Timor-Leste

Pharmaceuticals in Health Care Delivery

Mission Report 6-17 February 2012

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Kathleen A Holloway

Regional Advisor in Essential Drugs and Other Medicines

World Health Organization,
Regional Office for South East Asia,
New Delhi

Contents

Programme Agenda

Monday, Feb 6th
Morning: WHO Representative; Department Pharmacy MOH;
Afternoon: National Community Health Directorate.

Tuesday, Feb 7th
Morning: Department of Hospitals MOH
SAMES (Drug procurement & supply); Pharmacy Association
Afternoon: In-service training Institute (INS); Medical Association

Wednesday, Feb 8th
Morning: Customs Department; National Hospital;
Faculty of Medicine UNTL;
Afternoon: Community Health Centre & private Pharmacy Dili district.

Thursday, Feb 9th
Morning: Dili - Bacau District;
Afternoon: Bacau District Hospital.

Friday, Feb 10th
Morning: Walili and Laga Community Health Centres;
Afternoon: Walili and Laga HPs.

Saturday, Feb 11th
Morning: Private pharmacies in Bacau
Afternoon: Bacau - Lospalos

Sunday, Feb 12th
Morning: Hospital Director, Pharmacy Chief, Lospalos;
Afternoon: Free.

Monday, Feb 13th
Morning: District Hospital, Lospalos;
Afternoon: Private pharmacies, Lospalos.

Tuesday, Feb 14th
Morning: Community Health Centre, Lautem;
Afternoon: Health Post, Lavai.

Wednesday, Feb 15th
Morning: Bacau - Dili
Afternoon: World Bank and AusAid

Thursday, Feb 16th **Workshop for national stakeholders**
Morning: Presentation of findings by Dr. K.A.Holloway
Plenary discussion of findings and group work;
Afternoon: Presentation of group work;
Plenary discussion of group work;
Development of recommendations.

Friday, Feb 17th

Morning: Debriefing with DG MOH and WR;
Afternoon: Departure for Delhi.

Acronyms

ABC ABC analysis – method for measuring drug consumption
ADR Adverse Drug Reaction
ARI Acute Respiratory Infection
CHC Community Health Centre
CPD Continuing professional development
CME Continuing medical education
CRAF Commission for Regulation of Pharmaceuticals
DHS Department of Health Services
DIC Drug Information Centre
DHO District Health Office
DOP Department of Pharmacy, MOH
DRA Drug Regulatory Authority
DTC Drug and Therapeutic Committees
EDL Essential Drug List
EML Essential Medicines List
HQ Headquarters
HP Health Post
HPIC Health Post in Charge
INS National Institute of In-service Training
IPD Inpatient department
LMIS Logistics Drug Management Inventory System
MIC Medicine Information Centre
MO Medical Officer (doctor)
MOE Ministry of Education
MOF Ministry of Finance
MOH Ministry of Health
MRA Medicines Regulatory Authority
MTC Medicines and Therapeutic Committee
NGO Non-governmental organization
NDP National Drug Policy
NMP National Medicines Policy
OPD Outpatient department
OTC Over-the-counter
RUM Rational use of medicines
SAMES Service Autonomo de Medicamentos e Equipamentos de Saude
SISCa Outreach clinics operated from CHCs
SOP Standard Operating Procedures
STG Standard Treatment Guidelines
TLMA Timor-Leste Medical Association
TLPA Timor-Leste Pharmacy Association
TOR Terms of Reference
UNTL National University of Timor Leste
VEN Vital Essential Non-Essential – method for classifying drug importance
WHO World Health Organization

Executive summary

A visit was made to Timor-Leste during February 6-17, 2012. The programme was arranged in agreement with the MOH. The TOR were to undertake a situational analysis of the pharmaceutical situation, focusing on health care delivery, and to conduct a 1-day workshop with stakeholders to discuss the findings and develop a roadmap for national action. Visits were made to public health facilities and private pharmacies in three districts, the major MOH departments (including the Department of Drug Pharmacy and SAMES), the Faculty of Medicine in the National University of Timor-Leste, the Institute of In-Service Training, the National Referral Hospital and the Timor-Leste Medical Association and Pharmacy Association. It was found that Timor-Leste has an extensive health care system in difficult terrain with trained health care personnel. However, there are a number of serious problems in the pharmaceutical sector concerning drug supply, selection, use, regulation, policy, information and coordination, as highlighted below, but there are sufficient resources and capacity to address many of the problems.

