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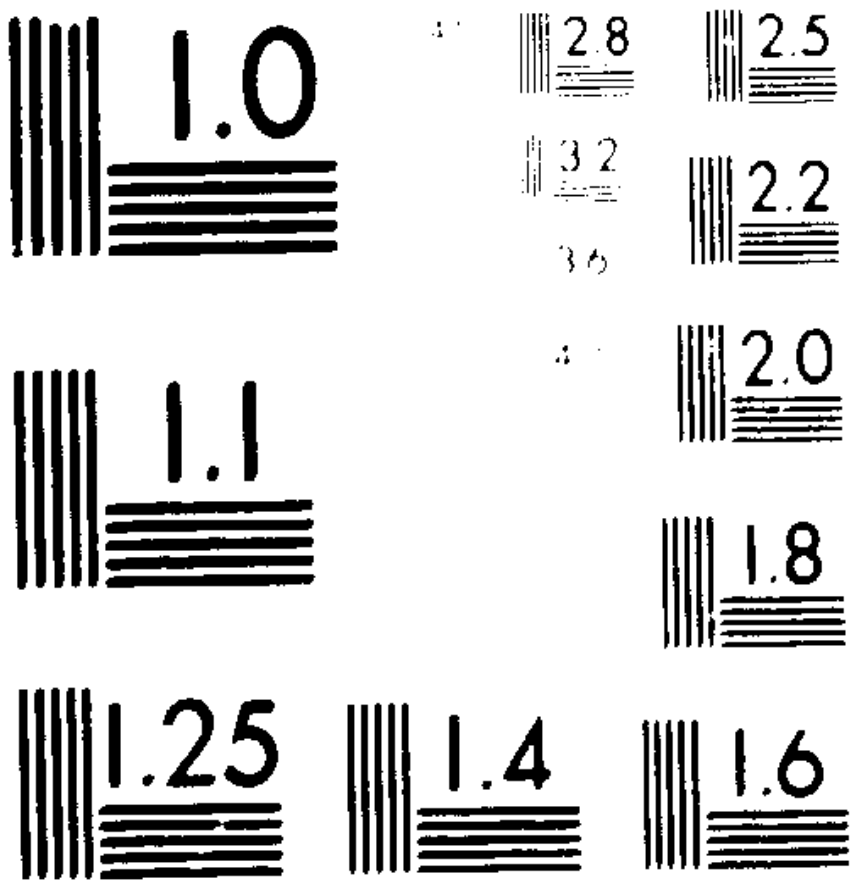

09640

Distr.
LIMITED

UNIDO/IOD.352
12 December 1979

English

UNITED NATIONS INDUSTRIAL
DEVELOPMENT ORGANIZATION

PRODUCTION OF ORAL REHYDRATION SALTS (ORS).

RP/MDV/78/001

MALDIVES

Technical report : Feasibility study on local ORS production

Prepared for the Government of Maldives
by the United Nations Industrial Development Organization

Based on the work of Borislav J. Budlimić, chemical engineer

Explanatory notes

The monetary unit in Maldives in the rupee (MRs). During the period covered by the report, the value of the rupee in relation to the United States dollar was $US 1 = MRs 8.70.

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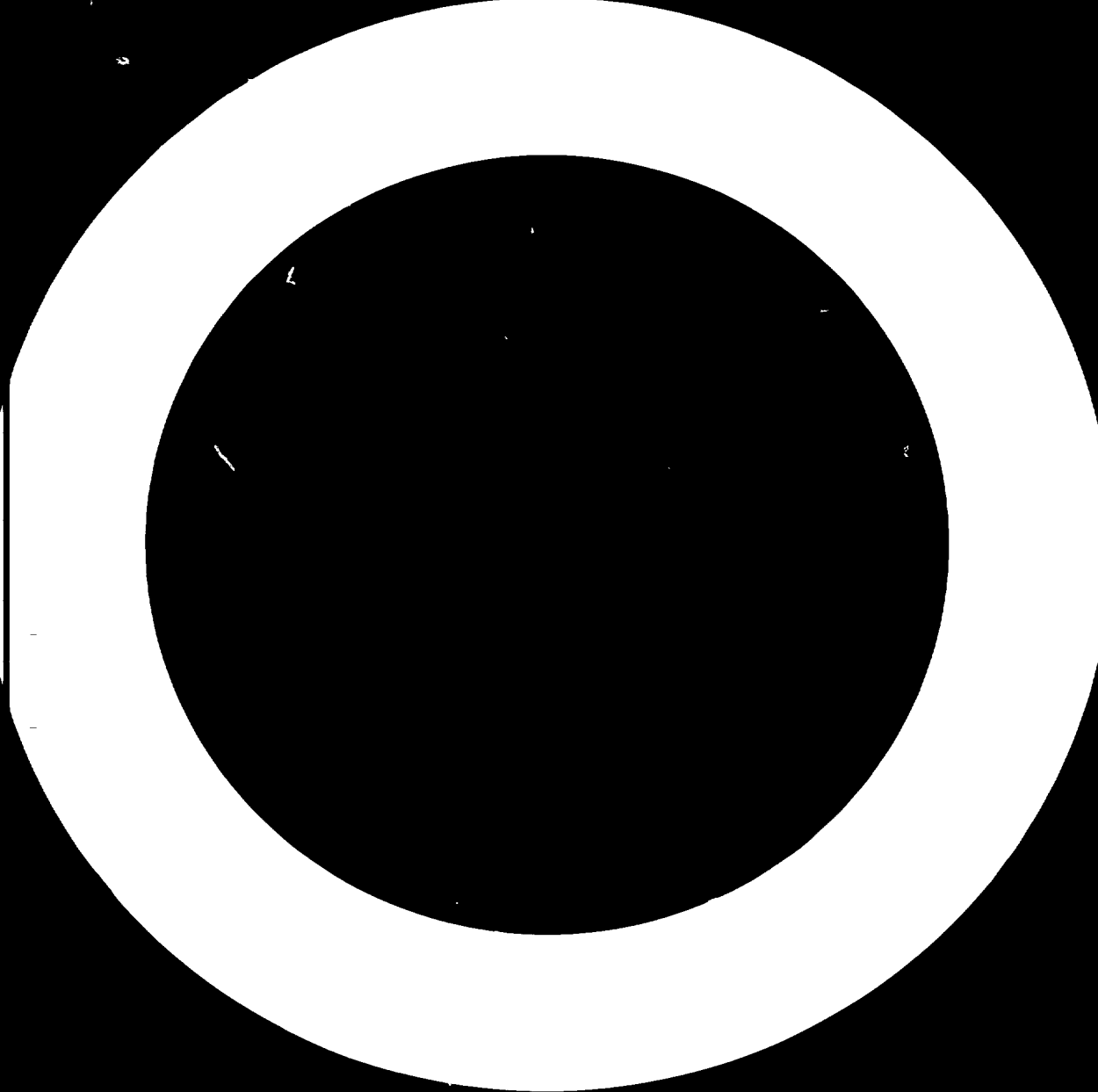
ABSTRACT

In November 1977 the Government of Maldives, which has shown interest in a previously prepared project proposal, requested the United Nations Industrial Development Organization (UNIDO) for assistance in setting up a local production of oral rehydration salts (ORS). On 29 December 1977 UNIDO approved the project "Production of oral rehydration salts (ORS)"(RP/ MDV/78/001). The allocation of $US 23,600 included the service of one expert for four months, to be split into two missions of two months each. The report covers the first part of the expert's mission from 1 October to end November 1978.

The expert assessed the country's needs for ORS and gathered data and other information relevant to the feasibility study of a local ORS production. He elaborated in some detail three different approaches to the problem, thus providing a basis for the selection of the most suitable alternative with respect to factors such as existing technical capabilities, availability of skilled labour, investment cost and maintenance.

