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APPROPRIATE TECHNOLOGY FOR THE MANUFACTURE OF DRUGS AND PHARMACEUTICALS

CHOICE AND ADAPTATION OF APPROPRIATE TECHNOLOGY IN PROMOTING HEALTH-CARE IN ZAMBIA

Background Paper

78-6901

CHOICE AND ADAPTATION OF APPROPRIATE TECHNOLOGY IN PROMOTING HEALTHCARE IN ZAMBIA

by

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INTRODUCTION

It is important to note that healthcare, particularly in developing countries like Zambia, has direct relationship with the socio-economic growth of the country and a welfare state should treat production, procurement and distribution of drugs and pharmaceuticals as a social responsibility just as important as the adequate supply of food and shelter.

It is against this background that the choice and adaptation of technology in the promotion of healthcare should be viewed. For the purpose of this paper technology can be taken to refer to the knowledge, skills, methods, machinery and equipment and process for designing, operating and maintaining drug and pharmaceutical production. By daptation is meant the transplantation of a basically foreign technology, which is not tailor-made or necessarily perfectly suited to the country of adoption and by the term 'choice' assumes and implies existence of alternative technologies for a given productive purpose.

The purpose of this paper is to look at the healthcare in Zambia prior and after independence. What the countries goals are and what technology can be adopted to achieve those goals in the healthcare services with special reference to drugs and pharmaceuticals and also to look at future role of the international pharmaceutical community in achieving those goals.

HEALTHCARE PRIOR AND AFTER INDEPENDENCE

Healthcare in its totality embodies such aspects as provision of hospitals, health centres, clinics, and the equipment which includes drugs and pharmaceuticals and lastly the provision of the manpower to man the institutions and utilise the equipment to the best advantage of the community. Other aspects connected with healthcare are the infra structures - such as the transport systems, provision of good portable water, proper sanitary system and good housing.

During the colonial era there were only a handful of health institutions and most of these were in the urban areas and were accessible to by a small proportion of the population. However missionaries provided and continue to provide an excellent service, particularly so in the rural areas. However most of the rural community largely depended on the services of the traditional healers using traditional medicine with successful results. It has not been easy to marry the allopathic and traditional medicine. Efforts are being made towards this, as described elsewhere. Because of limited resources most of the healthcare was concentrated on curative medicine.

After independence there was a deliberate decision to increase the number of health institutions as well as increase the range and quality of service. In the process of doing this, there is need to look at the technology involved.