Drug Supply and selection

Medicines are procured and supplied to all public health facilities by a partially independent organization, accountable directly to the Minister of Health, Service Autonomo de Medicamentos e Equipamentos de Saude (SAMES). The Department of Pharmacy in the MOH is responsible for management of medicines in the districts and facilities and for quantification. A 'pull' system is used, the districts ordering drugs quarterly, and the hospitals monthly, from SAMES. Some short-dated drugs are 'pushed' down to the districts from the central level. All facilities complained of frequent stock-outs, although during the visit, drugs had been recently received by most health facilities so were few stock-outs observed. Short-dated and expired medicines (particularly Coartem tablets and injectables) were observed in some facilities. The drug management systems used by the Department of Pharmacy and SAMES are manual and not harmonized, the quantification process is poor and frequent emergency orders are made, sometimes weekly. Health workers deliberately exaggerate stock-outs and amounts needed to ensure SAMES sends some drugs and SAMES knows that health workers do this and so sends reduced quantities. Good data on distribution and consumption are needed to improve quantification but currently this is not possible due to a poor manual inventory control system in the district facilities. There is a national Essential Medicines List (NEML) 2010, which is followed by SAMES. Referral hospitals have some budget to buy specialist non-EML drugs which are requested by specialists and purchased by SAMES or from other distributors after approval by the MOH. There is no technical committee to decide upon whether these non-EML drugs are appropriate.

It is recommended that the drug management systems of the Department of Pharmacy and SAMES be harmonized and that an electronic logistic management inventory system operating centrally be extended down to the level of the district to improve stock control and quantification. It is further recommended that SAMES publish distribution data and the Department of Pharmacy consumption data annually and that all pharmacy technicians and assistants be trained in drug management and quantification. It is also recommended that a committee be established to judge the appropriateness of non-EML drug requests from the referral hospitals.

Drug use

Small surveys on medicine use have been undertaken in 2006 and 2011. The consultant also undertook a small prescription survey and observed prescribing that was similar to what has been previously published. High use of antibiotics, particularly for upper respiratory tract infection, and high use of vitamins was observed in all district level facilities. National standard treatment guidelines for primary care and referral hospitals have been published by the Department of Pharmacy in 2010, but few prescribers are using them or any other source of independent drug information. This was partly because of poor distribution and the STGs not being in the languages used by health workers (Tetum and Indonesian). The Faculty of Medicine was not using the MOH Standard Treatment Guidelines and the Cuban doctors (responsible for training new Timorese doctors) used their own guidelines (in Spanish). While, prescribing principles are taught at undergraduate pre-clinical level, this knowledge is later undermined by clinical studies and later work. Continuing professional development (CPD) is adhoc and most supervision is by the vertical disease control programs or restricted to management issues. There is very little refresher training on general prescribing. No hospitals have Drug and Therapeutic Committees or undertake any prescription audit.

It is recommended that regular monitoring of drug prescription be undertaken in all facilities, with a requirement for districts and hospitals to report on their results to the Department of Pharmacy, MOH, annually. Other interventions recommended include: establishing Drug and Therapeutic Committees (DTCs) in all hospitals (to monitor adherence to the National EML, undertake prescription audit and coordinate refresher training of staff); distributing updated guidelines and incorporating them into undergraduate and Continuing Professional Development (CPD) curricula; and developing public education programs on medicines use to be delivered through community health workers attached to primary health care facilities. In order to facilitate coordination across departments to implement policies to promote rational use of medicines, it is recommended that a unit dedicated to regular monitoring of medicines use and implementing strategies to improve use be created within the Department of Pharmacy in the MOH.

Drug Regulation

There is currently no legislation for the regulation of drugs and no drug regulatory authority in Timor-Leste. A draft Drug Act is currently being considered by government. Drug regulatory issues are overseen by the Commission for Regulation of Pharmaceutical Activities (CRAF) appointed by government. CRAF has representation of various government departments, including SAMES and the Department of Pharmacy (DOP) and also the Customs, Police, Trade and Justice Departments. CRAF is responsible controlling the sales of narcotic and psychotherapeutic controlled drugs, approving importation of drugs and making recommendation for the issuance of drug outlet licenses. CRAF has a small budget but is not a technical or executive body. The Department of Pharmacy coordinates regulatory activities, mostly inspection of pharmacies, on behalf of CRAF, sometimes being able to use the CRAF budget after a lengthy MOH approval process. Since the Department of Pharmacy has only 6 staff and also covers drug management,

regulatory activities are extremely limited. There is no technical registration of drugs, no pharmacovigilance, no monitoring of drug promotion and no laboratory testing of drug quality.