Under the recommended alternative it is forseen to import the mixed and homogenized raw material for ORS in bulk and to pack it locally into the usual unit dosage packages. In such a plant the country's yearly requirement of 60,000 to 80,000 packages of ORS could be produced within three to four months and surplus capacity could be used for the packaging of other drugs. With regard to the availability of biologically safe water, which constitutes the foremost sanitary problem in Maldives, the expert recommends that the health assistants in charge of health centres which exist on each one of the atolls, be made responsible for the preparation and the supply of sufficient quatities of water to all recipients of ORS.



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INTRODUCTION

General

The Republic of Maldives is an archipelago in the Indial Ocean consisting of 1,273 islands of which 202 are inhabited. These islands are naturally grouped into 19 atolls. The climate is of the monsoon type and the temperature variance over the year is about 5°C.

At the last census in January 1978, the population of the country was 143,046, scattered over the islands with the greatest concentration at Malé, which is the only urban settlement and counts 29,555 inhabitants (see annex I).

There are 21 health centres throughout the atolls, staffed by health assistants or community health workers (see annex II). All medicines are supplied by the Ministry of Health on a monthly basis. The only hospital is located at Malé; there are four Maldivian doctors, two foreign doctors, one dentist, one druggist, and a number of trained personnel for health care distributed over the atolls. The drugs are distributed through governmental as well as private dispensaries. Figures on drug consumtion are not available.

There are no trained technicians and engineers in Maldives but there are some skilled craftsmen.

Project background

In order to meet the regular requirement of ORS and to be prepared for an epidemic of gastro-intestinal diseases which usually affects[a] in the first place infants and young children, the Government of Maldives wishes to establish a local ORS production. UNIDO was requested to initate and carry out preliminary investigations in that direction and to prepare a feasibility study. The last epidemic, during April and May 1978, produced 17,263 recorded cases within a period of one month and claimed 255 lives. Also, Maldives has a rather high rate of infant mortality (see annex III).

Gastro-intestinal diseases in infants and young children are accompanied by intense diarrhoea and vomiting. These symptoms are very similar to those of cholera, which causes dehydration and a loss of body salts that are indispensable for the normal functioning of the human organism.

The common treatment in such cases (see United States Pharmacopoeia XIV) is the administration of liquor Ringeri lactatum containing sodium chloride, potassium chloride, calcium chloride, sodium bicarbonate and glucose. There exist several slightly different compositions but using the same ingredients.

The preperation "Oralyte", which is distributed by the United Nations Children's Fund (UNICEF), code 15-511-00, contains 3.5 g of sodium chloride, 1.5 g of potassium chloride, 2.5 g of sodium bicarbonate and 20.0 g of glucose. Oralyte is dissolved in drinking water and administered to a patient every 5 to 10 minutes over a period of 24 hours or more. It was found that this simple treatment restores the lost fluids and the vitally important body salts.

An early treatment of dehydration is imperative to avoid the death of the child, which occurs very frequently in tropical climates or if the child is already in a precarious state of health or suffers from malnutrition.

The success of such a project depends, however, not only on the availability and the effective distribution of the mixture of salts but also on the availability of potable water on a wide scale. In Maldives, drinking water is generally obtained from rain water catchments and some shallow wells. The prevailing practice to dispose of human excreta directly into the soil, the high soil permeability and the shallow water table expose the public to polluted ground water containing pathogenic micro-organisms which are typical in a tropical climate.

Official arrangements

In November 1977 the Government of Maldives, who had shown interest in a previously prepared project proposal, requested the United Nations Industrial Development Organization (UNIDO) for assistance in implementing the local production of oral rehydration salts (ORS). The Government also suggested to explore alternative sources of funds, other than Internal Planning Figures (IPF). On 29 December 1977 UNIDO gave its approval to project "Production of oral rehydration salts (ORS)"(RP/MDV/78/001) and agreed to finance it from its Regular Programme of Technical Assistance. The allocation of $US 23,600 included the service of one expert for four months, to be split into two missions of two months each, as well as equipment and material.

The present report covers the first phase of the expert's mission from 1 October to end November 1978.

Objective of the mission

The objective of the first mission was to carry out preliminary investigations and to explore the possibility of a local production of ORS. According to his job description the expert was specifically expected to:

(a) Assess the country's needs for ORS;

(b) Study the feasibility of local production of ORS as against the importation of ORS through UNICEF;

(c) Investigate whether ORS can be produced by setting up an ORS production unit within an existing pharmaceutical plant or whether an independent plant should be established for this purpose;

(d) Study the drinking water conditions in the country and suggest the best methods for furnishing purified/sterilized water with ORS;

(e) Determine the capacity of the ORS production plant, prepare a complete list of equipment and cost estimates and work out a plan for setting up the plant.

I. FINDINGS

Overall sanitary situation

The occurrence of certain acute gastro-intestinal diseases provoking diarrhoea and vomiting is a consequence of the prevailing sanitary situation. The supply of drinking water as well as the disposal of sewage represent a serious problem and jeopardize the health of the inhabitants of Maldives. If the sanitary conditions were imporved, the cases of sickness would diminish and probably disappear. Actions directed towards remedying the situation are being undertaken by the Government with aid from the World Health Organization (WHO) and United Nations Children's Fund (UNICEF).

These organizations are providing, among others, handpumps and bleaching powder for the chlorination of drinking water. Catchments for rain water and storage tanks are being erected, which certainly represent a contribution to improved hygienic conditions.

The problem of undernourishment aggravates the situation, since abdominal parasitic infestations expand more easily in a weakened organism. Suitable preventive measures would, therefore, significantly diminish occurrences of that kind.

Supply of drugs

The Maldives has to import all drugs. The largest part of the drugs is donated by UNICEF and WHO and they are distributed to the patients free of charge. Smaller quantities which are imported by the Government are sold to the consumers in the governmental dispensaries by medical prescriptions. There is also a number of privately-owned dispensaries selling drugs. The quantity of drugs imported by the latter is unknown. The assortment of drugs is relatively narrow and consists mainly of antibiotics, corticosteroid ointments, multi-vitamins and different kinds of syrups against cough and similar ailments.

Demand for ORS

ORS have been applied a lot during the last epidemic of cholera in Maldives in April and May 1978. Before this, ORS were not very much used for the treatment of diarrhoea. It is estimated that during the above-mentioned period 122,600 packs of "Oralyte" were distributed to the health centres in the country.

No data are available to determine if all of these packs were used and what were the effects.

Since "Oralyte" has so far been donated by UNICEF, its local production represents an additional burden for the country's budget. According to an expert's study for Asian countries, the average import price for a pack of 28 g of "Oralyte" is about $US 0.15. If produced in Maldives, the price would be considerably lower i.e. about $US 0.06 - 0.08 per pack. The savings which could be realized in this way depend on the number of packs produced which would not exceed 60,000-30,000 packs per year. By improving the sanitary situation the quantity required could be reduced.

Packaging of ORS

A simple procedure for the packaging "Oralyte" should be used, as there is no skilled labour available for the maintenance of automatic or semi-automatic devices. But even with a simple technique it is possible to produce 300,000 packages of "Oralyte" per year, which is many times the annual requirement.

The packaging process should not cause any problems. It consists of operations which are easy to perform, the equipment is simple and no particular skills are required on the part of the staff. In fact, the labour could be fast and easily trained.

Depending on the entrepreneurial zeal of the organization, part of the equipment could be used for individual packaging of other tablets or capsules in the quantity of single therapeutic dosages or unit dosages of 6 to 12. In the dispensaries the drugs are at present packed by hand using ordinary paper.

For the packaging of ORS it is necessary to provide an air-conditioned room in order to maintain the necessary temperature and humidity. The walls should be coated with enamel paint to avoid contamination of the materials treated. Concerning the sterility, it is sufficient that the personnel wear protective masks like those commonly used in hospitals.

