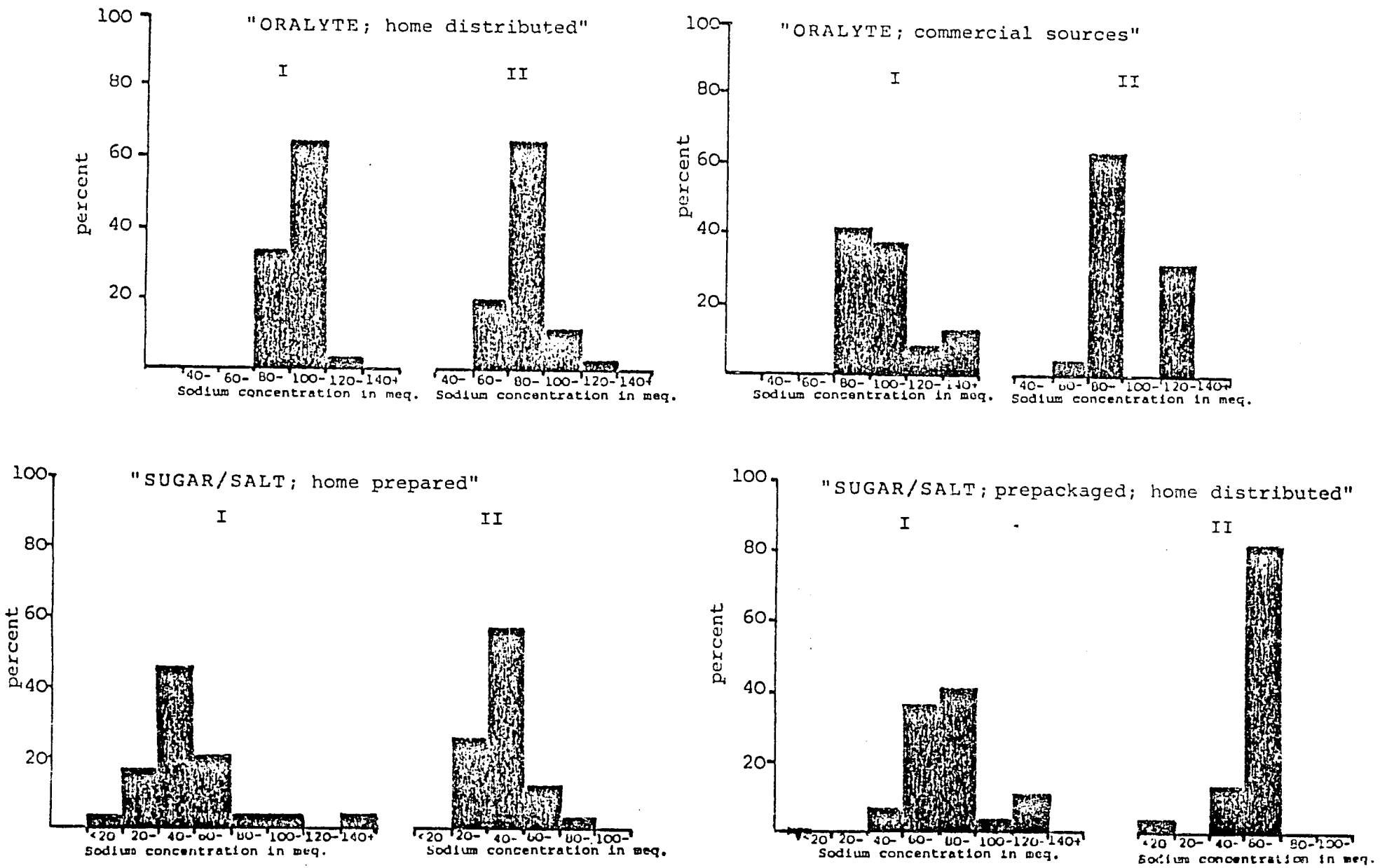


Table 7

CONSUMPTION OF PREPACKAGED REHYDRATION MIXTURES BY SOURCE AND STUDY CELL
(May through October 1980)

Study Cell	Distributed to homes		Commercial Procurement		Used in health facilities		Used by all sources	
	Number	Rate*	Number	Rate*	Number	Rate*	Number	Rate*
Control I pop.: 4400	–	–	–	–	182	0.04	182	0.04
Control 2 pop.: 6018	–	–	–	–	1,093	0.18	1,093	0.18
Oralyte home distributed pop.: 6875	21,799	3.17	–	–	1,541	0.22	23,340	3.39
Oralyte through commercial sources pop.: 2073	–	–	2,106	1.02	512	0.25	2,618	1.26
S/S home prepared pop.: 7023	–	–	–	–	2,571	0.36	2,571	0.36
S/S prepackaged; home-distr. pop.: 2461	12,833	5.21	–	–	631	0.26	13,464	5.47

* per child per six months

CONSUMPTION OF PREPACKAGED REHYDRATION MIXTURE
PER CHILD PER SIX MONTHS BY STUDY CELL
(MAY THROUGH OCTOBER 1980)

Table 8

REFERRAL TO HEALTH FACILITY FOR DIARRHEAL DISEASE OF ONE MONTH TO FIVE YEAR OLD CHILDREN BY AGE GROUP AND STUDY CELL (MAY THROUGH OCTOBER 1980)

STUDY CELL	Referred for Treatment									
	1 month - < 1 year		1 year to <2 yrs		2 yrs to <5 years		Unknown age		All	
	No.	%	No.	%	No.	%	No.	%	No.	%
Control 2 (4400 children)	221	5.0	228	5.2	191	4.3	0	0	640	14.5
Oralyte; home-distribution (6875 children)	342	5.0	218	3.2	143	2.1	4	0.1	707	10.3
Oralyte; commercial sources (2073 children)	47	2.3	42	2.0	36	1.7	1	0	126	6.1
S/S home prep. (7023 children)	371	5.3	280	4.0	191	2.7	0	0	842	12.0
S/S prep; home distribution (2461 children)	176	7.1	151	6.1	118	4.8	0	0	445	18.1
ALL	1157	5.1	919	4.0	679	3.0	5	0.02	2760	12.1

Table 9

PRESENTING SIGNS AND SYMPTOMS ON REFERRAL TO HEALTH FACILITY

MAY THROUGH OCTOBER 1980

STUDY CELL	TOTAL NO. REFERRED		SIGNS AND SYMPTOMS ON REFERRAL															
			DIARRH.		VOMIT.		DEHYD.		BLOOD/PUS		FEVER		Loc. Edema		Gen. Edema		Convuls.	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Control 2 (4400 children)	640	100 14.5	637	99.5 14.5	449	70.1 10.2	134	20.9 3.0	71	11.1 1.6	381	59.5 8.7	6	0.9 0.1	0	0.0 0.0	4	0.6 0.1
Oralyte; home distribution (6875 child.)	707	100 10.3	684	96.8 9.9	181	25.6 2.6	75	10.6 1.1	93	13.2 1.4	303	42.9 4.4	10	1.4 0.2	7	1.0 0.1	11	1.6 0.2
Oralyte; commercial sources; (2073 children)	126	100 6.1	126	100 6.1	55	43.6 2.6	29	23.0 1.4	9	7.1 0.4		33.3 2.0	3	2.4 0.1	2	1.6 0.1	3	2.4 0.1
S/S; home prep. (7023 children)	842	100 12.0	820	97.4 11.7	366	43.5 5.2	94	11.2 1.3	109	12.9 1.5	416	49.4 5.9	5	0.6 0.1	1	0.1 0	2	0.2 0
S/S; prepack; home distrib. (2462 children)	445	100 18.1	443	99.5 18.0	275	61.8 11.2	9	2.0 0.4	8	1.8 0.3	227	51.0 9.2	4	0.9 0.2	0	0 0	0	0 0
All (22832 Children)	2760	100 12.1	2710	98.2 11.9	1326	48.0 5.8	341	12.4 1.5	290	10.5 1.3	1369	49.6 6.0	28	1.0 0.1	10	0.4	20	0.7 0.1

Table 10

PHYSICIAN TREATMENT OF ONE MONTH TO FIVE YEAR OLD CHILDREN REFERRED TO THE HEALTH FACILITY FOR DIARRHEAL DISEASE BY STUDY CELL

MAY THROUGH OCTOBER 1980)