There are 38 private pharmacies in the country and, in many of them, dispensing is done by unqualified persons and prescription-only drugs such as antibiotics are often sold without prescription, contrary to rules issued by the MOH. The number of products in the market is unknown, although it may be possible to gain this information from the Customs Department since all drugs are imported. In one pharmacy shop in Dili, over 50 brands of vitamins were observed.

It is recommended that the Department of Pharmacy be proactive in explaining the new draft Drug Act to all relevant government departments and ministries and to parliamentarians in order to ensure that it is passed as soon as possible. It is further recommended that a fully resourced Drug Regulatory Authority be established as soon as possible. Further recommendations include: developing SOPs for all regulatory procedures, developing a technical drug registration process, developing and publishing drug schedules for OTC and prescription-only drugs, and starting units to monitor adverse drug reactions and drug promotional activities.

Coordination

Many functions such as monitoring of medicines use, coordinating CPD, supporting DTCs, ensuring adherence to the National EML, updating guidelines and ensuring their distribution and incorporation into CPD and undergraduate curricula, public education on medicines use are not properly undertaken by any MOH department. The National Drug Policy document, while comprehensive, is not implemented in many aspects. The relatively low position of the Department of Pharmacy in the MOH, being a department of 6 staff under the Directorate of Community Health Services, results in a lack of resources and authority to carry out coordinating functions with regard to drug policy across different directorates, departments and ministries.

It is recommended that a multidisciplinary mandated independent statutory committee, reporting directly to the Minister of Health, be established and that an executive unit, possibly a Directorate of Pharmacy, be established to carry out the recommendations of the statutory committee. It is also recommended that the Department of Pharmacy be elevated to a Directorate of Pharmacy in order to attract more resources and have greater authority to carry out the wishes of the mandated statutory committee and to coordinate drug policy across departments, directorates and ministries. It is further recommended that within the Directorate of Pharmacy there be a unit dedicated to monitoring medicines use and coordinating the implementation of strategies to improve use.

Terms of Reference

The objectives were:

(1) to meet senior officials of the Timor-Leste Ministry of Health (MOH).

(2) to undertake a rapid situational analysis of the pharmaceutical situation - with a focus on health care delivery and use of medicines.

(3) to conduct a 1-day workshop with national stakeholders to validate the findings of the situational analysis and to develop recommendations for future use by MOH, WHO and stakeholders in planning.

Background

This mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector in order to aid MOH in planning future action and also to plan for future WHO technical support.

The regional strategy to promote rational use of medicines (RUM), updated at the regional meeting of July 2010, recommends undertaking a situational analysis in order to plan for a more coordinated integrated approach to improving the use of medicines. The regional resolution, SEA/RC64/R5 on Essential Drug Policy including the rational use of medicines, made the same recommendation in 2011. This mission was undertaken during 5-17 February, 2012, for this purpose. During the situational analysis, a checklist/tool developed in HQ/WHO and now being revised in the region, was used. This tool allows the systematic collection of information. The persons met during the fact finding mission can be seen in annex 1. An integral part of this mission was a 1-day workshop with 69 stakeholders that was held at the end of the mission to discuss and validate the findings and to form a road map for action. The participants of the workshop can be seen in annex 2.

Timor-Leste is one of the poorest countries in the world, with nearly half of the population estimated to live below the national poverty line (MOF 2010). Nevertheless, the country has a fairly extensive health care delivery system with many trained staff. Part of this health delivery system includes delivery of medicines, free to the patient, in the public sector. However, there have been frequent complaints of stock-outs from many public health facilities and also there are concerns about irrational use of medicines. For these reasons, the situational analysis was undertaken. It is hoped that the recommendations made will be incorporated into future plans of action.

The words “medicine” and “drug” are used interchangeably in this report.