Possibile alternatives for the local production of ORS

As Maldives does not possess any kind of raw materials, its economy relies on the import of raw materials from abroad. For a local production of ORS it is consequently necessary to chose one of the following three alternatives:

1. To import the ingredients, to compound them and to pack them mechanically in the corresponding unit dosage packages;

2. To import the compounded mixture which is prepared on the request of the buyer and to pack the mixture mechanically or by hand in the corresponding dosage unit packages;

3. To pack the imported components individually by hand in the corresponding unit dosage packages.

If the first alternative of buying individual raw materials is adopted, i.e. to import the components, to compound and to pack them in the dosage form suitable for the preparation of the solution, it is also necessary to obtain the necessary equipment with which the following operations would be performed:

(a) Weighing of the individual components constituting the composition of the oral rehydration salts;

(b) Grinding of the individual components to get an equal particle size;

(c) Mixing i.e. homogenization of the components;

(d) Packaging of the homogeneous mixture (if possible under sterile conditions) in the unit dosage packages.

The complete equipment for work with powder materials would include a hammer mill, sieves, a homogenizer, an automatic machine for packaging, a labelling device and a weighing scale. Since the quantity of ORS requried for local consumption is not very high, or, in other words, the production is relatively small from an industrial point of view, it is necessary to consider the possibility of using this equipment for some other purposes.

The second possibility is to import the prepared mixture in bags of 5, 10 or 50 kg and to distribute it into unit dosage packages either mechanically as described before for alternative 1, or by hand into small bags bearing the directions of use printed in Divehi, the language of the Maldivians.

The equipment comprises in this case only a weighing scale, a device for sealing of the finished packages and a labelling device. The kind of packaging material to be used depends on the machine and is usually recommended by the producer of the equipment. The application of aluminium foil, coated with polyethylenic sheet, is very common. The aluminium foil give the mechanical

strength and the polyethlenic layer protects the content from humidity and other external influences like odours etc. For hand-packaging in polyethylene bags, the polyethylene foil must have sufficient mechanical resistance to protect the content of the bags. By heating the polyethylenic foil for a short time to a temperature close to the melting point, the bags can be tightly sealed.

The third alternative is to import the components and to pack them by hand in polyethylene bags after individually weighing of the components and without previous homogenization. This alternative presents the least problems with regard to maintenance and skilled labour as it comprises only the most elementary operations.

The three alternatives are described in more detail in chapter II.

In addition to the operative staff and the production facilities, it is also necessary to provide an administrative staff whose duty would be to purchase in due time the necessary raw materials for a regular production of ORS and to take care of the distribution of "Oralyte" to the dispenseries on the 19 atolls. It is advisable to use the existing distribution system, because the dispensaries could be of assistance in forcasting the estimated requirements of ORS and already existing stocks of ORS could simply be supplemented by new deliveries.

Raw materials

The following raw materials are needed for the production of ORS:

Sodium chloride
Potassium chloride
Sodium bicarbonate
Glucose anhydrous

Since most of these raw materials are also used in the food industry (e.g glucose in different kinds of beverages, sodium bicarbonate in bakery etc.), the quality which corresponds to the regulations valid for the food industry could be utilized for ORS. It is certainly recommendable that compounds needed in the health care conform to the level and quality of pharmacopoeia. In this case however, from an economical point of view, and considering the fact that oral rehydration salts are administered orally and dissolved in potable water, it would seem sufficient to use a quality which corresponds only to food standards. Care must be taken, however, to use only white and odourless glucose without chemical impurities.

Water for dissolving of ORS

The water needed to dissolve the contents of the ORS packages has to be biologically safe. The simplest solution would be to claim that the water must be distilled. However, this requirement can not always be fulfilled, especially in areas which are economically and industrially underdeveloped. As already mentioned, safe drinking water is one of the main problems of Maldives. There are two sources of water: rain water and wells which are relatively shallow due to the particular geological structure of the soil. Rain water is collected in storage tanks or rain water catchments and is used for various purposes. However, storage tanks are not everywhere available and on a number of islands these shallow wells, the water of which is not always biologically safe, are used. Taking into account the distances over which the islands and individual settlements are spread, the only solution in this case seems to be to ensure that on each atoll there is certain quantity of biologically safe water available, which is obtained by boiling or by usual chemical treatment. The person responsible for the quality of the water, in this case the health assistant or health worker who lives on each of the atolls and who takes care of health problems as well as the drugs needed, should deliver simultaneously with the package of ORS the quantity of water required to dissolve the package. Each person who calls for an intervention should therefore automatically also get water of suitable quality together with a direction how to use the medicament.

II. DESCRIPTION OF THREE ALTERNATIVE PRODUCTION POSSIBILITIES

In all three cases the final product will be an ORS with a total weight of the unit dosage of 27.5 g and with the following composition:

	g
Sodium chloride	3.5
Potassium chloride	1.5
Sodium bicarbonate	2.5
Glucose	20.0

For the ratio of components and the weight of ingredients for a given number of packages see annex IV.

Alternative one

Production process

The raw materials of a suitable quality are weighed individually for daily production, ground in the mill to the appropriate particle size, sieved and put in the homogenizer where they are mixed to get a uniform product. After homogenization samples of the mixture are taken and analyzed. The contents of the homogenizer is then transferred in a bin to the automatic packaging machine. The bulk density of the mixture has to be determined in advance so that the machine can be adjusted to the correct weight. The packaging material is aluminium foil coated with polyethylene on which the instructions for use and other relevant information should be printed. The machine is also provided with an automatic counter for the packages. The finished unit dosages are appropriately marked, packed in bigger units and stored.

Control of raw materials and finished products

Raw materials are controlled to ensure that they correspond to accepted standards. The procedures for the analysis are according to one of the accepted pharmacopoeias and are carried out in a laboratory. The procedures in question are the argentometric determination of chlorides, standard method, the acidimetric determination of bicarbonates and the determination of glucose.

The sodium and potassium content in the finished product is analysed by the flame-spectrometric method. For the operation of the flame photometer an experienced chemist or pharmacist is required.

Equipment

(a) Production and packaging equipment

Quantity	Description	Power (KW)	Value ($US)
1	Hammer mill, capacity 25-50 kg/h	2.2	7,500
1	Twin shell blender, capacity 50 kg	1.5	2,500
1	Homogenizer with filling device	1.2	5,000
1	Sealing machine, 200 packs/h	0.75	1,500
1	Semi-automatic labelling device		500
1	Weighing scale with dial, capacity 50 kg		1,200
1	Air conditioner	1.2	750
			13,950
	Spare parts		2,000
			20,950

(b) Control equipment

	General laboratory equipment		5,000
1	FLM3 flame photometer with necessary accessories for Na and K determination (Radiometer, Copenhagen)		6,150
			11,150
		Total	32,100

Packaging material

Aluminium foil coated with polyethylene.

Raw materials for 10,000 packages

Sodium chloride	35 kg
Potassium chloride	15 kg
Sodium bicarbonate	25 kg
Glucose anhydrous	200 kg

Operating personnel

Number	Function	Qualification
1	Senior superviser	Pharmacist (B.A. or B.S.) or chemist (B.A.)
1	Analyst	Chemist (B.A.) or pharmacist (B.A)
3	Skilled workers	Graduated chemist (2) Graduated mechanic (1)(for maintenance of equipment)
6	Unskilled workers	
1	Administrative assistant	

Alternative two

Production process

The four components required for ORS production available all over the world. It should therefore be easy to obtain the compounded mixture in bulk and to pack it locally. No processing equipment will be required; the process and the equipment for weighing and packaging is the same as described for the first alternative.

Control of raw materials and finished products

The original compounded mixture and the finished product have to be analysed with respect to the sodium and potassium content. Other ingredients are analysed by the usual methods i.e. acidimetric determination of bicarbonate and iodometric determination of glucose. The sodium package mixture is determined by spectrophotometry. The humidity of the package mixture is determined by the Karl Fischer method.

Equipment

(a) Production and packaging equipment

Quantity	Description	Power (KW)	Value ($US)
1	Sealing machine with filling device	2.0	6,500
1	Semi-automatic labelling device		500
1	Weighing scale with dial, capacity 50 kg		1,200
1	Air conditioner		750
			8,950
	Spare parts		1,000
			9,950

(b) Control equipment

	General laboratory equipment		5,000
1	FML3 flame photometer with necessary accessories for Na and K determination (Radiometer, Copenhagen)		6,150
			11,150
		Total	21,100

Packaging material

Alluminium foil coated with polyethylene.