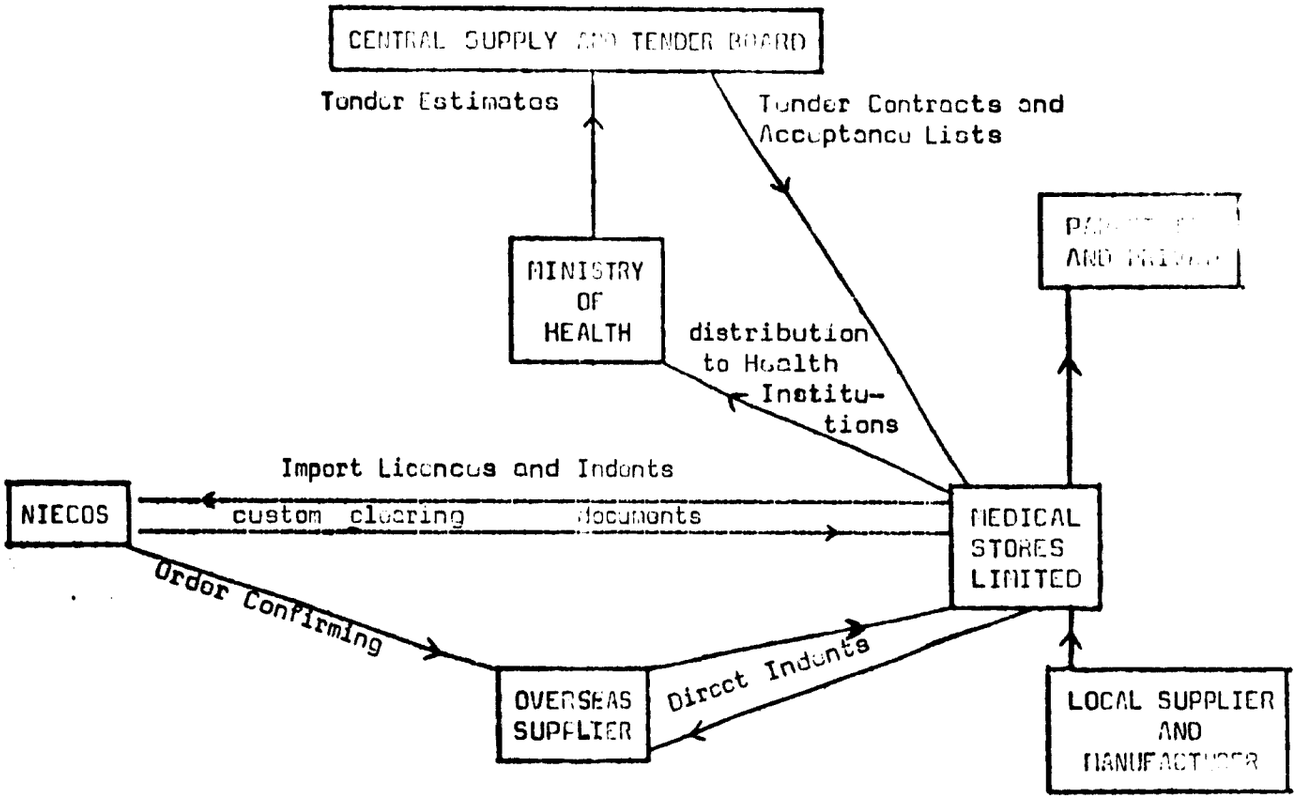
The aim of the Party and its Government is to improve and expand health services so as to cover all areas in the republic and in doing so to continue to make the health services efficient and available free for all people in the republic. The provision of free medical services poses a challenge in the choice, adoption adaptation of appropriate technology in the promotion of healthcare, particularly the provision of drugs and pharmaceuticals. The appropriate technology and its adoption should aim at an aggregate of whatever is necessary to either produce new drugs and pharmaceuticals and services or to produce the ones already available better or more cheaply. Therefore when assessing the type of technology, the need to improve the production of drugs and pharmaceuticals at a reduced cost and eventually improve the welfare of the State, it is necessary to consider the state of existing technology, its success and in particular its failure, taking into account the local environment. It is the failure that will provide environment for improvement and innovation. Unlike some other modern industries, the pharmaceutical industry consists of several thousand units ranging from very small establishments specialising in the manufacture of one item to enormous manufacturing empires. However processes of manufacturing can be greatly affected by altitude, weather, general geographical conditions and pollution. So that the design of certain machinery will take these into consideration. For example humidity greatly affects the manufacture of soluble tablets in Zambia. One can only produce these during the period July to October when relative humidity is low. (Medical facilities in Zambia 1964-76 Table I).

PRESENT SETTING

1. PROCUREMENT OF DRUGS AND PHARMACEUTICALS

The basic principle of Government procurement of pharmaceuticals has not changed, however the mechanics of it have changed considerably. The buying is still done by tender. The Ministry of Health submits tender estimates to the Central Supply and Tender Board which processes and adjucates the tenders. At present tenders are still a mixture of ethicals and generics. The Tender Board sends tender contracts and acceptance lists to Medical Stores Limited which then prepares import licences and indents which are then passed to National Import & Export Overseas Services Zambia Limited (NIEOS). These confirm orders and afterwards send custom clearing documents back to Medical Stores. Suppliers consign their goods direct to Medical Stores Limited, who then distribute to various health institutions and sell directly to other organisations and the public. Some of the tenders are awarded to local importers and manufacturers. At present Medical Stores also places direct orders on suppliers.

GOVERNMENT PROCUREMENT OF PHARMACEUTICALS DIAGRAMATICALLY



The Tender Board is responsible to the Ministry of Finance and the principle of lowest quotation is applied. For local manufacturers there is a weightage of 10 and an additional 2½% for local agents. There is room to raise the former. The obvious disadvantages of the tender system are (a) time consuming and (b) likely exposure to being offered cheap drugs. However steps have been taken by the establishment of the Food and Drugs Act and the establishment of Quality Control Laboratory to enforce the provisions of the Act. Both imported and locally manufactured pharmaceuticals are supposed to be quality controlled prior to being accepted by Medical Stores. This is one area where it is important to scrutinise the type of technology to be chosen. There is need to chose the type of instrumentation that can not only be easily adapted but should also be capable of being serviced locally by local expertise.