Medicines Supply

Drugs are procured and distributed by *Servico Autonomo de Medicamentos e Equipamentos de Saude* (SAMES). This is a semi-autonomous agency that has a mandate from parliament to procure, store and distribute medicines, consumables and laboratory items for the public health care delivery system. It is the policy that medicines are dispensed free of charge to patients in the public sector at all levels. There is no alternative health insurance in Timor-Leste. Currently, the budget is supplied directly from Ministry of Finance (MOF) to SAMES for purchase of medicines for distribution to health facilities. The budget last year was about 3.8 million USD, and nearly 1 million USD worth of pharmaceuticals for vertical programmes were received from UNICEF, UNFPA and Global Fund. This year the budget has been increased to 5 million USD but SAMES has a debt of 1.7 million USD from last year. There is a plan to capitalize SAMES. This would involve the government providing about 10 million USD to SAMES to enable it to purchase medicines up-front and then get payment from MOF afterwards. This would enable SAMES to avoid delays in executing their procurement plan due to late disbursement of funds from MOF. Nevertheless, this system would not enable SAMES to avoid debt if MOF was late in payment over a number of years. Currently SAMES does not sell to the private sector and is totally dependent on payment from MOF (whether or not there is capitalization).

Only medicines belonging to the National List of Essential Medicines (NEML) can be purchased for distribution to the districts. Referral hospitals have an additional budget that can be used to purchase non-EML medicines after approval from the Commission of Regulation of Pharmaceuticals Activities (CRAF). Responsibility for how drugs are managed in the districts and health facilities rests with the Department of Pharmacy (DOP), who should inform SAMES about stock levels, quantities needed etc. MOH/DOP has produced extensive guidelines for good pharmacy practice (GPP) and a checklist for audit and inspection of pharmacies (MOH 2010). However, the DOP only has 6 staff and is also responsible for various drug regulatory activities as well as development of the NEML and national guidelines so their capacity for supervisory visits to the districts is very limited. The National Referral hospital and the other referral hospitals have some budget to buy non-EML and specialist drugs, which can be bought from other distributors if SAMES does not have these drugs with permission from MOH. By contrast, the districts can only order EML drugs from SAMES.

Distribution

Medicines are distributed from SAMES to the districts and to referral hospitals. There are 5 referral hospitals, 1 national referral hospital, 13 districts (each with a district hospital), 65 Community Health Centres (CHCs) and 203 Health Posts. Ordering and distribution occur quarterly from districts but monthly from hospitals. Only drugs belonging to the NEML can be procured and distributed, with the exception of the referral hospitals who may procure non-EML drugs after approval from CRAF. There are 11 pharmacists (BPharm), 50 pharmacy technicians (diploma) and 106 pharmacy assistants (certificate level) in the country. Pharmacy technicians or assistants are generally in charge of pharmacies at referral hospitals and CHCs but the pharmacies of HPs are managed by senior nurses. Drugs from the vertical disease control

programs also pass through SAMES. Drugs are delivered to the hospitals and district centres by SAMES. Districts store the deliveries destined for distribution to CHCs and HPs but staff from these facilities must come to collect the packages which the District Health Office (DHO) does not open. The DHO has a pharmacy technician and/or assistant whose job is to supervise drug management and report to the DOP after approval of the reports by the District Health Officer.

The distribution system is a “Pull” system from the districts and hospitals to the central level. There is no official "Push" in the system nor any budget allocation reserved for individual facilities although small amounts of budget are reserved for different facilities. SAMES waits for orders and then supplies what they estimate they can supply - which is often below what is requested. Health workers mentioned that not only do they receive less than requested of the drugs that they have ordered but that they also receive some items not requested, particularly short-dated items. Some staff mentioned that they put zero stock in the quarterly order form and request more quantities than needed in order to ensure that some drugs are supplied.

Procurement

SAMES undertakes central annual procurement by international tender. There is a general procurement decree-law no.10/2005 of 21 November that sets the procurement legal regime and there is the decree-law no.02/2009 of 15 January which sets the specific procurement regime of SAMES. Under this legal framework there is a Permanent Procurement Commission (PPC) with members appointed annually by MOH to oversee procurement. The Department of Pharmacy was represented in previous years but not this year (2012). Current members of the PPC are representatives of the National Laboratory, the National Hospital, , 2 Directors of SAMES, , Medical Equipment Department and the Pharmacy Advisor to SAMES. The PPC is responsible for tender evaluation and making recommendations for contract award to SAMES Council of Administration. This latter council gives the final approval for procurement. The procurement process follows World Bank rules. There is a technical review as well as a price review for all tenders. Some members mentioned that the review system did not always separate technical and financial reviews of tenders.