Raw materials for 10,000 packages

280 kg of homogenized mixture containing:

	Percentage
Sodium chloride	12.72
Potassium chloride	5.45
Sodium bicarbonate	9.09
Glucose anhydrous	72.73

Operating personnel

Number	Function	Qualification
1	Senior supervisor	Pharmacist (B.A. or B.S.) or chemist (B.A. or equivalent)
1	Analyst	Chemist (B.A.) or pharmacist (B.A. or equivalent)
2	Skilled workers	Graduated chemist (1) Graduated mechanic (1) (for maintenance of equipment)
4	Unskilled workers	
1	Administrative assistant	

Alternative three

Production process

In this case it is proposed to pack the ORS manually. Most of the equipment that is necessary for the other two alternatives for e.g. grinding, sieving, homogenizing etc. could be dispensed with. The salt would actually be produced in the same way in which pharmacists prepare drugs in pharmacies, i.e. each ingredient is separately weighed and put into a plastic sachet which is eventually sealed.

For this process five balances with a weighing capacity of 100 g have to be installed in a row, and each worker has to weigh one of the constituents (3.5 g of sodium chloride, 1.5 g of potassium chloride, 2.5 g of sodium bicarbonate and 20.0 g of glucose).

These balances should be designed for work with powder materials and enable easy pouring into the sachets.

The fifth balance is used to control the total weight.

The sachets are sealed manually by heating the polyethylene foil near the edges which ensures an air-tight closure of the package. The sachet should bear instructions in Divehi on how to use the ORS, specifications of the contents as well as recommendations concerning the water to be used for dissolving the salts. It should also give the date of manufacture and batch number.

This information can be directly printed on the sachets or on etiquettes which are glued to one side of the package. The sachets can be made out of opaque polyethylene sheet in the dimension of 9.7 cm x 8.8 cm (3.5 in. x 3.8 in.).

If it is assumed that the weighing of one component takes at the most 20 seconds, 1,080 packs could be prepared in six working hours and in 300 days about 324,000 packs could be produced. The handling time per package could probably later be reduced to 10 seconds and thus the production be doubled.

Control of raw materials and finished products

Raw materials have to be analysed in the laboratory to make sure that they correspond to accepted standards. The methods in question are the following: argentometric determination of chlorides, standard procedure, acidimetric determination of bicarbonate and iodometric determination of glucose. The finished product has to be controlled by weight.

Equipment

(a) Production and packaging equipment

Quantity	Description	Power (kW)	Value ($US)
5	Balance, capacity 0.1 kg		1,250
1	Labelling device		500
2	Manual sealing device	0.5	1,200
1	Weighing scale with dial, capacity 50 kg		1,200
1	Air conditioner	1.2	750
			4,900
	Spare parts		750
			5,650

(b) Control equipment

General laboratory equipment		5,000
		5,000
	Total	10,650

Packaging material

Polyethylene bags.

Raw materials for 10,000 packages

High-grade food quality of the following components:

	kg
Sodium chloride	35
Potassium chloride	15
Sodium bicarbonate	25
Glucose anhydrous	200

Operating personnel

Number	Function	Qualification
1	Senior supervisor	Pharmacist (B.A.) or chemist (B.A. or equivalent)
1	Skilled worker	Graduated chemist
6	Unskilled workers	
1	Administrative assistant	

Figure I. Comparison of equipment needed for the three alternative production methods

Equipment needed	Alternative production possibility		
	One	Two	Three
Laboratory multi-purpose mill	X		
Double-coned mixer	X		
Turbo mixer/homogenizer	X		
Automatic sealing machine	X	X	
Air conditioner	X	X	X
Labelling device	X	X	X
Balances, capacity 50 kg	X	X	X
Balance, capacity 100 g			X
Aluminium foil coated with polyethylene	X	X	
Hand sealing device for polyethylene foil bags			X
Capacity (packages per hour)	200	200	100 to 300

III. THE MOST SUITABLE PRODUCTION METHOD

Comparison of previously described production possibilities

When choosing the most suitable of the proposed alternatives the required quantity of ORS is a decisive factor to be considered. As previously mentioned the consumption is estimated to be 60,000 - 80,000 packs per year, which is a relatively small quantity. The automatic equipment foreseen in alternative one has a much larger capacity and calls for good maintenance service as well as skilled personnel for its operation. Therefore, it does not seem to be a good proposal. Such equipment however ensures the highest possible quality of the finished product.

Alternative three seems to be more suitable as far as the capacity and the degree of automation of the equipment and the required skills are concerned. It is, however, not acceptable if a constant uniform quality is wanted. Due to the fact that several persons are weighing the individual components of the ORS, a procedure where errors may easily occur, the finished product will most likely not always have the same, accurate composition. A spot check of the content of some packages will not reflect the true picture of the overall quality of the product.

Alternative two comes in between the two other proposals. It contains all necessary elements to ensure a uniform product, because there is the possibility of controlling both, the raw material prior to packaging and the content of the unit dosage packages, and the production equipment is rather simple. Since an already compounded mixture is purchased, all operations and equipment for the preparation of the mixture can be excluded.

The second proposal seems therefore to have several advantages over the other two alternatives. It requires less investment in equipment, fewer skilled and unskilled staff and fulfils the conditions of good manufacturing practice.

Description of the selected production method

In order to picture more clearly the plant for production of oral rehydration salts, the following assumption are being made:

(a) Only one product will be manufactured;

(b) The capacity of the plant will be approximately 200 packages/hour;

(c) The plant will operate one 8-hour shift per day, 5 days per week;

(d) The raw material will be purchased in bulk; it is a mixture of the following ingredients.

Sodium chloride	12.72%
Potassium chloride	5.45%
Sodium bicarbonate	9.09%
Glucose anhydrous	72.75%;

(e) The raw material will be packaged in unit packs containing:

Sodium chloride	3.5 g
Potassium chloride	1.5 g
Sodium bicarbonate	2.5 g
Glucose anhydrous	20.0 g,

the total weight being 27,5 g;

(f) The product will be distributed locally and will be used for the treatment of gastroenteric disturbances which are specific for the country;

(g) The necessary facilities (electricity, water) will be available;

(h) The preparation will employ a raw material of a quality according to the pharmacopeia.

Production process

The production of ORS is divided into the following operations:

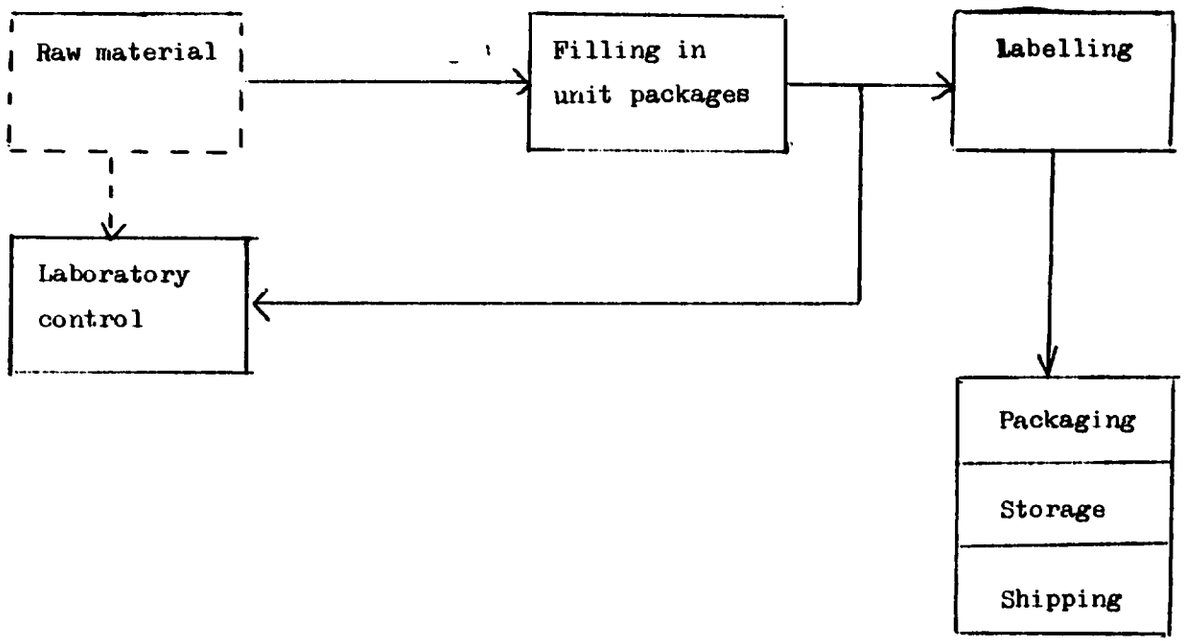
(a) Weighing of the raw material for daily production;
(b) Packaging in unit packages on the corresponding equipment;
(c) Labelling of the unit packages;
(d) Packaging of unit packs in bigger lots for delivery;
(e) Storage.