2. PHARMACEUTICALS BEING PROCURED

The types of drugs and pharmaceuticals that are being imported are largely influenced by the type of diseases that are prevalent in the country. The main diseases in Zambia are those common to the whole of Africa. A major number is associated with malnutrition, environmental and social diseases, see tables below.

HEALTH CENTRES MORBIDITY 1975/76
(All Ages both Sexes)

CAUSE	1975	1976
Malaria	30,285	30,009
Respiratory diseases	27,558	28,077
Digestive/Abdominal disorders	25,667	24,590
Measles	12,095	10,268
All other Infections/Parasitic diseases excluding Gastric Enteric	10,819	11,016
Diseases of the Skin	5,642	6,782
Eye disorders	4,316	4,989
Anaemia	3,185	3,315
Malnutrition	2,926	3,111

HOSPITALISED MORBIDITY 1975/76
(All Ages both Sexes)

CAUSE	1975	1976
Respiratory diseases	40,945	45,359
Malaria	33,491	36,057
Non Infective Gastro Intestinal diseases	17,628	19,020
Genitor Urinary diseases	16,779	17,934
Typhoid/Dysentry/Infective Gastro Intestical	15,656	14,765
Measles	14,032	19,250
Diseases of the Skin	13,403	15,554
Anaemia	8,536	9,404
Malnutrition	8,152	9,523

HOSPITAL OUT PATIENT MORBIDITY
(All Ages both Sexes)

CAUSE	1975	1976
Respiratory diseases	359,344	472,343
Digestive/Abdominal disorders	441,399	465,714
Injuries and Accidents	233,047	263,608
All Other Infections/Parasitic	241,803	250,512
Malaria	160,541	173,134
Diseases of the Skin	102,894	144,939
Eye disorders	109,980	122,799
Disorders of Tooth	52,097	108,073
Venereal diseases	37,990	49,024
Genito Urinary	44,894	42,313

PSYCHIATRIC SERVICES IN ZAMBIA 1965 - 1976
(Admissions and cases treated)

1965	1966	1967	1968	1969	1970	1971	1972	1973	1974	1975	1976
1401	2705	3132	3207	4181	4596	4937	5397	5801	6327	5931	[illegible]

It can be seen from the tables that there is an upward trend in attendance with a corresponding increase in the consumption of drugs and pharmaceuticals. With rising costs and limited funds it will be necessary to produce some of the pharmaceuticals locally using generic names. The use of brand names as opposed to generic names enables pharmaceutical firms to sell essentially similar drug formulations at widely varying prices. For developing countries it is important to establish a list of essentiel drugs consonant with the disease pattern of the country. Special efforts need to be made to ensure that the country devotes adequate attention to producing drugs and medicines which are most essential to the large mass of people and that these are produced at a reasonable price within the reach of common man. In choosing the type of technology in drug production it is important to bear in mind one important characteristic of the industry which is quick product change.

In Zambia the problem of the over-increasing costs of providing drugs and medical supplies has been recognised. Efforts are being made to explore ways and means of effecting economies. The University Teaching Hospital which is the largest health institution in the country has drawn up a formulary. However in order to cut down on the cost of providing drugs and pharmaceuticals it is important to seriously look at the role of the traditional healer, who uses medicine native to the territory. In fact this is one area with greatest potential in the development of the drug industry in the country. Efforts are being made to bring the traditional healer into healthcare services.

Traditional medicine is an area where efforts should be made to develop a technology which is skill orientated to suit local conditions utilising as far as possible indegenous raw materials. The training of the traditional healer has been mainly horizontal. There will be need to resort to vertical training schemes. By integrating scientific know-how it should be possible to broaden the basis of his (traditional healer's) knowledge of medicines so that he can contribute towards a responsible manpower pool that will serve the drug and pharmaceutical industry.