STUDY CELL	All		TREATMENT PROVIDED													
			Oralyte		Nasogast. tube		Parenteral Rehyd.		Antibiotics		Intest. Antiseptics		Antiemetics		Referred to Hospital	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Control 2 (4400 children)	640	100 14.5	299	46.7 6.8	18	2.8 0.4	91	14.2 2.1	547	85.5 12.4	550	85.9 12.5	410	64.1 9.3	48	7.5 1.1
Oralyte; home distribution (6875 children)	707	100 10.3	696	98.4 10.1	11	1.6 0.2	15	2.1 0.2	287	40.6 4.2	559	79.1 8.1	130	18.4 1.9	12	1.7 0.2
Oralyte; commercial sources (2073 children)	126	100 6.1	113	90.0 5.4	3	2.4 0.1	4	3.2 0.2	38	30.1 1.8	106	84.1 5.1	44	34.9 2.1	2	1.6 0.1
S/S home Prep. (7023 children)	842	100 12.0	839	99.6 11.9	12	1.4 0.2	9	1.1 0.1	376	44.6 5.3	568	67.4 8.1	219	26.0 3.1	1	0.1 0
S/S prep; home-distribution (2461 children)	445	100 18.1	427	95.9 17.3	4	0.9 0.2	2	0.4 0.1	76	17.1 3.1	217	48.8 8.8	53	11.9 2.1	0	0 0.0
ALL (22832 children)	2740	100	2374	86.0	48	1.7	121	4.4	1324	48.0	2000	72.5	856	31.0	63	2.3

Table 11

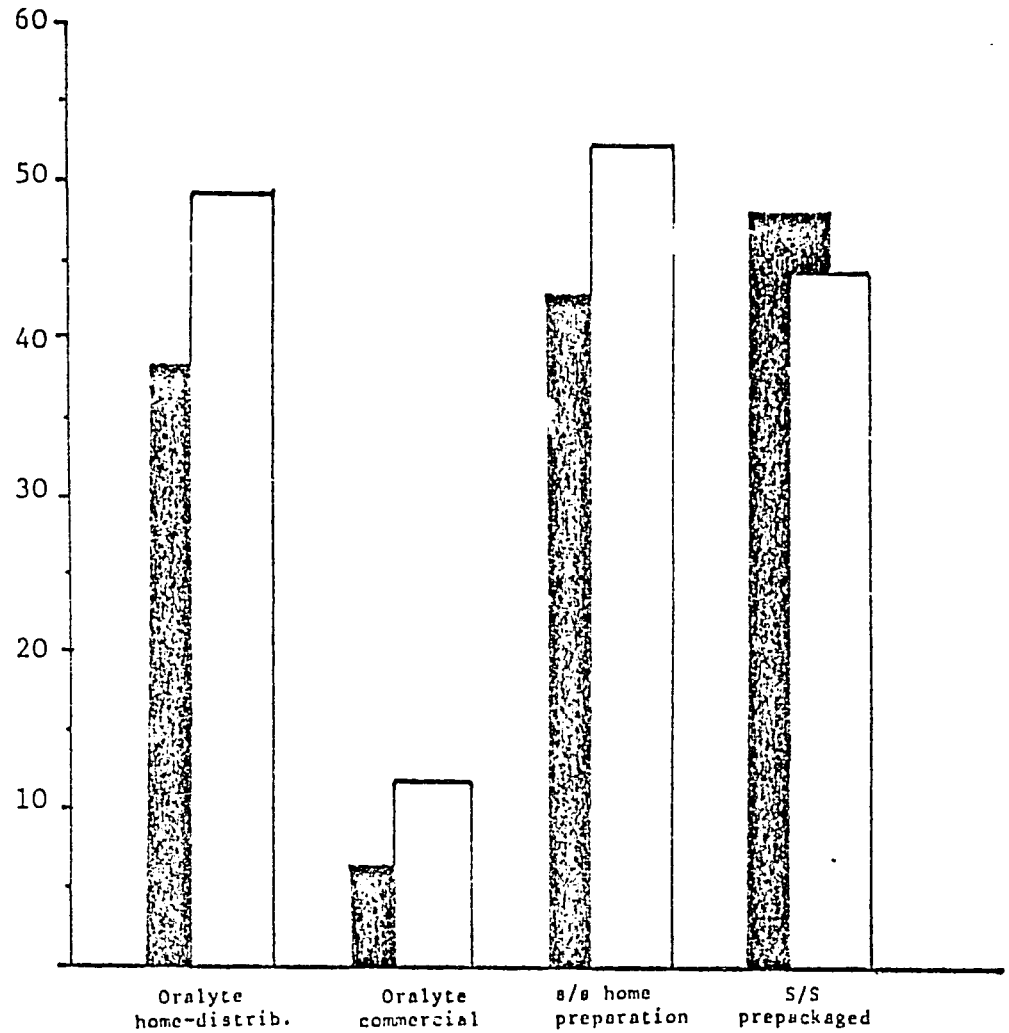
CHILD DEATHS BETWEEN ONE MONTH AND FIVE YEARS OF AGE
BY STUDY CELL (MAY THROUGH OCOTBER 1980)

Study Cell	All Deaths		Diarrhea-specific Deaths	
	Number	Rate*	Number	Rate*
Control 1 (4400 children)	76	17.3	68	15.5
Control 2 (6018 children)	113	18.8	91	15.1
Oralyte home-distrib. (6875 children)	77	11.2	53	7.7
Oralyte commercial sources (2073 children)	35	16.9	28	13.5
S/S home prep. (7023 children)	72	10.3	51	7.3
S/S prep, home distrib. (2461 children)	23	9.3	21	8.5

* per 1000 Children per six months

Figure V

PERCENT REDUCTION IN CHILD DEATHS
BETWEEN ONE MONTH AND FIVE YEARS OF AGE BY STUDY CELL
USING THE TWO CONTROL CELLS AS REFERENCE
(MAY THROUGH OCTOBER 1980)



= All deaths 1 month to < 5 years

= Diarrhea-specific deaths 1 month to<5 years

Table 12

Child Deaths Between One Month and Five Years of Age
During May through October 1976/79 and 1980 by Study Cell

Study Cell	Child mortality 1 month to less than 5 years						Percent difference	Significance "P"
	1976 - 1979			1980				
	Child pop.	No. of deaths	Rate	Child pop.	No. of deaths	Rate		
"Control-1"	7719	150	19.4	4400	76	17.3	-10.8	n.s.
"Control-2"	20318	436	21.5	6018	113	18.8	-14.4	n.s.
"Oralyte; home distribution"	25600	483	18.9	6875	77	11.2	-40.7	<.005
"Oralyte;commercial sources"	7736	154	19.9	2073	35	16.9	-15,1	n.s.
"s/s; home preparation"	29601	523	17.7	7023	72	10.3	-41.8	<.005
"s/s; prepackaged home distribution	9194	215	23.4	2461	23	9.3	-60.3	<.005
All cells	100169	1961	19.6	28850	396	13.7	-30.0	<.005

Figure VI

CHILD MORTALITY BETWEEN ONE MONTH AND FIVE YEARS OF AGE
BY MODE OF O.R.T. PROGRAM DELIVERY
(MAY THROUGH OCTOBER 1976 THROUGH 1980)