Besides these operations, it is also necessary to carry out the analytical control of raw materials and unit dosage packages before labelling and before delivery. Figure II shows the production flow.

Technical specifications for production and quality control

The raw material, preferably packed in 25-kg lots, is stored in a warehouse. To avoid contamination, it is advantageous to obtain the raw material in properly sealed polyethylene bags. By using larger packages of raw materials the possibility of contamination of the rest of the package is always present, since the daily raw material requirement is about 25 kg.

Figure II. Production flow sheet



Out of 25 kg mentioned about 900 unit dosages can be made and to obtain 60,000 packages it is necessary to work about 65 days. The whole yearly requirement of ORS could therefore be satisfied by working three to four months.

The analytical laboratory checks the actual composition of the raw material and the humidity and gives its approval on the quality of the packed preparation. The samples for analysis are taken according to the accepted principles valid for control laboratories. The content of sodium and potassium is analysed by flame spectrophotometry and that of chlorine, carbonates, water and glucose by titrimetric methods. The ORS are made from a raw material of the quality which corresponds to that given in one of the accepted pharmacopoeias.

Location and layout of plant

The plant will be located at Malé, the only urban settlement in Maldives. Malé has a harbour and an airport. There should not be any problem with water and electricity since this kind of production plant does not necessitate these facilities in large quantities. The question of pollution does not arise since this kind of production belongs to the "clean" ones.

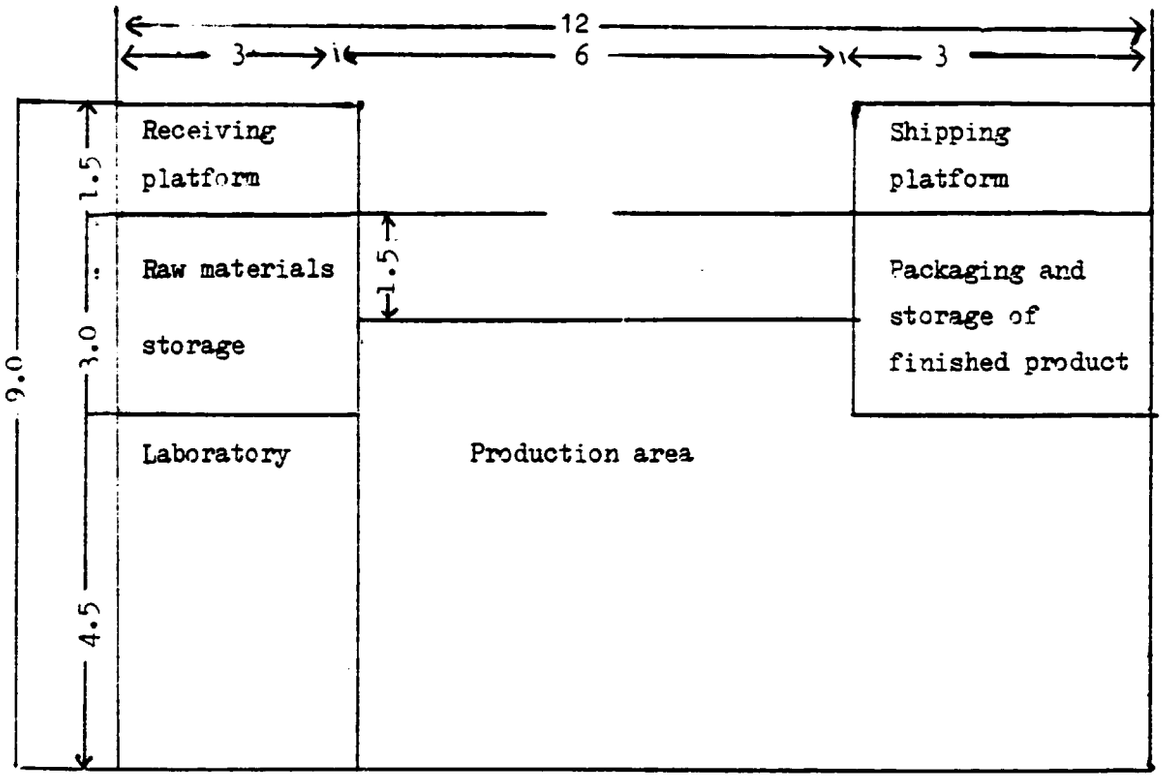
The building should be 12 m long and 9 m wide (108 m^2) and have a layout as shown in figure III.

Equipment

	Estimated cost ($US)
Sealing machine with filling device	6,500
Semi-automatic labelling device	500
Weighing scale with dial, capacity 50 kg	1,200
Air conditionner	750
Quality control equipment (general laboratory equipment and flame photometer)	11,150
Spare parts	1,000
Total	21,100

In addition to the above mechanical equipment other items such as work benches, various auxiliary tools etc. are needed, which can be handmade locally.

Figure III. Possible layout for ORS production plant



Manpower requirements and training

The following staff is required for the efficient operation of the ORS production plant:

Number	Function	Duties	Estimated monthly salary ($US)
1	Manager (senior supervisor)	Manage plant, maintain equipment, keep records	150
1	Analyst	Manage laboratory, accomplish analytical laboratory work, assist manager	135
2	Skilled workers	Handle production equipment (2 x $US 60)	120
4	Unskilled workers	Work in connection with production, packaging and deliver (4 x $US 50)	200
1	Office assistant	Assist in record keeping, sales, typing, correspondence	60
		Total monthly salaries	665

At present there is no personnel available in Maldives that has the required qualifications. The Government should therefore undertake the training of a certain number of people, or engage qualified personnel from abroad until the local staff will be in a position to take over. It should be borne in mind that the manager and the analyst must be highly-qualified and experienced persons.

In order to reduce the time for such training it is recommended to specialize and to limit the instruction of the skilled workers to the specific exigencies of their future posts.

The duration of any training programme will depend on the initial qualifications of the applicants. It should be at least two months for highly qualified persons, while a person not so highly qualified would need at least three to six months to acquire the necessary knowledge for the management of a plant or of an analytical laboratory for the control of the production and of the raw materials. The training could be carried out in institutions where similar analyses are being performed.

Raw material requirements

The material listed below is sufficient for a normal operation of the plant for one month (20 working days), the monthly output being about 20,000 packages of ORS.

	Quantity		Estimated cost ($US)
Mixture of salts	600 kg		432
Aluminium foil coated with polyethylene, two-colour printing, 30 g/m^2	35 - 36 kg		180
Retail packages	400		40
		Total	652

This estimate is based on prices that are valid for Europe and may vary to a certain extent in other areas.