In Zambia there are two areas where flow of technology is of prime importance with regard to drugs and pharmaceuticals. The first concerns imported drugs. As mentioned already, it is important to produce some of these under generic names, using wherever possible locally available materials. The second concerns traditional medicine. There will be need to research into traditional herbs. This technology has to deal with research and introduction of new drugs to treat diseases which do not

respond to allopathic medicine. Two areas where traditional healers have had great success are in the treatment of mental illness and infertility. So that there are prospects for research of psychotropic and fertility drugs.

3. THE PHARMACEUTICAL INDUSTRY

The industry is still very small and is basically dealing with manufacture (formulation) of generic medicaments such as tablets, capsules, mixtures and ointments. It also has a large proportion of its interest in the manufacture of toiletries and cosmetics. An Intravenous Fluid Plant under the joint venture of Induco and VIFOR is still under construction and will soon be commissioned. The total capacity of the plant is 1 million bags - a mixture of 500 ml, 100 ml and 150 ml packs.

Due to the small population of Zambia - about 5 million the industry is not able to finance any research in drug development but relies heavily on development and research work from other more developed countries. At present most of the inputs for local production are imported.

Some of the problems facing the industry with regard to the transfer of appropriate technology are lack of finance, know-how and absence of basic material industry. Lack of finance affects expansion of existing 'plants' so that those products that are formulated locally can be produced in sufficient quantity to satisfy the local demand. At present some of the local manufacturers can only afford machinery with very limited capacities. There is therefore need to expand existing plants, although there is still room for new plants. For this to be possible in certain areas it will be necessary for the companies concerned to be committed to contracts with the Ministry of Health. This will allow the companies to negotiate for bulk buying of materials and ensure that proper production planning is made. In fact these contracts could be done at regional level in order to provide large through put with reserves for export market. However, investment in plant and machinery alone will not solve the problem. At present lack of know-how is more critical than lack of finance. As the industry makes efforts to expand, it will be necessary for the international pharmaceutical community to help to provide know-how either by providing short courses, but above all by going into franchise manufacturing arrangements with local firms. The Ministry of Industry through the Industrial Development Act 1977 provides a wide range of incentives for would be investors - regarding agreements for transfer of technology and expertise. However it is important to mention that the Act allows no restrictions by the Agreement on :-

1. Use of competitive techniques.
2. The right of the manufacturer to export to other countries.
3. The right of the manufacturer to purchase supplies from elsewhere.

4. Volume or structure of production.
5. The right to use any pantented process as seen fit.

An enterprise must qualify as a priority enterprise in order to qualify for incentives and the criteria for qualification are as follows:-

1. Maximum utilisation of domestic raw materials.
2. Production of intermediate goods which are used by other industries.
3. Diversification of its industrial structure.
4. Creation of substantial opportunities for permanent employment.
5. Improvement of domestic industrial skills or fostering the development of domestic technology.
6. Promoting industrial development in rural areas.

As it can be seen the Act provides sufficient environment for the development of certain basic pharmaceutical industries. There are certain raw materials now being imported which could be manufactured locally or manufactured in greater quantities to meet the country's needs. These products include starch, talcum powder, liquid glucose, alcohol, glycerin, zinc oxide, lead oxide, copper sulphate, nitric acid, ammonia, acetic acid, methylated spirits. Some of the products are agro-chemical based and these include the following oils; arachis (groundnut), linseed, castor, lemon, orange, turpentine, eucalyptus, cottonseed, lemmon grass and oleoresin. Honey and beeswax are being produced but there is need to improve the technology of processing as well as the quantity. The industry is self sufficient in sugar which is a major component in cough preparations. Other products are petrol chemical based such as liquid paraffin, white soft paraffin. For packaging materials the following are already being produced locally; glass bottles, corrugated cartons, cardboard cartons, plastic containers, shrink wrap, aluminium caps and adhesives. However there are prospects for manufacturing of aluminium tubes as a lot of tooth-paste is manufactured. All the paper is imported and yet there is no paper reprocessing industry.

COMPANIES INVOLVED IN PHARMACEUTICAL MANUFACTURE

1. ASPRO-NICHOLAS - Located in Ndola.
   Tied basically to own products.

2. General Pharmaceuticals Limited - Located in Kabwe.
   The factory will be wholly concerned with the production of intravenous solutions. It has yet to be commissioned.
   It has an initial production capacity of 500,00 x ½ litre. However this will be increased to 1 million bags of pack sized 500 ml, 150 ml and 100 ml.