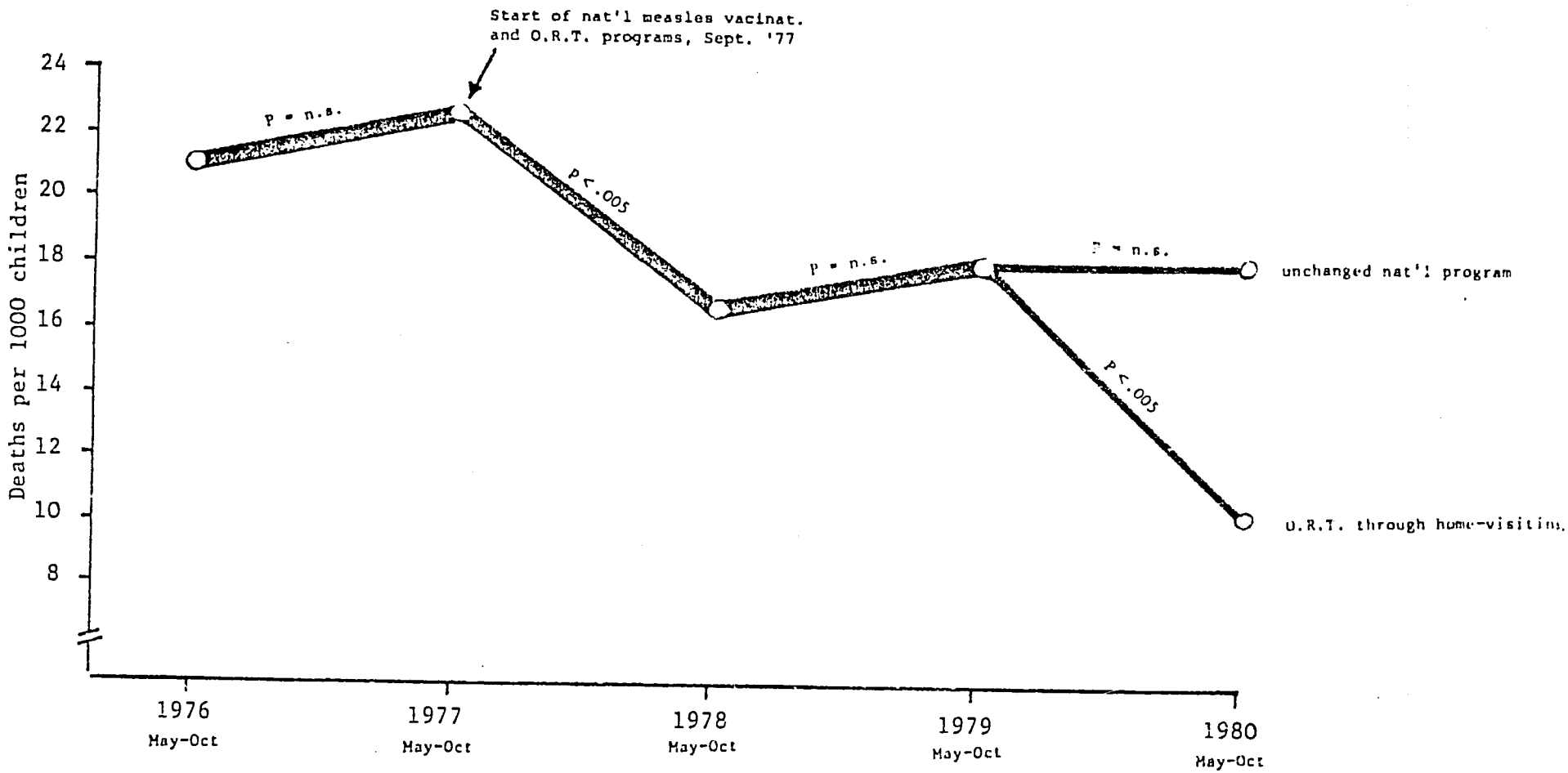


Table 13

COST EFFECTIVENESS OF VARIOUS MEANS OF O.R.T. PROGRAM DELIVERY

COST ITEMS*	STUDY CELL					ALL
	CONTROL II	Oralyte Home distr.	Oralyte Commercial	S/S home-prepared	S/S prep. home dist.	
REHYDRATION SALTS						
Oralyte @ 10 pt/package S/S prep. @ 6 pt/package	84.40	2,305.56	253.23	228.05	822.90	3,694.14
SALARY SUPPLEMENTS						
Nurses, Sanitarians	----	630.-	240.-	720.-	720.-	
Facility Physicians	210.-	288.-	144.-	384.-	144.-	
Supervisory Teams (3)	174.60	181.70	55.-	189.70	65.-	
Periph. Study Admin.	299.-	311.-	94.-	325.-	111.2	
	683.60	1410.70	533.-	1618.70	560.20	4,836.20
TRANSPORT	197.-	205.-	61.50	213.60	73.10	750.20
TRAINING Equipment and food	1.89	15.28	5.47	16.63	6.24	45.51
POSTERS	----	36.97	11.11	38.60	13.22	99.90
Total	966.89	3,973.51	864.31	2,115.58	1505,66	9,425.95
No. of Children covered by program	6018	6875	2073	7023	2461	24,513
Cost per child covered (L.E.)	0.16	0.57	0.42	0.30	0.61	0.38
No. of Deaths averted	2	53	4	58	17	134
Cost per Death averted (L.E.)	483.45	72.97	216.08	36.48	88.57	70.34

* Cost up and beyond that encountered in the Control I cell.

The total cost of the program divided by this number then provides a mean cost per death averted in the study. Extending this calculation to all individual study cells, the cost-effectiveness of each mode of program delivery was established as shown in Figure VII. The cost per death averted ranged from L.E. 36.5 ($ 52) in the"Sugar/Salt; home prepared" cell to L.E. 483.5 ($ 691) in the "Control-2" cell. In the "Oralyte; home distributed" cell it was L.E. 73.- ($ 104).

DISCUSSION

The DDCS was carried out as practical applied research exercise in order to provide information useful for strengthening rural health services in Egypt. The study took great care to develop a practical investigation which could lead to information useful for realistic, nationwide replication of any positive results. In this regard, the SRHD Project was obliged to investigate the early use of a home prepared sugar and salt ORT, since for the forseeable future the ability to distribute Oralyte at the level consistant with need might not exist in Egypt. The kind of information needed by the MOH required the investigators to:

- Ascertain the efficacy and safety of alternative configurations of treatment and their cost.

- Ascertain the effect of different configuration of service delivery on such factors as mortality, utilization, referral and cost.

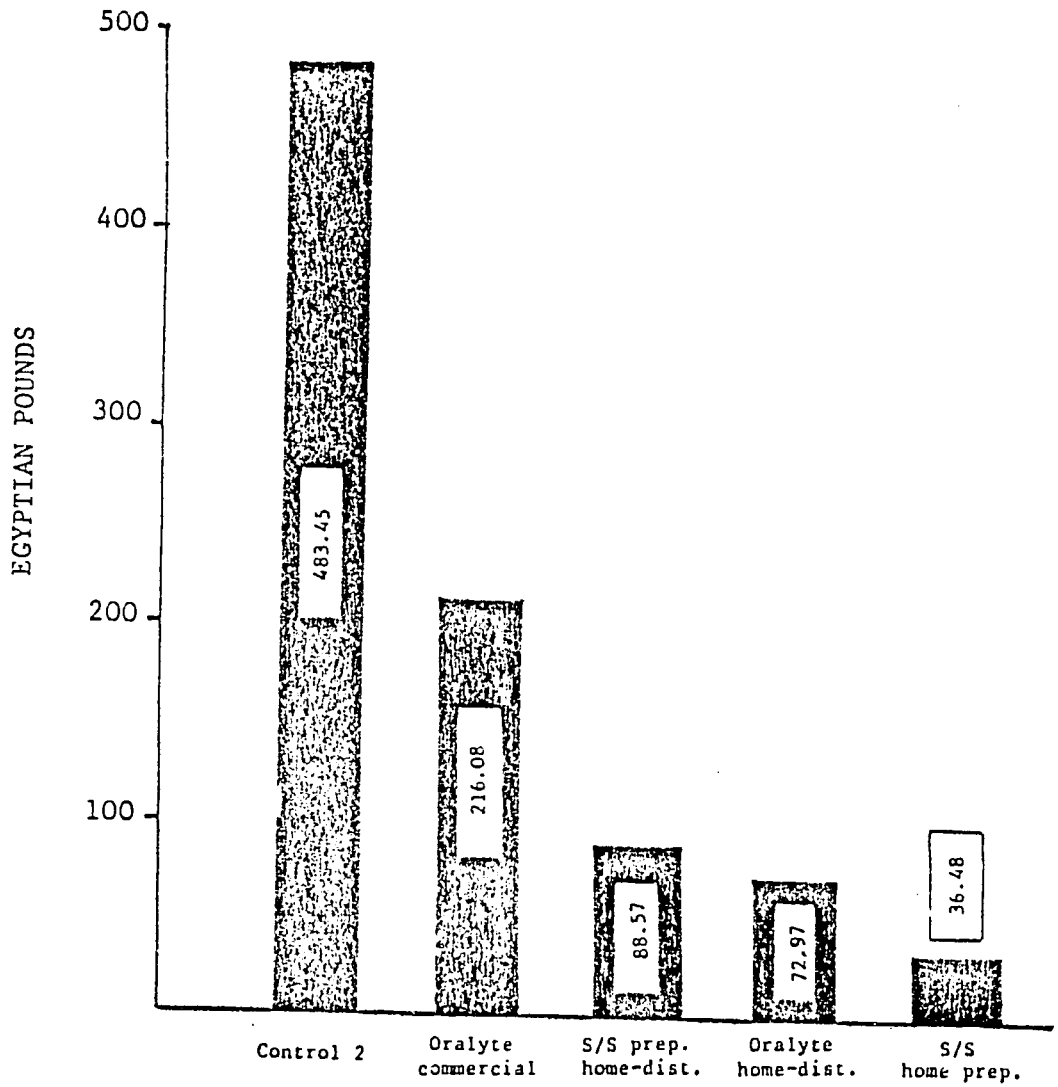
In this study different variations of ORT and alternative service delivery patterns have been examined. Answers have been obtained to many of the questions which provided the inputs for undertaking this study. This investigation has demonstrated that several configurations of ORT can be effective in reducing child deaths from diarrhea.

Mortality results based on child populations as denominator are less reliable than when calculated on the basis of disease incidence. Disease incidence however, is difficult if not impossible, to obtain to any extent of accuracy in other than either the hospital setting or the small scale, intensive research effort currently carried out by special research institutes in but few locations in the world.