Overhead

Depreciation

Item	Estimated cost ($US)	Life (years)	Estimated yearly depreciation ($US)
Building	5,000	25	200
Production equipment	8,200	15	410
Miscellaneous equipment (laboratory, office etc.)	11,900	15	714
Maintenance (3% of building and equipment cost)			753
		Total	2,077

Estimated monthly depreciation and maintenance

$$\frac{2,077}{12} = 173.08$$

Utilities

	$US
Estimated monthly consumption of electricity (production, laboratory etc.)	157
Estimated monthly water consumption, 5 m^3	50

Total monthly overhead

	$US
Electricity	157
Water	50
Depreciation	173
	380

Unit cost of production

		$US
Labour:	$US665 / 20,000 packages	0.033
Overhead:	$US380 / 20,000 packages	0.019
Materials:	$US652 / 20,000 packages	0.032
	Total	0.084

Capital requirements

Working capital for one month		$US
Materials		652
Operating cost		
Labour	665	
Electricity	157	
Water	50	872
	Total working capital	1,524

Fixed assets	$US
Building	5,000
Equipment	21,100
Total fixed assets	26,100
Reserves (operating and incendental expenses)	3,000
Total capital requirements	30,624

Sales revenue

The price for one package of ORS provided through UNICEF is $US 0.15. For the monthly production the revenue would thus be: 20,000 packages x $US 0.15 = $US 3,000 and for the yearly production: 240,000 packages x $US 0.15 = $US 36,000.

However, only 60,000 packages are needed for consumption so that the revenue will be only $US 9,000.

Projected profit

For yearly production of 240,000 packages	$US
Sales revenue	36,000
Less production cost	20,160
Operating profit	15,840

For a three month period of production of 60,000 packages	$US
Sales revenue	9,000
Less production cost	5,040
Operating profit	3,960

Taxes and any other expenses have not been considered and will reduce the above operating profit.

Material cost for 60,000 and 80,000 packages of ORS

Material	Unit cost $US	Unit cost MR.	For 60,000 packages Quantity	For 60,000 packages Total cost $US	For 60,000 packages Total cost MR	For 80,000 packages Quantity	For 80,000 packages Total cost $US	For 80,000 packages Total cost MR
Sodium chloride	0.067	0.589	212 kg	14.20	124.86	283 kg	18.96	166.68
Potassium chloride	0.77	6.776	92 kg	70.84	623.39	122 kg	93.94	826.67
Sodium bicarbonate	0.222	1.953	153 kg	33.96	298.80	205 kg	45.51	400.36
Glucose anhydrous	0.77	6.776	1,202 kg	925.54	8,144.75	1,605 kg	1,235.85	10,875.48
Total raw materials				1,044.54	9,191.80		1,394.26	12,269.19
Polyethylene bags	0.0048	0.0425	60,600	290.88	2,575.50	80,800	387.84	3,434.00
Total material cost				1,335.42	11,767.30		1,782.10	15,703.19
Cost of raw material per package				0.0174	0.1534		0.0174	0.1534
Cost of packaging material per package				0.0048	0.0425		0.0048	0.0425

IV. CONCLUSIONS

The assessment of the Republic of Maldives' needs for ORS, which was made on the basis of the available data and estimated to be in the range of 60,000 to 80,000 packages per year, can be considered sufficiently reliable, taking into consideration the local climate and other hygienic and sanitary conditions, together with the incidences of the gastro-enteric diseases in this area.

Although the necessary data for the elaboration of a more complete feasibility study have not been available, it would appear that a considerable saving can be achieved by the local manufacture of ORS from imported raw materials. This is due to the fact that manpower in Maldives is cheap and that there are no government taxes. Furthermore, the initial investment in production equipment is rather modest so that the manufacture of ORS under direct Maldivian management would seem to be practicable.

The country does not have any pharmaceutical production facilities within which a controlled production of ORS could be set up. This could possibly be initiated within the framework of existing hospital dispensaries or within a central drug storehouse, under the supervision of the Ministry of Health.

The availability of biologically safe water is the foremost sanitary problem of the entire area of Malidves, especially when considering the particular characteristics of the ground water table as well as certain unsanitary habits practised by the population. The most suitable way for providing biologically safe water under existing conditions is to distribute the water through health centres located on each of the atolls.

V. RECOMMENDATIONS

1. For the production of ORS alternative two should be adopted for the following reasons: it is easily applicable in the existing situation, it does not require a very sophisticated and skilled staff, its capacity satisfies the total requirement of the country of ORS and it involves relatively small financial expenses with the same result that would be obtained with very sophisticated equipment.

2. The surplus capacity of the ORS production plant should be used for the packaging of other finished pharmaceutical products such as asprin, sulphonamides, multivitamines etc. These drugs should be imported in wholesale quantities i.e. in lots of 200,000 pieces or more (tablets, capsules or similar usable forms)and packed into unit dosage packages. From this operation could be derived additional profit.

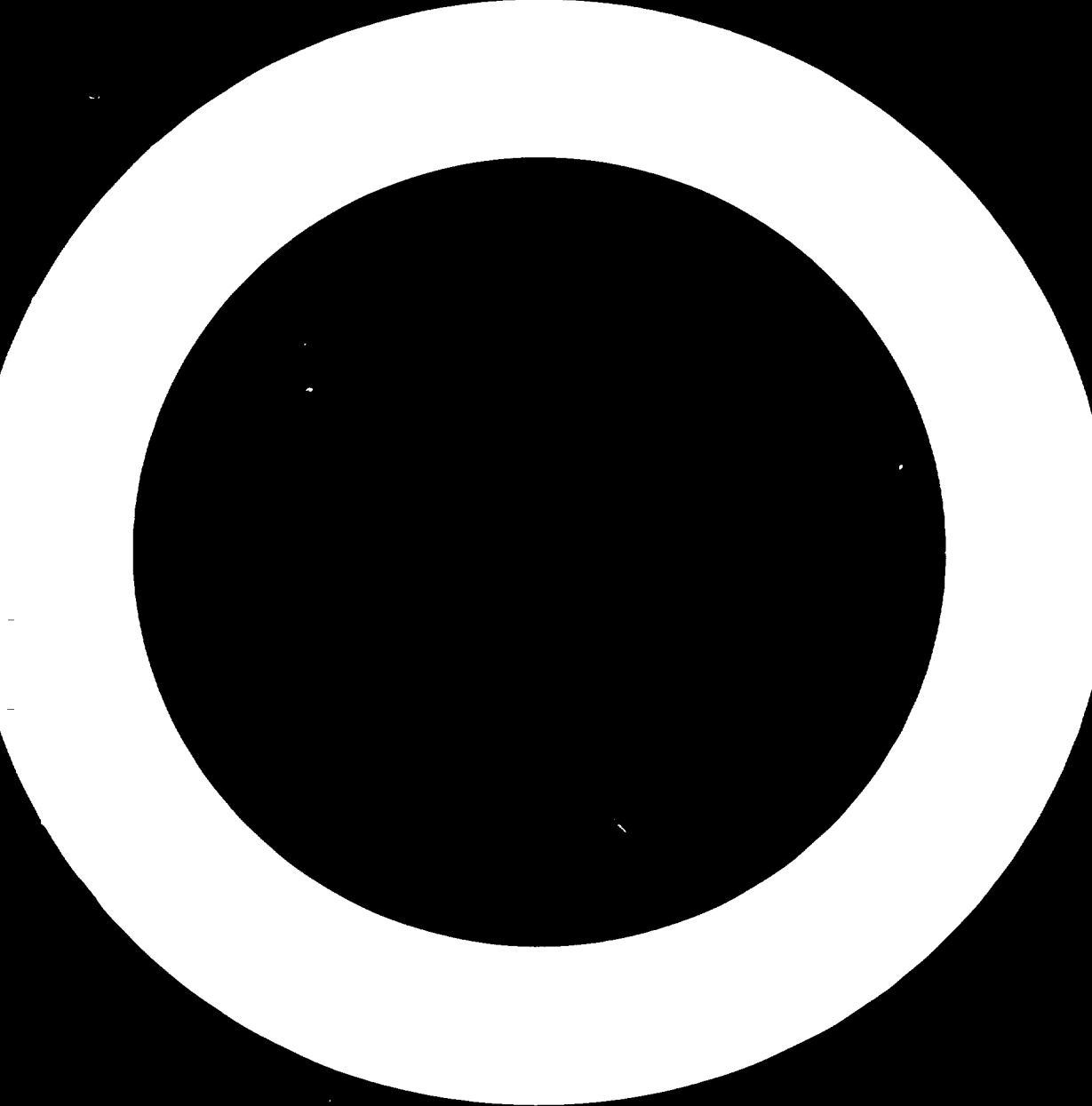
3. The production of ORS should be set up within the framework of existing hospital dispensaries which would distribute the finished product and would be responsible for a regular supply and also for the procurement of the necessary raw materials.