3. International Chemicals Limited - Located in Lusaka.
   At present it manufactures household products and over the counter products

in liquid form. Estimated capacity 80,000 litres. The company has plans to move to pharmaceutical production.

4. I.T.R. Pharmaceuticals Limited - Located in Lusaka.
It manufactures its own brand of tablets and mixtures. It has a small sterile section for the manufacture of eye preparations and injections only in embryo stage at present time. Estimated capacities: 20 million tablets/annum, oral mixtures 10,000 litres/annum.

5. Medical Stores Limited - Located in Lusaka.
It manufactures mainly bulk preparations for large pack distribution to Hospitals, clinics and health centres.

A. Oral Liquid Preparations

Type	Total Capacity	Average Capacity in Use
Cough Mixtures and Linctuses	69,000 litres	49,000 litres
Antidiarrheal Mixtures	33,000 "	23,000 "
Antacid Suspensions	16,000 "	11,000 "
B. Solutions, Emulsions, Applications, Lotions and Liniments	70,000 "	50,000 "
	70,000 "	50,000 "
C. Miscellaneous Syrups	56,000 "	40,000 "
D. Tinctures, Ear Drops and Elixirs	12,000 "	8,500 "
E. Ointments and Creams	12,000 kg	6,000 kg.

6. National Drug Company Limited - Located in Lusaka.
This is the largest manufacturing unit with a fairly comprehensive quality control laboratory. It manufactures products under its own brand name, generics and also does franchise manufacturing.
Capacities (8 hours shift)

Uncoated tablets	150 million/annum
Coated "	25 " "
Capsules	10 " "
Oral Liquids	45,000 litres/annum
Other Liquids	20,000 " "
Ointments/Creams	20,000 Kg/annum

7. Sterling Winthrop Limited - Located in Ndola
Tied basically to own products.

8. Vindas Drug House - Located in Lusaka.
Manufactures generic tablets, liquids, ointments, creams and a range of brand medicines. Estimated capacities: Uncoated tablets 40 million/annum Oral Liquids 20,000 litres/annum, Ointments 10,000 Kg/annum.

ADDENDUM: to section 3 - The Pharmaceutical Industry

Industrial Development Act 1977 - Incentives applicable to priority enterprises:

(a) preferential treatment with respect to Government purchasing unless the tender price submitted by such enterprise exceeds the lowest bid by one hundred and ten per centum or more;

(b) preferential treatment with respect to the granting and processing of import licences;

(c) rebates on customs duty payable on capital equipment, raw materials and other intermediate goods where:-

(i) in the case of capital equipment, labour intensive techniques of production are not a viable alternative;

(ii) in the case of raw materials, they are not available from domestic sources of supply;

(iii) in the case of intermediate goods, they do not inhibit the creation of domestic value-added;

(d) relief from sales tax in respect of the items described in paragraph (c), subject to the provisions of the said paragraph;

(e) relief from Selective Employment tax, for such period as the Minister responsible for the administration thereof may prescribe;

(f) relief from Income tax in such manner and for such period as the Minister responsible for the administration thereof may prescribe.

THE ROLE OF TRADITIONAL MEDICINE

Zambia has a long tradition of using herbal medicines. Their effectiveness in curing and soothing a range of human ailments as well as their easy accessibility to the common man are some of the virtues which survived them throughout history. During the long history of the use of this system traditional healers in different parts of the country tried to utilise locally growing plants and accepted those found useful after trial for treatment of diseases. This has led to some kind of confusion in the nomenclature and identity of some very useful drugs. This lack of any written document has added to the confusion as the knowledge continues to be passed verbally from one member of the family to the other. The traditional healer emphasises on the use of the plant part as a whole. Therefore the method of evaluating the active principles is quite different from that used in modern clinical medicine. There is therefore great need of evolving techniques where action under prescribed form can be evaluated. There is need for multi disciplinary research into the values of traditional medicine with a view of establishing the possibility of marrying traditional and allopathic medicine. The Government through the National Council for Scientific Research (NCSR) and the University of Zambia, School of Natural Sciences are investigating the local medicines in depth in an attempt to separate active principles of therapeutic use and although this is still embryonic there will be immense development in this field. Therefore the choice and adopted technology required should be such as to utilise local skills and local participation. There is need to pool the resources of the NCSR, the University of Zambia, Schools of Natural Resources, Medicine, Agriculture and field workers in the Ministry of Forestry. This should go a long way in the survey of plant research, identification, collection of medicinal plants and experimental cultivation of some of them and identification, extraction and evaluation of active constituents.