In general SAMES feels that their procurement system works well though it may be slow. In 2011, MOF did not release the 2011 budget until October 2011 and MOH did not release the budget for emergency drugs until August 2011. They feel the main problem of stock-outs is due to inadequate budgets disbursed late with poor consumption data from the field and numerous emergency orders. Over the last few years, 2 out of 15 suppliers have been black-listed for defaulting. Nevertheless, supplier default and late disbursement by MOF of funds is not the only reason for a lengthy procurement process. It was mentioned by the customs department that one recent consignment of SAMES had rested in the port for more than 5 months before all the papers were submitted and the goods cleared. SAMES mentioned that this consignment concerned three items from the 2010 order delivered late by one supplier. However, the Customs Department mentioned that other consignments have been delayed and it is not clear whether such delays are due to the failure of the supplier to alert SAMES to the shipment of goods in good time or whether the procurement unit had failed to clear the goods. The Customs department mentioned

that SAMES had stated to them that clearance was delayed due to lack of funds to pay the customs duties, although clearance would have been granted on the understanding that payment would be made later. The Customs department further mentioned that they only had a manual system of cargo clearance and so could not give an alert to SAMES that drugs had arrived in port.

Up until 2011, SAMES had to ensure quality as far as possible using the technical specifications provided by suppliers. However, in June 2011 quality testing using the Global Pharma Health Fund (GPHF) Mini-lab was started and it was found that 1 item (aspirin failed a dissolution test) out of 18 medicines in SAMES warehouse that were tested failed the quality test. Unfortunately most of that batch of aspirin had already been distributed and used. However, the batches are now tested upon arrival at SAMES warehouse.

In general all public sector procurement is done by SAMES. Only some non-EML hospital drug items, which SAMES does not have in stock and whose purchase MOH has approved, may be purchased from other suppliers. It was observed by one pharmacy retailer that the prices shown in the invoice of an emergency order for the National Referral Hospital in January 2012 were higher than what were paid in his retail pharmacy and resulted in a cost increase of 26% (USD 5,000). Higher prices are likely with smaller orders, which would occur if purchasing power were de-centralized to the districts.

Quantification

Quantification is based on last year's consumption (distribution data is used as proxy for consumption). There is no central allocation of funds according to population or case-mix. Since there have been complaints of stock-out it is likely that past quantification exercises have under-estimate need. Also the budget from Ministry of Finance (MOF) is always less than required so all procurement plans are done according to budget and not need. It was stated that there is never enough budget to maintain any buffer stock either centrally or in the districts. The current quantification formula aims to replace the consumption of the previous 3 months without any buffer. In theory, the DOP should supervise quantification in the districts and inform SAMES. In practice, there is no accurate district or health facility consumption data and drug management is inadequate so SAMES estimates need according to their own records of past distribution. In 2010 a comparison was made of district consumption estimates using SAMES data and district data collected by the DOP. There was a discrepancy of millions of USD - so it is clear that district consumption data is inadequate. Different health workers were using different quantification formula and, as previously mentioned, some stated that they deliberately over-estimated stock-out and need in order to guarantee that some medicines would come. Poor quantification together with late release of budget was the major cause of stock-outs in 2011.

Drug Availability and Stock management

It was generally observed that availability of EML drugs was quite good, especially for outpatients, since supplies had arrived only 2 weeks previously. However, there were reports and records of serious stock-outs during 2011. A number of drugs, particularly non-EML drugs in referral hospitals, were still out-of-stock such as

injectable atenolol, apresoline and haloperidol and oral spironlactone, sodium bicarbonate, propranolol, loperamide, ketoconazole, quinine, methotrexate and metformin. It was mentioned that irrational use of medicines also contributes to stock-outs and prescribing was clearly affected by stock levels. For example, in one facility OPD, during the stock-out period, the average number of drugs prescribed per patient was 3.0 and the % prescribed multivitamins was 50% while during the well-stocked period patients received on average 3.9 drugs and 93% received multivitamins. Antibiotic use remained the same during both periods. In this same facility, it was observed that there was short-dated erythromycin which was being pushed for use - such that most outpatients (some unnecessarily) were receiving erythromycin that day.