The fact that our mortality results are virtually identical whether looked at longitudinally - by study cell over the preceding four years, or vertically - by comparing treatment with control cells, greatly strengthens their validity and tends to prove the efficacy of the various modules of O.R.T. delivery tried in this program.

Figure VII

COST PER DEATH AVERTED IN EGYPTIAN POUNDS BY STUDY CELL
USING CONTROL 1 AS REFERENCE
(MAY THROUGH OCTOBER 1980)



Indeed depending on the specific service configuration and the delivery system, ORT can be the basis of an inexpensive program for combatting diarrhea-specific deaths, and easily integrated with the existing health service. At high levels of diarrheal disease prevalence and high mortality from diarrheal disease, ORT in the form of a simple sugar and salt solution in the hands of mothers and backed by a balanced electrolyte solution in the hands of the health care provider is a viable and cost-effective way of reducing child mortality. It must be underscored, however, that diarrhea-specific deaths constitute a substantial portion of child deaths both in absolute and percentage terms in Egypt; hence, the rather dramatic reduction in total child mortality seen in this study. Total child mortality might not drop so precipitously in other countries where the distribution of the causes of child deaths is less skewed.

More important than showing that a program based on ORT using sugar and salt and balanced electrolyte solution was equally effective as one based entirely on balanced electrolyte solution was the demonstration that both were effective when used early on in disease by the mother. This largely underscores the need for and importance of intensive maternal education in, and delegation to her for, initial diagnosis and management of the condition. Considering that in rural Egypt alone, annually almost 100,000 pre-school children die from diarrheal disease and that up to half of these deaths could be prevented by an intensive program, treatment alternatives become essential both with respect to resource availability/accessibility over-time and overall cost. In our study an average of 12% of all preschool children were seen on an outpatient basis, each requiring 2.3 packages. Extraprolating this figure to all of rural Egypt's 20 million, 940,000 packages of Oralyte would be required only for in-facility use. Additionally an average of four packages per child per 6 month was needed in home distribution cells adding 13.6 million packages which brings the total for rural Egypt and for the six summer months to 23 million packets, an amount that could certainly be supplied within four to five years but not this year, the next or the year after. In the meantime, however, the sugar and salt alternative offers the advantages of ready availability - only 1 million packages per summer season of Oralyte would be required for rural Egypt, - and cost - the program is half as expensive. Interestingly the Narangwal Study carried out ten years ago in India, was able to avert a child-death (non-specific) with an integrated health service package which concentrated on MCH services* for about the same amount that it cost us in the "Sugar and Salt; home preparation" cell.

Of great importance to the Egyptian MOH is that ORT can be effective programatically, when carried out as a part of the exisiting MOH in-frastructure. This study was run entirely by MOH personnel in the field supplemented only by the SRHD central staff. A major concern before undertaking this study was the eventual reproducibility of the results should this be warranted.

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* *R. L. Parker, C. E. Taylor, A. A. Kielmann et. al., the Narangwal experiment on interactions of nutrition and infections: III. Measurement of services and costs and their relation to outcome. Indian J med Res (Suppl.) 68., 42, 1978.*

Four areas have been identified as crucial to the success of any ORT program which might be instituted in Egypt.

- The existing health care delivery system needs to be modified to the extent that home-visiting must become a routine part of the health services to assure availability and use of services.

- Unfamiliarity with ORT by health workers necessitates training of workers in the use of ORT.

- Supervision of health staff in Egypt currently proceeds at an unsatisfactory level, and is substantively not as useful as would be expected of such a vast supervisory network. Both the quantity and quality of supervision need to be put into the supervisory network.

- Staff in the DDCS do a significant amount of extra work to implement a diarrheal disease control program. Incentives must be paid to make the program a success. Incentives have been made at a level in this study which can be realistically reproduced nation-wide by the MOH.

One of the most exciting aspects of this investigation has been the demonstration that mothers can be taught, and that they can become proficient in early management of diarrheal disease using ORT. However, it needs to be underscored that a health education effort needs to be repeated and continuous. Judging from both the mortality data as well as the diarrhea treatment and referral survey results, rehydration by mothers with sugar and salt seemed at least equally safe as with Oralyte. Thus incidences of periorbital edema, generalized edema and convulsions (possible indicators of hypernatemia) were no higher in the sugar and salt cells than in the Oralyte cells

Success with village mothers suggests a potential for greater participation by the mother in the care of her child as guided by government health services. Indeed, community participation at the most meaningful level has been demonstrated and can be built upon. Almost all mothers were proficient at the end of nine visits by the nurse in using an acceptable teaspoon (volume), correctly measuring one liter of water, and in producing a safe and useful ORT solution. From the "rehydration-on-larger-scale" point of view, nine visits may not be feasible. However, in our study, maternal knowledge and skill rose to "acceptable levels already after three home visits. Whether less than these three visits would have sufficed, cannot be assumed here, but the fact that up to four percent of rehydration mixtures in the home-preparation villages showed too high a sodium concentration even after these three visits seems to negate the question. Another illustration of maternal concern may be the observation that from among those children that

died, 91% had consulted a qualified medical practitioner (private, M.D., facility M.D. or hospital), 46% had consulted a second, and 9% yet a third "qualified" source.

It was somewhat surprising that the pharmacist / shopkeeper provided such disappointing performance as a source of ORT. Relative to the other study cells where pre-packaged oral rehydrant was distributed, a small amount of Oralyte was purchased by the community amounting to only one packet per child per six months. Moreover, among those mothers in the "Oralyte Commercial Sources" cell and only in this cell, there was an unacceptably high proportion of mothers who prepared an unsafe ORT. Reasons for this poor performance are probably rooted more in project design and with the pharmacist/shopkeepers than with the mothers. The project simply did not provide a strong training program for pharmacists/shopkeepers. A spot check of the pharmacists/shopkeepers during the DDCS revealed that none of these persons could give correct instruction on the use of pre-packaged oral rehydrant. However, lack of education was not the only factor contributing to the poor performance in this study cell. Shopkeepers and pharmacists conceded that the profitability of pre-packaged oral rehydrant was insufficient. It seems highly unlikely that without intensive education of pharmacists/shopkeepers as well as motivation, commercial outlets are an effective way of delivering oral rehydrants. At best, however, it seems improbable that this distribution alternative can be as cost-effective as sugar and salt home preparation. In addition, a commercial outlet is open for only a limited number of hours a day: a problem shared by the health facility and one reason for seeking alternatives to the health facility as distribution source complementary to the health facility. It is certain that the household survey, as yet not analyzed, will contribute further meaningful information on this subject.

Also with regard to consumption of pre-packaged rehydration mixture an interesting pattern emerged in the different study cells. The use by all sources of Oralyte in the "Oralyte; home distribution" cell was about half of the rate of that from all sources of oral rehydrants used in the "Sugar/Salt; pre-packaged, home distribution" villages. As the in-facility use for both cells was not statistically different, the cause of the difference lay in the rate of use of Oralyte or prepackaged Sugar/Salt in the home. Reasons for this difference are not clear. Perhaps because pre-packaged sugar/salt ORS is not a balanced electroyte ORT, the diarrheal disease contineud some-what longer and more of the solution was needed to have the same physiologic effect as a lesser quantity of Oralyte.

The study also rather clearly showed that the concentration of the principal electrolyte - sodium - need not be within the narrow range commonly assumed. In our study the range of sodium concentrations was deliberately chosen to be between 40 and 90 meq. yet mortality effects in the cells with these different sodium con-

concentrations were virtually identical. This last finding would tend to qualify the program effected in the "Sugar/Salt; home prepared" villages, where home supplies were used in conjunction with Oralyte as one "Appropriate Technology" intervention.

PART II

FINANCIAL REPORT

COSTING

Up-to-date expenditure including cost for Oralyte imported from the U.S. has amounted to L.E. 8.485.15 and US$ 22,255.28. This represents less than one fifth of the total pound funds and less than two thirds of the Dollar funds available for the study. A sizeable portion of Dollar funds spent (46%) went into shipping and handling of Oralyte from abroad.