On the clinical side, efforts have been made by holding the "First National Workshop on Traditional Medicine and its role in the development of primary Healthcare in Zambia". Amongst the objectives of the workshop were:-

1. To establish a dialogue between allopathic and traditional practioners.
2. Gain an understanding of the contribution being made to primary healthcare in both systems and
3. To establish areas of collaboration between the two healthcare systems.

LINE OF APPROACH FOR CLINICAL CO-OPERATION

In my view clinical research will be a fruitful line of approach for clarification of the principles and methods of diagnosis and treatment of diseases as practised by the traditional healers. This should necessitate the need to provide room at hospitals, clinics and health centres for traditional healers to attend to patients. If correctly carried out, clinical research will not only help in the

proper comprehension of the basic traditional medicine but also be of immense value to the economic development of the country and the proper use of the available resources in the promotion of healthcare. Elderly women in rural areas could be educated in rudiments of midwifery and these can provide a useful service in deliveries particularly where elderly mothers are concerned and who may view delivery by a young nurse with mixed feelings. Patients would be observed for effects of diet habits as it is common knowledge for traditional healers to prescribe eating habits of their patients, by prohibiting the patients from eating certain foods. There will be need to research into the dose-effect relationship so that proper effective and safe dosage may be established, classified and fixed. From these findings it may be possible in certain cases to establish proper dosage forms.

PERSPECTIVES

The development and promotion of healthcare services will be directed by the national goals.

1. The development of an effective and integrated national healthcare system.
2. Development of basic health services in the rural areas priority being given to those areas where no such facilities exist.
3. Movement towards complete integration and expansion of preventive and curative services.
4. Provision of health protection to an increasing number of mothers, infants, school children and certain vulnerable categories to workers.
5. Decentralisation of basic health services.
6. The nutritional well-being of the population with particular reference to vulnerable groups.

The choice and adaptation of technology will take these goals into consideration. There will be need for health education so that problems like malnutrition can be cut down. At present this is not so much a problem of poverty but of ignorance. There will be need to introduce basic technical skills of diagnosing diseases and providing first line treatment so that costs on transport can be minimised. It will be necessary to step up production of existing units by improvement of technology through some kind of research and development activities. It will still be necessary in certain crucial areas to obtain technology from elsewhere for certain operations. By harnessing the available limited resources of research and development, and by concentrating on selected fields and also by improving imported processes, the prospects for the future should be bright. However, in all this it will be absolutely necessary to critically examine the choice and adopted technology and evaluate the project in question because lack of this can create more problems than those that were intended to be solved and result in the wastage of available resources.

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2. " " " Development Planning
3. " " " Commerce & Foreign Trade
4. " " " Health

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MEDICAL FACILITIES IN ZAMBIA : TIME TRENDS 1964 - 76

YEAR	64	65	66	67	68	69	70	71	72	73	74	75	76
HOSPITALS	48	50	53	54	62	66	72	76	76	79	79	79	81
NO OF BEDS AND COTS	7710	8330	8750	9210	9970	10550	11520	11910	12370	12870	13570	14400	14670
HEALTH CENTRES	306	311	343	380	419	464	501	556	595	612	625	671	685
BEDS AND COTS	3140	3440	3810	3960	3970	4080	4220	4190	4530	4630	5030	4980	5070
TOTAL NO PITALS AND HEALTH CENTRES	354	361	396	434	481	530	573	632	671	691	704	750	766
NO OF IN PATIENT BEDS AND COTS	10850	11770	12560	13070	13940	14630	15740	16300	17400	18700	18900	19300	19740
NO OF BASSARIA	33	30	32	30	24	22	21	20	19	17	17	17	17
TOTAL IN PATIENT ADMISSIONS	338400	351300	368450	400950	415750	446500	472700	466400	496000	513300	502400	532900	574900
OUT PATIENT ATTENDANCES	14409200	15465400	14927300	17403900	18390400	19631000	22481400	24082400	24564900	22078200	23634300	24754400	26011300