Record keeping of drug stock was not standardized. There were no standardized forms. In one DHO, hand-written forms detailing drug consumption and stock are sent from CHCs and HPs and the information is compiled according to an individual method used by the concerned pharmacy technician in charge. In a hospital, bin cards were used. Expired items were not dealt with in a timely and standardized manner. According to the rules, all expired items should be returned to SAMES. However, many health facilities and districts lack the means to return such items. Some facilities are getting permission for local destruction and some DHOs are keeping monthly records on quantities expired. However, in other facilities expired items were left on the shelves amongst in-date items. In one hospital ward, expired injectable apresoline, promethazine, aminophylline, phenytoin and atropine and oral metoclopramide, folic acid, lopresor, clindamycin, amitriptiline, gliclazide, bisacodyl, nalidixic acid, metformin, quinine, hyoscine, penicillin V, theophylline and potassium chloride were observed. In many health facilities, hundreds of blister packs of 24 Coartem tablets were found to have expired. In some CHCs and HPs, injectables were not much used and expired injections were found e.g. benzathine penicillin, procaine penicillin, gentamicin, ceftriaxone, lidocaine and chloramphenicol injections. The cost of these expired items was more than 1000 USD in one facility.

SAMES mentioned that they have introduced a new electronic drug management inventory system (mSupply software). New forms for tracking orders between health facilities and SAMES together with a new stock-book (pre-printed) for ordering and reporting are planned to be introduced during 2012. There is a plan for Australian volunteer pharmacist to come in July 2012 to undertake training of all district staff in drug stock management, quantification and ordering. Although there were pharmacy technicians and/or assistants in all hospitals and DHOs visited, they did not seem to undertake much supervision of subordinate staff such as nurses or pharmacy assistants in other facilities (in the case of the district health office). One hospital pharmacy technician stated "*Monitoring expired drugs on the ward is not my job, it is the job of the nurses."* Another DHO Pharmacy Technician stated "*I should visit Health Posts quarterly but there is often no transport and anyway I do not have enough time as I frequently have to go to Dili to collect emergency supplies".*

The DOP mentioned that drug management skills in the districts are poor. It was mentioned that the DOP and Institute of In-service (INS) training had already set up a working group to develop a curriculum for training of nurses and pharmacy assistants on stock management, quantification and ordering. The INS had, until quite recently, undertaken pre-service training of pharmacy technicians and assistants and so has

curricula and training modules from these courses. Therefore it is more a question of updating the curricula and training modules based on a needs assessment done by the DOP in the field, rather than developing curricula and teaching material from scratch. Nevertheless any curricula developed would need approval by the Minister of Health and there is no immediate plan for implementation of such a training program.

Possible Solutions

1. Institute pre-printed standardized forms of stock control, harmonized between SAMES and DOP, to manage stock and undertake quantification. This should include:
   - Bin cards with recording of stock coming in and going out and stock balance;
   - Order forms with accurate estimates of past consumption and specific instruction on how to estimate need.

2. Establish a feasible system for managing and monitoring expired drugs locally.

3. Train all pharmacy technicians and assistants in stock management, quantification and how to supervise nurses managing drug stocks.

4. Once a standardized stock-control system is instituted with standardized forms, start a process of extending an electronic logistics drug management inventory system from the central level at SAMES to the district centres and hospitals in order to:
   - improve stock management and quantification;
   - enable monitoring of drug consumption in the public sector.

5. Make it a requirement for drug distribution and consumption data to be published annually and therefore available to all planners:
   - SAMES to publish an annual report on drug distribution, to include various analyses including ABC analysis and distribution by district & hospital;
   - Districts and Department of Pharmacy to publish annual reports on drug consumption.

6. Ensure that every district health office/district hospital employs a pharmacy technician and train such staff to supervise stock management and quantification and monitor drug consumption in all facilities under their care including CHCs, HPs and SISCa clinics.

7. Require all secondary or tertiary level hospitals to employ a pharmacist to:
   - manage drug procurement, quantification and distribution;
   - act as the secretary to the hospital Drug and Therapeutics Committee (DTC);
   - monitor drug consumption and undertake prescription audit and to report the results to the DTC.

8. Establish a technical working group led by the Department of Pharmacy and including SAMES and all relevant programs of MOH, to improve coordination and communication with regard to medicines management.

Medicines Selection and Consumption

Timor-Leste published a National Essential Medicines List (NEML) in 2010. There are about 380 drugs (covering about 160 molecules), categorized by level of facility on the list. Unfortunately, the list is not printed in booklet form with a contents and index section. Therefore it is not very accessible to prescribers. The development of the NEML was done by a Commission specially set up with technical coordination by the Department of Pharmacy. There was input from SAMES, the National Referral Hospitals, other hospitals, the vertical diseases control programs, WHO, World Bank and other partners.