EXPENDITURES (April 21, 1980 through October 31, 1980)

Category	SOURCE OF FUNDS					
	U S A I D			W H O		
	Funded	Spent	Balance	Funded	Spent	Balance
A) Personnel 1- Local 2- Expatriate - salary - per diem	L.E. 14,110.- US$ 24.100.-*	L.E. 3,482.45 US$ 800.- L.E. 413.60				
B) 1- Equipment 2- Oral Reh. Salts	L.E. 47,000.-	L.E. 3,755.850 US$ 16,474,87**	L.E. 33,144.15	US$ 10,000	US$ 4,980.41***	US$ 5,019.59
C) In Country Transportation (Incl. Per diem)	L.E. 500.-	L.E. 244.-	L.E. 256.-			
D) Training and Conferences	L.E. 700.-	L.E. 589.25	L.E. 110.75			
Subtotal Contingency	L.E. 62,310.- L.E. 6,290.-	L.E. 8,485.15				
T O T A L	L.E. 68,600.- US$ 24,100.-	L.E. 8,485.15 US$ 17,274.87	L.E. 60,114.85 US$ 6,825.13	US$ 10,000	US$ 4,980.41	US$ 5,019.59

* *Intended for expatriate consultant*

** *This amount includes cost of 100,000 packages of Oralyte ($ 7000.-) and their transport and handling charges ($ 9,474.87).*

*** *US$ 2143.- (L.E.1500.-) for local production of 25,000 prepackaged Sugar-Salt mixtures; US$ 2097.- for 29,9600.- packets of Oralyte, and US$ 740.41 (SFr 1,258.70) for their shipping and handling.*

PART III

ADDITIONAL PERSONNEL ACTIVE IN THE STUDY

List of additional Personnel active in the Study (listed alphabetically)

I) CENTRAL (SRHD) OFFICE

Dr. C. Ajello (expatriate consultant) - data collection, household survey preparation, data analysis, acting technical advisor.

Mr. B. B. Attallah (adm. assistant) - data collection, data analysis

Miss Amna Bastawi (training assistant) - preparation of survey forms.

Mr. Hassan A. Hassan (statistical assistant) - preparation of household survey forms, monitoring of all survey activities, data analysis.

Dr. C. McCord (expatriate, voluntary consultant) - preparation of study proposal.

Dr. A. Nagaty (executive project director) - development of study proposal, training of program staff.

Dr. M. El-Nomroussy (consultant) - preparation of study proposal, data analysis.

Mr. Faiez T. Sourial (accountant) - financial administration of study.

Miss Mona Kamel Youssef (secretary) - typing of forms and reports.

II) PERIPHERAL (GOVERNORATE AND DISTRICT) PERSONNEL

1) Consultants

Dr. M. Bassussi, professor of pediatrics, Mansurah University
Dr. A. Mohssen, Undersecretary of State, Dakahlia governorate.

2) Acting (local) Study Directors

Dr. M. Mouafi (facility physician)
Dr. Saber Saber El Sayes (facility physician)
Dr. M. Sabry Osman (facility physician)

3) Supervisory Teams:

Sinbellawen:
Dr. Mahmoud El Sayed Mahmoud Ebeed, Physican
Mr. Soliman El Saied Soliman, Sanitarian
Mrs. Nargess Farag Youssef, Nurse

Dekernis:
Dr. Osman Ali Osman, Physician
Mr. Mohamed Mohamed Abdalla, Sanitarian
Mrs. Magda Abaza, Nurse

Miniet El Nasr:
Dr. Mohamed Sabry Osman, Physician
Mr. Atef Mohamed Abdel Aziz, Sanitarian
Mrs. Afaf Mohamed Abdel Rahman El Mohandes, Nurse

4) "Flying Doctors":

Dr. Mohamed Gad Mohamed Ibrahim	(facility physician, Kafr Alam)
Dr. Mostafa Abdel Moneim El Sabruti	(facility physician, Mit Assem)
Dr. Saber Saber El Sayes	(facility physician, Ashmoun Roman)
Dr. Sabet Khattas Assaad	(facility physician, Abou Dawood)
Dr. Sami Abdel Khafar Ali	(facility physician, Mit Adlan)

5) Survey Team:

Mrs. Ekram Abou El Maged	(social scientist, team leader)
Ms. Hewaida Taha Shoeieb	(interviewer)
Ms. Ragaa Mohamed Abdou	(interviewer)

6) Facility Physicians

Sinbellawen

Dr. Sabet Khattas Assaad	(Abou Daoud)
Dr. Mahmoud Hamed Saker	(Bar Hamtush)
Dr. Mahmoud Hamed Mouafi	(Kafr Ghannam)
Dr. Mohamed Mohamed Ibrahim	(Teranis)
Dr. Mahmoud El Sayed Mahmoud	(Barkein)
Dr. Ahmed Saad El Bayoumy	(Mit Gharita)
Dr. Mahmoud Hamed Saker	(Kafr El Ananaa)
Dr. Ali Mansour Ali	(Abu Seer)
Dr. Rabaa Abdel Megid Abdel Kalik	(Tuch Al Aklam)
Dr. Ahmed Abdel Hamid S. Ahmed	(El Zaheira)
Dr. Eid El Hakkim El Saied Mohamed	(Mukataa)

Dekernis

Dr. Osman Ali Osman	(Beni Ebid)
Dr. Sami Abdel Khafar Ali	(Mit Adlan)
Dr. El Sayed Abdel Aziz	(Nigir)
Dr. Morcos Abdel Missieh	(Mit Dafer)
Dr. Hamed Abdel Wahab	(Dimuh)
Dr. Saber Saber El Sayes	(Ashmoun Roman)
Dr. Ahmed Abdel Latif Habib	(Mit Sued)
Dr. El Sayed Ahmed Ali	(Mit Taarif)
Dr. Mohamed Mohamed El Dawoody	(Kalyobeya)

Miniet El Nasr

Dr. Mohamed Gad Mohamed Ibrahim	(Kafr Alam)
Dr. Mostapha A.M. El Sabruti	(Kafr Abu Zikri)
Dr. Mohamed Gad M. Ibrahim	(Brembal Gedida)
Dr. Nabaweya Gomaa Shaaban	(Mit Kholi Mo'men)
Dr. Mostapha A.M. El Sabruti	(Mit Hadid)
Dr. Fatma Mohamed Marei	(Riad)

7) Facility Nurses

Sinbellawen

Ms. Afaf Mohamed Khalil	(Mukataa)
Ms. Nadia Hassan Ibrahim	(Mukataa)
Ms. Nadia Abdel Azim Ibrahim	(Abu Seer)
Ms. Fatma Mohamed Abdel Fatah	(Abu Seer)
Ms. Khayreya Ali Khalil	(Abu Seer)

Ms. Fatma Mohamed Afifi	(Mit Gharita)
Ms. Aza Abdel Hamid Shaaban	(Mit Gharita)
Ms. Nadia Abdel Azim Mohamed	(Mit Gharita)
Ms. Soad Abdel Ghafar Mahmoud	(Mit Gharita)
Ms. Amina Sadek El Sherbini	(Tuch el Aklam)
Ms. Laila Mansour Hamama	(Tuch Al Aklam)
Ms. Ayda Mohamed Amin	(Abou Daoud)
Ms. Fatma Ismail Abdel Al	(Abu Daoud)
Ms. El Sayeda Ali Rashad	(Barkein)
Ms. Laila Malak Ismail	(Barkein)
Ms. Noussa Malak Youssef	(Kafr El Ananaa)
Ms. Om Hashem Abdel Hafez	(Kafr El Ananaa)
Ms. Tafadi Mohamed Ali	(Kafr El Ananaa)
Ms. Laila Saad Bassal	(Kafr Ghanam)
Ms. Nawal Mohamed el Gharib	(Kafr Ghanam)
Ms. Magda Fathi Ismail	(Teranis)
Ms. Hanaa El Sebai Mohamed	(Teranis)
Ms. Wafdeya Mahmoud Selim	(El Zaheira)
Ms. Laila Ahmed Gomaa	(El Zaheira)
Ms. Soad Abdel Ghafar Mahmoud	(El Zaheira)

Dekernis

Ms. Laila Mahmoud El Sayed	(Beni Ebid)
Ms. Amina Mohamed Ibrahim	(Beni Ebid)
Ms. Zeinab Sadek Abdallah	(Beni Ebid)
Ms. Asmahan Fahmi Ossman	(Beni Ebid)
Ms. Kamelya Mohamed Hassan	(Beni Ebid)
Ms. Fatma Ahmed Abdel Fattah	(Beni Ebid)
Ms. Badia Abdel Hamid Hegazi	(Beni Ebid)
Ms. Nawzat Abdel Salam Mohamed	(Mit Adlan)
Ms. Sahar Hassan Hussein	(Mit Adlan)
Ms. Hoda El Sayed Ibrahim	(Mit Adlan)
Ms. Hanem Ali	(Nigir)
Ms. Khadiga Kamel Mohamed	(Mit Dafer)
Ms. Bouthayna Abdel Razek Hassan	(Dimuh)
Ms. Manal Ragab Badr El Din	(Ashmoun Roman)
Ms. Rabha Shabban Mohamed	(Mit Sued)
Ms. Rawya Mohamed El Sayed	(Mit Taarif)
Ms. Rouyat Ramadan El Moursy	(Kalyobeya)