4. It should be made compulsory to report monthly about the consumption of ORS in order to be able to plan the production accordingly and to ensure the supply of the necessary raw materials in good time.

5. On all atolls, which practically represent also administrative entities (districts), a reserve of ORS, proportional to the number of inhabitants, should be secured. Consumed ORS should be supplemented on a regular basis, e.g. monthly, using the principle "last in - last out". In this way it should be possible to react very fast in cases of diseases on a wider scale.

6. The health assistants in charge of the health centres on the atolls should secure the biologically safe water for the dissolution of the ORS. Biologically safe water can be obtained by chlorination or by boiling the water; there should always be a reserve of water.

7. When supplying patients with ORS the importance and the absolute need to use biologically safe water or to boil the water with which the ORS solution is prepared should be stressed.



Annex I

DISTRIBUTION OF THE POPULATION

Code no.	Name of atoll/ island	Population Male	Female	Total
	HAA ALIF			
A 1	Thuraakunu	142	139	281
A 2	Uligamu	113	88	201
A 3	Berimmadhoo	44	40	84
A 4	Hathifushi	74	63	137
A 5	Mulhadhoo	92	87	179
A 6	Huvarafushi	708	666	1374
A 7	Ihavandhoo	451	458	909
A 8	Kelaa	466	424	890
A 9	Vashafaru	175	158	333
A 10	Dhidhdhoo	875	795	1670
A 11	Filladhoo	219	204	423
A 12	Maarandhoo	151	179	330
A 13	Thakandhoo	211	204	415
A 14	Utheem	164	176	340
A 15	Muraidhoo	149	147	296
A 16	Baarah	343	398	741
(16)	TOTAL	4377	4226	8603
	HAA DHAAL			
B 1	Faridhoo	64	55	119
B 2	Hodaidhoo	48	41	89
B 3	Hanimaadhoo	226	244	470
B 4	Finey	110	124	234
B 5	Naivaadhoo	195	184	379
B 6	Hirimaradhoo	125	132	257
B 7	Nolhivaranfaru	123	140	263
B 8	Nellaidhoo	222	209	431
B 9	Nolhivaram	431	412	843
B 10	Kuribi	136	134	270
B 11	Kuburudhoo	87	83	170
B 12	Kulhudhuffushi	1801	1540	3341
B 13	Kumundhoo	389	341	730
B 14	Neykurendhoo	297	302	599
B 15	Vaikaradhoo	486	446	932
B 16	Naivaadhoo	105	99	204
B 17	Makunudhoo	317	276	593
(17)	TOTAL	5162	4762	
	SHAVIYANI			
C 1	Kanditheem	264	239	503
C 2	Noomaraa	139	137	276
C 3	Goidhoo	158	120	278
C 4	Feydhoo	232	222	454
C 5	Feevah	197	193	390
C 6	Bileffahi	166	134	300
C 7	Foakaidhoo	268	238	506
C 8	Narudhoo	106	95	201
C 9	Maakadoodhoo	458	422	880
C 10	Maroshi	217	221	438
C 11	Lhaimagu	143	143	286
C 12	Firubaidhoo	183	185	368
C 13	Komandoo	389	402	791
C 14	Maaugoodhoo	227	206	433
C 15	Farukolhufunadhoo	123	135	258
(15)	TOTAL	3270	3092	6362
	NOON			
D 2	Hebadhoo	144	129	273
D 3	Kedhikulhudhoo	273	269	542
D 4	Tholhendhoo	43	53	96
D 5	Maalhendhoo	157	170	327
D 6	Kudafari	175	134	309
D 7	Landhoo	200	171	371
D 8	Maafaru	276	204	480
D 9	Lhohi	170	156	326
D 10	Miladhoo	356	306	662
D 11	Magoodhoo	108	66	174
D 12	Manadhoo	342	295	637

Code no.	Name of atoll/ islands	Population Male	Female	Total
D 13	Holhudhoo	513	463	976
D 14	Fodhdhoo	65	80	145
D 15	Velidhoo	480	484	964
(14)	TOTAL	3302	2980	6282
	RAA			
E 1	Alifushi	457	489	946
E 2	Vaadhoo	99	87	186
E 3	Rasgetheem	210	218	428
E 4	Agolhitheem	84	80	164
E 5	Gaaudoodhoo	125	137	262
E 6	Ugulu	138	152	290
E 7	Ugoofaaru	240	219	459
E 8	Kadholhudhoo	810	765	1575
E 9	Maakurathu	211	209	420
E 10	Rasmaadhoo	180	197	377
E 11	Innamaadhoo	145	111	256
E 12	Maduvvari	421	374	795
E 13	Iguraidhoo	352	301	653
E 14	Fainu	79	72	151
E 16	Meedhoo	394	341	735
E 17	Kinolhas	114	95	209
(16)	TOTAL	4059	3847	7906
	BAA			
F 1	Kudarikilu	139	110	249
F 2	Kamadhoo	101	99	200
F 3	Kendhoo	235	181	416
F 6	Kihaadhoo	78	73	151
F 7	Dhonfanu	114	110	224
F 8	Dharavandhoo	206	207	413
F 9	Maalhos	127	111	238
F 10	Eydhafushi	801	700	1501
F 12	Thulhaadhoo	672	597	1269
F 13	Hithaadhoo	316	284	600
F 14	Fulhadhoo	69	60	129
F 15	Fehendhoo	46	34	80
F 16	Goidhoo	174	121	295
(13)	TOTAL	3078	2687	5765

Code no.	Name of atoll/ islands	Population Male	Female	Total
	LHAVIYANI			
G 1	Hinnavaru	1244	1100	2344
G 2	Naifaru	1251	1091	2342
G 3	Kurendhoo	384	380	764
G 4	Olhavelifushi	120	121	241
(4)	TOTAL	2999	2692	5691
	KAAF			
H 1	Kaashidhoo	501	436	937
H 2	Gaafaru	222	192	414
H 3	Dhiffushi	264	230	494
H 4	Thulusdhoo	186	156	342
H 5	Huraa	171	147	318
H 6	Himmafushi	205	170	375
H 11	Gulhi	162	122	284
H 12	Maafushi	232	201	433
H 13	Guraidhoo	311	254	565
(9)	TOTAL	2254	1908	4162
	ALIF			
I 1	Thoddoo	320	282	602
I 2	Rasdhoo	221	185	406
I 3	Ukulhas	142	147	289
I 5	Mathiveri	132	111	243
I 6	Boduholhudhoo	120	107	227
I 7	Feridhoo	142	137	279
I 8	Maalhos	142	125	267
I 9	Himendhoo	135	106	241
I 10	Hagnaameedhoo	139	108	247
I 11	Omadhoo	199	175	374
I 12	Kuburudhoo	102	90	192
I 13	Mahibadhoo	439	390	829
I 14	Mandhoo	131	80	211
I 15	Dhagethi	197	158	355
I 16	Dhigurah	143	124	267
I 17	Fenfushi	202	148	350
I 18	Dhidhdhoo	39	46	785
I 19	Maamigili	403	356	759
(18)	TOTAL	3348	2875	6223