As previously mentioned, all facilities are supplied with NEML drugs procured by SAMES. Only the hospitals have a budget to purchase specialist drugs and some non-EML drugs, after getting permission from CRAF. Purchase of such drugs is decided by the Director of the hospitals on the basis of specialist request. There are no committees to decide non-EML purchase. In an emergency order in January 2012 from the National Referral Hospital, 43% of the items and 52% of the cost were for non-EML drugs.

The total value of drugs and other medical consumables (e.g. dressings) purchased in 2011 was USD 5,190,727 – approximately USD 5 per capita per year. This amount represents greater public expenditure on essential drugs than in many other countries of the region. Table 1 shows the top 20 drugs which cost 17.4% of the procurement. Antibiotics constituted 14% and vitamins 1% of procurement. Since non-drug consumables constitute a large part of the purchase the proportion of the drug budget spent on antibiotics and vitamins is large.

Table 1: Top 20 drugs by value (USD) purchased by SAMES in 2011

	Drug Name	Value		Drug Name	Value
1	Amoxycillin 250mg	196,966	11	Albumin Solution	24,800
2	Griseofulvin 500mg	114,462	12	Ciprofloxacin 250mg	23,400
3	Cotrimoxazol 480mg	95,380	13	Amoxy/Clav 625mg	22,050
4	Erythromycin 250mg	77,696	14	Promethazine 25mg	21,950
5	Ceftriaxone 1gm inj	42,675	15	Ranitidine 150mg	21,608
6	Ibuprofen 400mg	41,130	16	Surgical Spirit	20,067
7	Cloxacillin 250mg	40,080	17	Beclomethasone 250mcg / dose	19,892
8	Cloxacillin 125mg/5ml	33,394	18	Multivitamin tab	19,738
9	Halothane 250ml	21,147	19	Haemacell solution	19,038
10	Paracetamol 500mg	25,300	20	Morphine 10mg inj	16,650
Total value of top 20 items: USD 903,425					

A prescription audit (see section on rational use) found overuse of antibiotics and vitamins and thus considerable cost savings could be made if such over-use were curtailed.

For the most part there is consistency between the SAMES procurement list and the NEML as per MOH policy. Nevertheless, there were a few inconsistencies. For example, captopril and OBH (cough medicine) were being distributed by SAMES even though they are not on the most recent NEML.

Possible solutions

1. Ensure consistency between the NEML and other lists such as that used by SAMES.

2. Establish Drug and Therapeutic Committees or Hospital Specialist Boards to provide guidance on what specialist drugs are "reasonable" for non-EML purchase (which should not be greater than 10% of the budget).

3. Continue to regularly update the NEML, publish the selection criteria, widely disseminate it to all facilities and include it into pre-service and in-service training curricula in order to further sensitize doctors to the utility of following the NEML.

Medicines Use

There have been few surveys of drug use in Timor-Leste. One survey done in 2006 showed that the average number of drugs per patient was 2.4, that 44% of patients received an antibiotic, 40% a vitamin and only 0.4% an injection (Higuchi 2008). The DOP undertook surveys of drug use 2011 in the National Referral Hospital (DOP/MOH 2011) and Community Health Centres (CHCs) of 3 districts (DOP/MOH 2012). In the National Referral Hospital outpatients received 5 drugs on average and 77% received an antibiotic. In the CHCs, outpatients received 3 drugs on average, 77% received an antibiotic and only 0.1% received an injection. More than 90% of drugs were prescribed by generic name.

The consultant undertook a rapid prescribing survey in the outpatient departments in 10 public facilities (serving mostly acute patients) and 3 private pharmacies (serving acute and chronic patients). In each facility 30 prescriptions at the pharmacy or 30 patient encounters from the OPD register were examined. In one pharmacy no prescriptions were kept so a prescription audit could only be conducted in two pharmacies only. In two CHCs, the patient registers from recent outreach clinics (SISCa) were also examined. In addition, the records of patients who had been seen the day of the visit were examined prior to filing in order to match diagnosis against drug prescription with regard to antibiotic use in upper respiratory tract infection cases. The results are shown in table 2.