Miniet el Nasr

Ms. Sabra Mohamed Hussein El Imam	(Kafr Alam)
Ms. Faten Abdel Wehab	(Kafr Alam)
Ms. Salwa Ali Amer	(Kafr Alam)
Ms. Fatma Ramadan el Sayed	(Kafr Alam)
Ms. Salwa Saad Salem	(Kafr Alam)
Ms. Samya Sagued Abdel Hadi	(Brembal)
Ms. Laila Ahmed El Ketani	(Brembal)
Ms. Azhar Maati	(Brembal)
Ms. Ganaa Mohamed Ali Daoud	(Brembal)
Ms. Rabha Abdel Ghafar Eguez	(Brembal)
Ms. Khalila Abdou Habib Ayoub	(Brembal)
Ms. Zeinab Lotfi Kamel	(Brembal)

Ms. Fawzeya Mahmoud Mosharaf	(Mit Assem)
Ms. Hanem El Sayed Mostafa	(Mit Assem)
Ms. Bashira Abdel Moneim	(Mit Kholi Mo'men)
Ms. Fatma Mohamed El Sayed	(Mit Kholi Mo'men)
Ms. Fatma Mohamed El Werdani	(Mit Kholi Mo'men)
Ms. Hamida Mohamed Kamal	(Mit Kholi Mo'men)

8) Facility Sanitarians

Sinbellawen

Ismat Ragab Gafar	(Abou-Daoud)
Mohamed Abdel Rahman Khalil	(Bar Hamtush)
Fahim Boulous	(Kafr Ghannam)
Mousaad Mohamed Hegazy	(Teranis)
Ahmed Mohamed Mouman	(Barkein)
Ibrahim Youssry El Ataf	(Mit Gharita)
Mohamed Abdel Rahman Khalil	(Kafr El Ananaa)
Atef Michael Fahmy	(Abu Seer)
Ali Ismail Ali	(Tuch Al Aklam)
Salah Mohamed El Essawy	(El Zaheira)
Soliman El Sayed Soiman	(Mukataa)

Dekernis

El Sayed Abdel Moneim Abdel Kadei	(Beni Ebid)
Kassem Ali Hussein	(Mit Adlan)
Badawi Abdel Moneim Mohamed Omar	(Nigir)
Mohamed Sami Ali	(Mit Dafar)
El Sayed El Hassanein Ibrahim	(Dimuh)
Ahmed Mahmoud Hegazy	(Ashmoun Roman)
Ali Abdel Khafar Mohamed	(Mit Sued)
Mahmoud Abdel Bary El Zayat	(Mit Taarif)
Mohmoud Abdel Bary El Zayat	(Kalyobeya)

Miniet El Nasr

Adel Awaad El Mitawli	(Kafr Alam)
Ibrahim Ahmed Abdel Latif	(Kafr Abu Zikri)
Ahmed Mohamed Ebid	(Brembal Gedida)
Awaad El Mitwali Awad	(Mit Kholi Mo'men)
Mohamed Hassan El Wassif	(Mit Hadid).
Ahmed Mohamed Ageez	(Riad)

9) District and Governorate Clerks

Salah Mohamed El Awadi	(Sinbellawen)
Mohamed Abdel Hadi Shabi	(Dekernis)
Gamal Mahmoud El Saied	(Miniet El Nasr)

10) Other Staff

Mr. Wagih Ibrahim El Shourbagy	(Governorate General Assistant)
Mrs. Kamilia Hassan Mitwally	(Typist)

APPENDIX III

TREATMENT AND REFERRAL

METHODOLOGY

Design:

The home-visiting program by the nurse had been implemented as a a routine part of the SRHD program prior to the study. Hence home-visiting served as a means to deliver the study activities, and to maintain a high preschool children coverage.

During home-visits, nurses instructed mothers on how to early detect child diarrhea. Mothers were instructed on how to prepere Oral Rehydration Solution (ORS), the method was dependent on the study cell. Mothers were then instructed on how to adminster the ORS, and continue feeding as appropriate. Nurses encountering a child with diarrheal disease during home-visiting,were instructed to prepare ORS along with the mother, give it to the child, and ask the mother to continue to adminster the solution to the child. If the physical condition of the child warranted referral to the doctor, the nurse initiate Oral Rehydration Therapy (ORT) using Oralyte and had the child brought to the clinic .

Mother was instructed to refer her child immediately to the health facility under any of several circumstances:

- o Child has either of two locally, well reconganized conditions:
  - "Nazla" (diarrhea and vomiting).
  - "Dysenteria" (diarrhea and blood &/or pus in stool).
- o Child looks no better or worse on the day following start of ORT.
- o Child continues to have diarrhea for more than two days after ORT starts.
- o Mother felt unsure or worried at any time.

The treatment regimen used at the health facility was identical in all treatment and " Control -2" cells irrespctive of other experimental differences. The treatment was to rehydrate using ORT specifically in the form of Oralyte, and to refer severely dehydrated children or children in shock to the district or governorate hospital. In "Control -1" facilities no effort was made to influence doctors' current treatment regimen.

Data Collection:

Physicians in all treatment villages as well as in "Control -2" cell villages were instructed to record, regularly, the number of all preschool child patients seen for diarrheal disease in the course of their routine outpatient as well as after-hours private practice. The treatment and referral record was designed to obtain information about presenting signs/symptoms, treatment prescribed, and referral. This survey was not done in "Control-1" villages. Filled-in forms were collected from the facilities on a weekly basis.

RESULTS

General:

- In total, 3455 children were seen in the course of outpatient clinics of the rural health facilities and diagnosed as suffering from diarrheal disease. These children, who represent 14% of under five child population of the study villages were seen during the 9 months study period May 1980 through Jan. 1981. Fifty six percent of these were male children and 44% were females. The vast majority, 94%, were seen during the regular working hours. The remainder 6% were seen after hours in the course of "Private" practice.

- Table 1 shows distribution of cases by study cell. The rate of children seen ranged from 7% of the child population in Oralye Commercial Distribution (OR-CD) cell, to 21% in Sugar/Salt Prepacked Home Distribution (SS-PP)cell. The rate in each of the Sugar/Salt Home Prepared (SS-HP), Oralyte Home Distribution (OR-HD), and Control cells, were around the average rate of 14%.

Table 1: Distribution of Children with Diarrheal Diseae seen in Clinics by study cell

Sutdy Cell	Child Pop.	Cases		% cases seen on Private
		No.	%	
SS - HP	7,023	929	13.2	7.5
OR - HD	6,875	918	13.4	5.6
SS - PP	2,461	516	21.0	8.5
OR - CD	2,073	151	7.3	10.2
Control	6,018	904	15.0	3.0
All	24,450	3418 *	14.0	6.1

* 37 cases were undefined.

- Table 2 and Graph 1 shwo distribution of cases seen by month of study. The highest referrals to the facilities were during the hot months May through August, with the peak in July. November, however shows a rise of 70% over October.

- Fourty two percent of cases (table 3) were under one year of age, 33% in the second year, 15% in the third year, and only 9% over 3 years of age. Despite the phenomenon of accumulation of cases at rounded ages, almost 30% of all cases were 6 to less than 12 months of age.

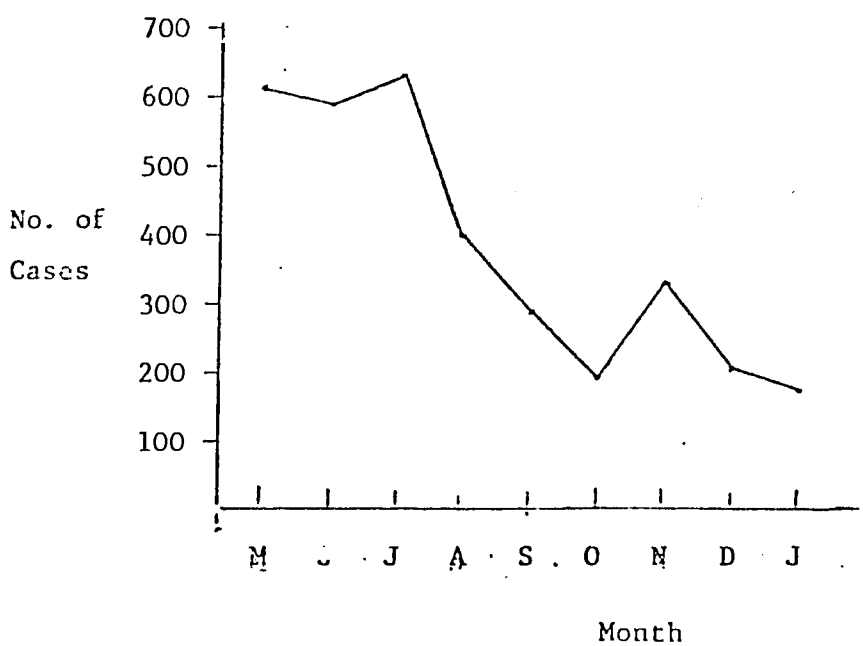
Table 2: Distribution of cases by month of Study

Month	No.	%
May 1980	616	17.8
June	588	17.0
July	635	18.4
August	400	11.6
September	288	8.3
October	197	5.7
November	335	9.7
December	212	6.1
January 1981	184	5.3

Table 3: Distriution of cases by age

Age in mo.	No.	%	
0 -	[illegible]	2.8	42.4
3 -	342	9.9	
6 -	628	18.2	
9 -	395	11.5	
12 -	792	23.0	33.3
18 -	354	10.3	
24 -	518	15.0	
36 -	217	6.3	
48 -	73	2.1	
60 +	30	0.9	

Graph 1: Distribution of cases by month of Study



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Presenting Symptoms/Signs:

- Almost 99% of all cases presented on examination by the facility doctor with the chief complaint of diarrhea. Almost half were vomiting &/or febrile, but 12.6% showed signs of Dehydration. Ten percent presented history of passing blood and/or pus in stool. One percent showed peri-orbital oedema, half percent showed generalized oedema and one percent presented a history of convulsions.