Code no.	Name of atoll/ islands	Population Male	Female	Total
	VAAV			
J 1	Fulidhoo	90	82	172
J 2	Thinadhoo	74	48	122
J 3	Felidhoo	137	108	245
J 4	Keyodhoo	168	161	329
J 5	Rakeedhoo	113	97	210
J (5)	TOTAL	582	496	1078
	MEEM			
K 1	Raimmandhoo	51	53	104
K 2	Madifushi	47	54	101
K 3	Veyvah	63	56	119
K 4	Mulah	302	287	589
K 5	Muli	189	184	373
K 6	Naalaafushi	133	96	229
K 7	Kolhufushi	306	296	602
K 8	Dhiggaru	336	304	640
K 9	Maduvvari	177	161	338
(9)	TOTAL	1604	1491	3095
	FAAF			
L 1	Feeali	215	207	422
L 3	Biledhdhoo	257	225	482
L 4	Magoodhoo	159	142	301
L 5	Dharaboodhoo	98	54	152
L 6	Nilandhoo	358	297	655
(5)	TOTAL	1087	923	2012
	DHAAL			
M 1	Meedhoo	259	199	458
M 2	Badidhoo	165	150	315
M 3	Ribudhoo	150	145	295
M 4	Hulhudheli	172	179	351
M 5	Gemendhoo	112	111	223
M 6	Vaani	91	94	185
M 7	Maaeboodhoo	195	176	371
M 8	Kudahuvadhoo	402	403	805
(8)	TOTAL	1546	1457	3003

Code no.	Name of islands	Population Male	Female	Total
	THAA			
N 1	Buruni	126	122	248
N 2	Vilufushi	442	416	858
N 3	Madifushi	209	212	421
N 4	Dhiyamigili	186	181	367
N 5	Guraidhoo	371	356	727
N 6	Kadoodhoo	181	168	349
N 7	Vandhoo	121	97	218
N 8	Hirilandhoo	180	217	397
N 9	Gaadhiffushi	123	117	240
N 10	Thimarafushi	614	549	1163
N 11	Veymandhoo	215	204	419
N 12	Kibidhoo	217	243	460
N 13	Omadhoo	194	163	357
(13)	TOTAL	3179	3045	6224
	LAAM			
O 1	Isdhoo	442	432	874
O 2	Dhabidhoo	203	185	388
O 3	Maabaidhoo	192	170	362
O 4	Mundoo	153	138	291
O 5	Kalaidhoo	113	109	222
O 6	Gamu	513	483	996
O 7	Maavah	437	357	794
O 8	Fonadhoo	451	366	817
O 9	Gaadhoo	119	90	209
O 10	Maamendhoo	274	254	528
O 11	Hithadhoo	191	184	375
O 12	Kunahandhoo	176	131	307
(12)	TOTAL	3264	2899	6163
	GAAF ALIF			
P 1	Kolamaafushi	354	311	665
P 2	Viligili	628	577	1205
P 3	Maamendhoo	266	259	525
P 4	Nilandhoo	194	160	354
P 5	Dhaandhoo	379	357	736
P 6	Dhevvadhoo	223	203	426

Code no.	Name of atoll/ islands	Population Male	Female	Total
P 7	Kodey	79	83	162
P 8	Dhiyadhoo	75	58	133
P 9	Gemanafushi	239	228	467
P 10	Kaduhulhudhoo	152	153	305
(10)	TOTAL	2589	2339	4978
	GAAF DHAAL			
Q 1	Madaveli	338	330	668
Q 2	Hoadedhdhoo	218	211	429
Q 3	Nadalla	219	248	467
Q 4	Gadhdhoo	597	602	1199
Q 5	Rathafandhoo	279	290	569
Q 6	Vaadhoo	283	309	592
Q 7	Fiyoari	319	285	604
Q 8	Maathodaa	181	153	334
Q 9	Fares	189	181	370
Q 10	Havaruthinadhoo	1194	1294	2488
(10)	TOTAL	3817	3903	7720
	GNAVIYANI			
R 1	Fuahmulah	2118	2086	4204
	SEEN			
S 1	Meedhoo	632	667	1299
S 2	Hithadhoo	3122	3199	6321
S 3	Maradhoo	726	747	1473
S 4	Feydhoo	1141	1243	2384
S 5	Maradhoofeydhoo	397	370	767
S 6	Hulhudhoo	945	907	1852
(6)	TOTAL	6963	7133	14096
T 10	Malé	16623	12932	29555

Number of inhabited islands 201

	M	F	Total
Total population	75 223	67 823	143 046

Data obtained from Bulletin No. 2 Elections Division 10.6.1978

Annex II

ISLANDS WITH HEALTH CENTRES

Atoll	Island	Number of centres
Haa Alif	Huvarafushi	1
Haa Dhaal	Nolhivaranfaru	1
	Kulhudhuffushi	1
Shaviyani	Farukolhufunadhoo	1
Noonu	Manadhoo	1
Raa	Ugoofaaru	1
Baa	Eydhafushi	1
Lhaviyani	Naifaru	1
Kaaf	Male'	1
	Guraidhoo	1
Alif	Mahibadhoo	1
Vaav	Felidhoo	1
Meemu	Muli	1
Faafu	Magoodhoo	1
Dhaal	Kudahuvadhoo	1
Thaa	Veymandoo	1
Laam	Hithadhoo	1
Gaaf Alif	Vilingili	1
Gaaf Dhaal	Havaruthinadhoo	1
Gnaviyani	Fua Mulaku	1
Seenu	Hithadhoo	1
	Total	21

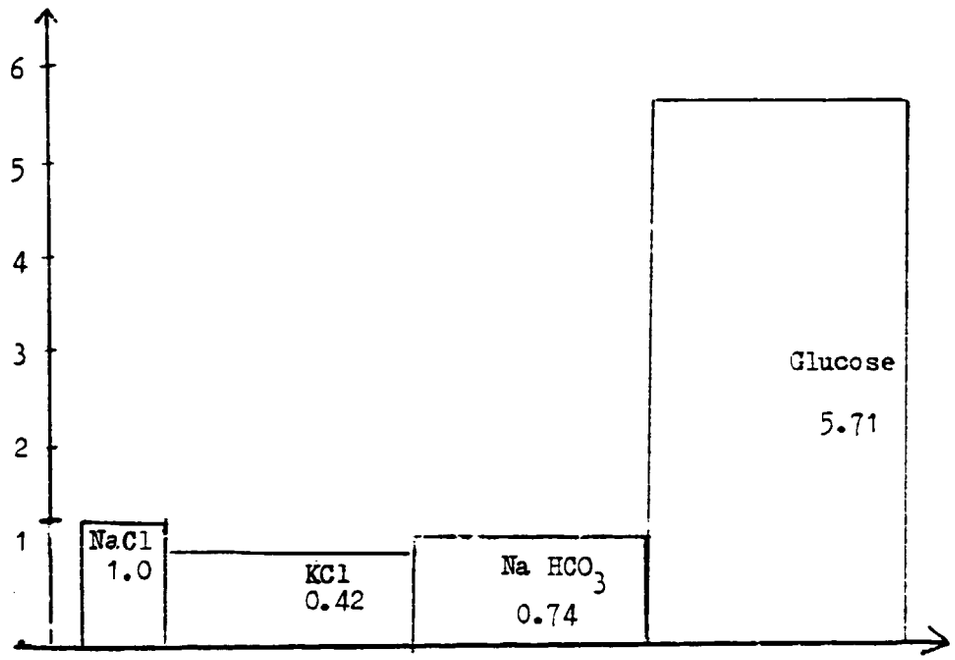
Annex III

DEMOGRAPHIC DATA

	1974	1975	1976	1977
Population	128,696	135,308	139,868	143,046
Growth over previous year (%)	2.15	5.14	3.37	2.27
Death rate	17.33	10.54	11.57	11.78
Birth rate	38.07	39.80	45.31	40.47
Infant mortality rate	136.54	88.38	106.18	120.67

Annex IV

RATIO OF COMPONENTS IN ORS UNIT DOSAGE



Number of packs (thousands)	Weight (kg)				
	Sodium chloride	Potassium chloride	Sodium bicarbonate	Glucose anhydrous	Total
10	35	15	25	200	275
20	70	30	50	400	550
30	105	45	75	600	325
40	140	60	100	800	1,100
50	175	75	125	1,000	1,375
100	350	150	250	2,000	1,750
120	420	180	300	2,400	3,300
150	525	225	375	3,000	4,125