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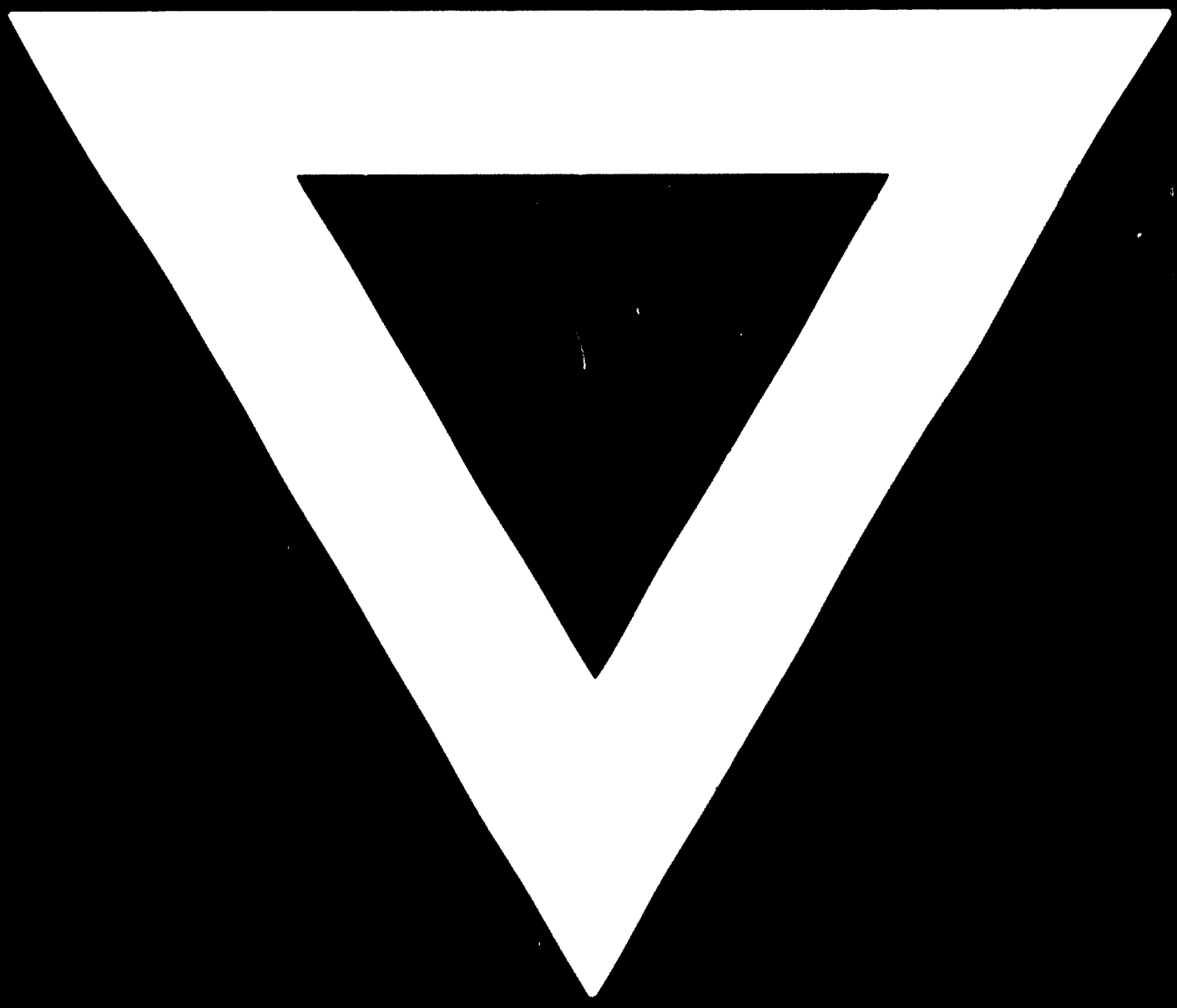

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