- Table 4 details percentages of presenting Symptoms/Signs by study cell. Other than Diarrhea, 72% of patients in the Control cell presented with Vomiting and 63% were febrile. Of inerests is to note that Dehydration were of high frequency in the OR-CD and Control cells (24 & 20% respectively), of moderate frequency in SS-HP and OR-HD cells(11% each), but apparently of a relatively very low frequency (2%) in the SS-PP cell. Passing blood/pus in stool was relatively frequent in the SS-HP (14%), Control and OR-HD cells (10% each), compared to 5% and 2% in the OR-CD and SS-PP cell respectively. The signs that might be possible indicators of hyper-natremia,(i.e generalized and/or periorbital oedema and/or convulsions) were most frequent in the OR-CD (9.2%) and OR-HD (3.5%), but less frequent in the SS-HP, SS-PP and Control cells (1.1, 0.8, and 1.4%, respectively).

Table 4: Presenting Symptoms/Signs in percent, by Study Cell

Study Cell	SS-HP	OR-HD	SS-PP	OR-CD	Control	ALL
Child Population	7023	6875	2461	2073	6018	24,450
No. of Cases	1032 *	815 *	516	151	904	3,418
Symtopms/Signs:						
- Diarrhea	99.3	97.4	99.8	98.7	99.3	98.6
- Vomiting	43.9	28.1	55.7	45.3	71.6	49.3
- Dehydration	11.4	10.8	2.1	23.8	19.6	12.6
- Blood/Pus	14.2	9.8	1.9	5.4	10.2	9.8
- Fever	51.6	42.1	46.6	38.3	62.9	51.0
- Periorbital Oedema	0.3	1.5	0.8	2.6	0.7	0.9
- Gen. Oedema	0.2	0.8	.0	2.0	0.3	0.4
- Convulsions	0.5	1.2	.0	4.6	0.4	0.8

* Differences from Table 1 are due to misplacement of one village in SS-HP cell instead of OR-HD cell in the course of computer data analysis. Corrections from raw data were made for the last three signs.

- Table 5 presents percent distribution of presenting Symptom/Signs Combinations by study cell. Overall four combinations accounted for 79% of cases. These are: Diarrhea alone (23%), Diarrhea - Vomiting - Fever(22%), Diarrhea - Fever (18%), and Diarrhea -Vomiting (16%) . While these combinations were the major presenting combinations in almost all cells, their order was not maintained. One third of patients in the OR-HD presented with Dirrhea alone , compared to 30% in each of the OR-CD & SS-PP cells, and 20% in the SS-HP cell, but only 10% in the Control cell. Diarrhea-Vomiting-Fever was the more frequent combination in the Control (36%) and the SS-PP (32%). Diarrhea- Fever was the more frequent combination (24%) in the SS-HP cell.

Table 5: Percent Distribution of Presenting Symptoms/Signs Combination by Study Cell, in order of their Overall Proportions

Symptoms/Signs Combinations	Study Cells					ALL
	SS-HP	OR-HD	SS-PP	OR-CD	Control	
- Diarrhea alone	20.0	33.4	29.8	29.9	10.1	22.5
- Diarhea, Vomiting, Fever	15.5	11.7	31.6	9.1	36.4	22.3
- Diarrhea, Fever	23.9	21.7	12.7	17.7	11.2	18.1
- Diarrhea, Vomiting	18.0	11.1	21.8	15.6	14.4	15.9
- Diarrhea, Vomiting, Fever, Dehyd.	1.9	0.2	1.4	8.2	8.4	3.4
- Diarrhea,Vom.,Dehyd.	1.2	1.7	0.2	10.2	7.1	3.1
- Diarhea, Dehyd.	3.3	7.0	0.6	2.7	0.8	3.1
- Diarrhea,Blood./Pus	2.4	3.7	1.0	2.7	2.2	2.5
- Diarrhea,Blood/Pus, Fever	2.8	3.4	0.4	.0	2.2	2.3
- Diarrhea, Blood/Pus, Fever, Vomiting	3.4	1.5	0.4	.0	2.0	2.0
- Other Combinations	7.6	4.5	0.2	3.4	5.3	4.9

Treatment:

- Table 6 shows the treatment provided by the physicians. Overall, ORT was given to 84% of children. Two percent received Oralyte through nasogastric tube and 4% were rehydrated parenterally. Only 48% of patients received ORT in the Control cell, compared to 88% in OR-CD cell and between 96% and 98% in the other 3 cells. Fluids adminstered parenterally and through nasogastric tuble were more frequent in the Control cell (13 & 4%), but much less frequent in the OR-HD cell (0.4 & 0.9%), and in the SS-PP cell (0.2 & 0.6%).

- Antibiotics were prescribed to 50% of all patients, but it ranged from only 14% in the SS-PP cell, to as high as 85% in the Control cell. While intestinal antiseptics were highly used in all cells (81% overall), they were heavily used in the SS-PP cell (94%) and Control cell (92%). Antiemetics were least used in SS-PP (9%), but more frequently used in the Control (65%). The overall rate of its use is 33%.

- Of all cases examined by physicians, 2.5% were referred to hospital. Referrals were highest among Control cell children (6.7%) and OR-CD cell (4.2%). moderate in the SS-HP cell (1.5%), and lowest in SS-PP (0.2%) and OR-HD (0.1%) cells.

Table 6: Treatment given (by drug Graph) and Referral to Hospital by Study Cell

DRUG	STUDY CELL					ALL
	SS-HP	OR-HD	SS-PP	OR-CD	Control	
Oral Rehydrant (OR)	1001 (97.0)	802 (98.4)	494 (95.7)	130 (87.8)	429 (47.5)	2856 (83.6)
Nasogastic Fluid	27 (2.6)	7 (0.9)	3 (0.6)	3 (2.1)	35 (3.9)	75 (2.2)
Parenteral Fluid	18 (1.7)	3 (0.4)	1 (0.2)	4 (2.8)	116 (12.8)	142 (4.2)
Antibiotic (AB)	486 (47.1)	328 (40.3)	70 (13.6)	50 (34.7)	763 (84.5)	1697 (49.8)
Antiseptic (AS)	667 (64.6)	639 (79.7)	486 (94.2)	118 (81.9)	832 (92.2)	2742 (80.7)
Antiemetic (AE)	273 (26.5)	148 (18.3)	44 (8.5)	55 (37.9)	585 (64.9)	1105 (32.5)
Other Drugs	206 (20.0)	29 (3.6)	0 0	26 (18.4)	196 (21.8)	457 (13.5)
Referral to Hospital	15 (1.5)	1 (0.1)	1 (0.2)	6 (4.2)	60 (6.7)	83 (2.5)

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- Percnt distribution of main treatment combinations are presented in table 7. The most common combinations used in the SS-HP cell were ORT alone (23%), ORT./antiseptic with or Without antibiotic(42%). In the OR- HD cell, ORT/antiseptic with or without antibiotic (63%), and ORT alone (15%) were the frequently used combinations. ORT/Antiseptic combination was used in 80% of cases in the SS-PP cell. In OR-CD cell, over one third (37%) used ORT/Antiseptic combination, and 42% used ORT/antisetic with antibiotic &/or antiemetic combination. Twenty seven percent of the Cont. cell patients used Antibiotic/Antiseptic/Antiemtic combination, 29% used the 3 drugs in combination with ORT, and 15% used the Antibiotic/Antiseptic combination.

- ORT alone was adminstered to as low as 0.7% of patients in the Control & 1.6% in the SS-PP cell, but as h gh as 15% in OR-HD and 23% in SS-HP cells.

- While Antibiotic/Antiseptic combination with or without Antiemetic was prescribed to 0.5% of cases in SS-HP, 0.9% in OR-HD, 2.0% in SS-PP and to 2.9% in OR-CD cells, it was prescribed to 42% of patients in the Control cell, i. e. 84 times its use in SS-HP cell.

Table 7: Percent Distribution of Main Treatment Combinations by Study Cell

Treatment Combination	Study Cell					A L L
	SS-HP	OR-HD	SS-PP	OR-CD	Control	
OR	22.8	15.1	1.6	5.8	0.7	11.1
OR + AB	6.7	2.9	2.1	2.2	1.8	3.6
OR + AS	18.7	36.6	79.6	37.4	1.8	28.6
AB + AS	0.3	0.5	1.2	2.9	15.2	4.5
OR + AB + AS	23.7	26.1	4.7	12.2	9.7	17.2
OR + AS + AE	8.3	5.8	1.7	14.4	4.1	5.8
AB + AS + AE	0.2	0.4	0.8	0	26.9	7.4
OR + AB + AS + AE	14.0	9.7	4.3	15.1	29.1	15.5
Other Combinations	5.3	2.9	4.0	10.0	10.7	6.3

Relationship of prescribed treatment and presenting Signs/Symptoms:

- It has been mentioned earlier that, overall, antibiotics were prescribed to half the cases, and half the cases were febrile. It is of interest to note that the treatment prescribed was not limited to cases presenting with the signs/symptoms for which the drug category is indicated. Tables 8 through 11 show the relationship between the signs/symptoms and the indicated treatment for the study versus Contorl Villages.

- Of all cases presented with diarrhea and/or dehydration, 85% received ORT (table 8). This rate is about one hundred percent (99.8%) in study villages, but only 48% in Control villages. In other words, in the Control villages, over one half (52%) of children presenting with diarrhea and/or dehydration, did not receive ORT.

- Table 9 shows that antibiotics were prescribed to only 43% of all febrile cases. On the other hand, antibiotics were prescribed to 56% of non- febrile cases. This latter rate is higher (75%) in Control villages, compared to 52% in study areas.

- Antiemetics were prescribed to 61% of all children presented with vomiting, and to 5% of children without vomiting. These two rates, however, were much higher in Control villages (87 and 9% respectively) than in the study villages (45 and 4% respectively).

- It seems from table 11 that passing blood and/or pus in stool was not the indication, in the physicians judgement, for prescribing intestinal antiseptic drugs. Overall, 92% of children for whom antiseptics were prescribed had no indication of passing blood/pus in stool. The rate is slightly higher in Study villages than in Control villages, but the difference is statistically not significant. Overall, 32% of cases with blood/pus did not receive antiseptics. The rate in the Study villages (38%) is more than double the rate in Control villages (16%).

Table 8: Distribution of Cases presenting with Diarrhea and/or Dehydration (D) in relation to prescription of ORT.

STUDY VILLAGES

		ORT +	ORT —	T
D	+	2365	5	2370
	—	48	86	134
	T	2413	91	2504

CONTROL VILLAGES

		ORT +	ORT —	T
D	+	428	469	897
	—	1	5	6
	T	429	474	903

ALL VILLAGES

		ORT +	ORT —	T
D	+	2793	474	3267
	—	4	91	140
	T	2842	565	3407

Table 9 : Distribution of Cases presenting with Fever (F), in relation to prescription of Antibiotics (AB)

STUDY VILLAGES

F \ AB	+	—	T
+	187	867	1054
—	750	700	1450
T	937	1567	2504

CONTROL VILLAGES

F \ AB	+	—	T
+	516	57	573
—	247	83	330
T	763	140	903

ALL VILLAGES

F \ AB	+	—	T
+	703	924	1627
—	997	783	1780
T	1700	1707	3407

Table 10 : Distribution of Cases presenting with Vomiting (V), in relation to prescription of Antiemetics (AE)

STUDY VILLAGES

V \ AE	+	—	T
+	467	573	1040
—	56	1411	1467
T	523	1984	2507

CONTROL VILLAGES

V \ AE	+	—	T
+	564	81	645
—	22	233	255
T	586	314	900

ALL VILLAGES

V \ AE	+	—	T
+	1031	654	1685
—	78	1644	1722
T	1109	2298	3407

Table 11 : Distribution of Cases presenting with Blood/Pus (B), in relation to prescription of Antiseptics (AS)

STUDY VILLAGES

B \ AS	+	—	T
+	147	90	237
—	1761	506	2267
T	1908	596	2504

CONTROL VILLAGES

B \ AS	+	—	T
+	81	15	96
—	758	49	807
T	839	64	903

ALL VILLAGES

B \ AS	+	—	T
+	228	105	333
—	2519	555	3074
T	2747	660	3407

b1

D I S C U S I O N

The purpose of the treatment and referral compnent of the SRHD Project Study on Child Diarrheal Diseas Contorl, was 3 fold:

1. To assess the rate at which preschool children are seen at rural health facility clinics.
2. To assess the possible combination of the common presenting Symptoms &/or Signs of child Diarrhea. Also to assess the proportion of signs that might be possible indicators of hypernatremia.
3. To assess KAP of rural physicians in management of childhood Diarrhea.

The results that have been presented have to be taken cautiously in terms of two factors:

1. Although the system of reporting was unique in all study and Control cells, acting physicians, as human beings, vary in their interest and dedication.
2. A village which counts for 3.1% of all cases, was misplaced in the data analysis in the SS-HP cell instead of being in the OR-HD cell. This factor has no effect on the other 3 cells, but might have an effect in comparing the first two cells. Because of the constraints we face in data analysis at present, this factor is ignored in this writing as its quanticative value is small.

Age distribution of cases, despite the fact that there are accumulations at rounded years of age, suggests that three quaters of cases were under 2 years. Being a major cause of death among preschool children, this observation may explain the very high mortality rates of the first and second years of live compared to mortality rates of other ages.

If we assume that referrals to rural health facilities reflect (but not represent) incidence of the disease in the community during the study period, it could be concluded that results are consistent with what is expected. The highest proportions coicide with ages when critical changes of child feeding practices take place. Based on the same assumption, the data suggest, that the incidence of the disease is higher in the hot season, May through July. The apparent increase during November may be artificial, as the drop in the proportion of referrals during August through October might be due to two factors limiting clinic attendance. One of such limiting factors might be the bairum holidays mid August during which clinics are off work. A second factor might be the harvesting season of September & October, during which rural families are generally busy.

The relatively high frequency of dehydration in OR-CD and Control cells may be attributed to the delay encounterd by mothers in initiating ORT in both cells, but as well, to the high proportion of febrile children in the Control cell. The relatively low frequency of dehydration in the SS-PP cell is difficult to explain. The rates of dehydration, however, explain the differences in the rates of referral to hospital. They also explain the difference in percent reduction in preschool child mortality rates in the five cells (table 12 of the DDCS report, May through October 1980, SRHD).

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Reasons for differences in rates of the signs possibly indicative of hypernatrmia could be due to improper mixing. As the expected Sodium concentration is 90 meq for Oralyte, 60 meq for SS-PP and only 40 meq for SS-HP; it is more probable to get hypernatremia from improper mixing of Oralyte than of Sugar/Salt Solutions. This is particulary true for the OR-CD villages, where instructions by sellers on mixing probably were less adequate. On the other hand, the rate of probable cases of hypernatremia is low in the Control villages probably because fewer children were exposed to ORT prior to seeking advise at health facilities.

The Diarrhea-Vomiting-Fever being the more frequent presenting symptoms/signs combination, is consistent with the inputs in the Control cell. The delay in seeking medical advice, in absence of a home-visiting program in the Control villages probably allows the disease to continue somewhat longer, resulting in presentation with such a combination. This reflects, as well, the relatively percentage of patients presenting with diarrhea alone.

The treatment pattern in each cell reflects the awareness of the physicians of the treatment regimen. ORT was less used in the Control cell as the physicians were not exposed to the short training given to the physicians. Physicians in the SS-HP cell counted on ORT alone more than in any other cell because most of them had been trained twice. The first was in the course of the SRHD Project pre-implementation training more than a year before conducting the study. ORT/antiseptic combination was seen as the first choice of treatment in the study villages, particulary in the SS-PP facilities. The relationship of prescribed treatment and presenting signs/symptoms reflects a major concern on the part of treatment practices by the rural health physicians. This is particularly true in terms of their heavy use of antibiotics (especially in the Control area) and intestinal antiseptics, without medical indication based on clinical grounds.

The types of drugs other than the four mentioned drugs were not explored. Our feeling is that they might be antispasmodics, tonics, or the likes.

In conclusion, the success in study villages over the Control villages (reflected as well by proportions of reduction of child mortality rates), could be attributed to a variety of factors. The most important of which are:

1. availability and accessibility of ORT.
2. intensive health education to mothers.
3. early detection and management of childhood diarrheas through a regular outreach program.
4. last, but not least, changes in physicians knowledge, attitudes and practices as an outcome of appropriate training.