Table 2: Drug use indicator survey

Drug use indicator	Hosp n=3	CHC n=4	HP n=3	SISCa n=2	Private pharmacy n=2
Average number of drugs per patient	2.9	2.4	2.2	2.8	2.1
% patients receiving antibiotics	52%	42%	59%	75%	27%
% upper respiratory tract infection cases receiving antibiotics	88%	69%	77%	-	-
% patients receiving injections	1.0%	0%	1.5%	-	0%-21%
% patients receiving vitamins	56%	45%	33%	45%	21%
% drugs prescribed by generic name	96%	97%	100%	98%	53%
% prescribed drugs belonging to the national EML	95%	98%	95%	100%	61%
% prescribed drugs that are dispensed	100%	100%	100%	100%	100%
Av.cost/Px (USD)	-	-	-	-	5.14

It can be clearly seen that the prescribing found in the consultant survey is similar to what was found in the other baseline surveys done in 2006 and 2011. The only large difference concerns the average number of drugs per patients in hospitals, which was much lower in the consultant survey than that found in the 2011 MOH survey. This was probably because only acute clinical cases, not chronic specialist cases, were included in the consultant WHO survey. Good aspects of prescribing are that in the public sector injection use is low and prescribing of NEML drugs and drugs by generic name is high. By contrast, in the private sector prescribing of NEML drugs and by generic name is much lower. The number of drugs per patient and the percentage of patients receiving antibiotics are lower in the private sector because many of the prescriptions included in the sample were supplementary prescriptions of patients who had received some of their medicines from a local public facility. In one pharmacy 21% of prescriptions contained an injection – these patients being emergency patients referred from the local hospital. In general, the higher the facility the more drugs were used as expected – thus HPs had lower drug use than hospitals. However, the prescribing rates in SISCa clinics, which are supposed to be for basic primary care, were very high and this requires investigation.

Of concern is the very high use of antibiotics both generally and for upper respiratory tract infection cases in all facility types. Only a minority of upper respiratory tract infection cases (non-pneumonia) should receive antibiotics but, in fact, the majority of such patients received them. A comparison of prescribing by doctors versus nurses was undertaken. It was found that the % of non-pneumonia cases treated with antibiotics was much higher for doctors than nurses – 63% vs 26% in one CHC and 57% vs 43% in another CHC. While more severe cases may be go to doctors rather than nurses, effort was made to ensure the comparison was for similar cases - upper respiratory tract infection cases (non-pneumonia) in patients over the age of 5 years.

Children under the age of 5 years tended to be seen by the IMCI nurse rather than in the OPD. Examination of the IMCI registers in two HPs showed that most children

with ARI were diagnosed with pneumonia and treated with antibiotics. This needs further investigation because the majority of childhood cases with ARI would not normally have pneumonia so it suggests over-diagnosis – perhaps to justify antibiotic prescription. There were also very high levels of vitamin use, particularly multivitamins, which have little therapeutic benefit and which were often prescribed in addition to other drugs. Unnecessary use of antibiotics and multivitamins is probably wasting considerable resources since they are among the top 20 drug items by value that were purchased in 2011. The author had some discussion with doctors and nurses about whether they thought antibiotic and vitamin prescribing was high. None thought there was over-prescribing and few were aware of the dangers of over-prescribing. This indicates that prescribers need sensitization to the wastefulness and hazards of over-prescribing.

In most of the public facilities visited, doctors and nurse prescribers were seeing about 20-30 patients per day. Thus most prescribers should not be constrained by overly short consultations from making proper diagnoses. It is not clear how many patients each prescriber is seeing in the SISCa clinics. If one prescriber is constrained to see many patients in a short period of time this may account for the high prescribing rates.

Dispensing was generally done by nurses. It was observed that the patient-dispenser contact time was often less than one minute, so allowing little time to give patients proper instruction on how to take their medicines. There was no labeling apart from sometimes writing the number of tablets and the frequency per day on the strip or plastic packaging.

Standard Treatment Guidelines (STG)

There is a national Standard Treatment Guideline, aimed at primary care, published in 2010. There are also several STG modules published in 2010 aimed at referral hospitals covering selected topics such as cardiovascular and respiratory tract conditions; obstetric, gynaecological and reproductive health conditions; neurology, pain control and mental health; and Dermatology and musculoskeletal conditions.

All the STGs - for both PHC and Referral Hospitals appear to have been drafted by the same group of 55 specialists and GPs from 4 referral hospitals. It is not clear whether all these authors were involved in every STG or whether the specialists were only involved in their own modules. The Faculty of Medicine, which includes many physicians who see patients and teach medical students in the National Referral Hospital, was not using the MOH STGs stating that they had not been sent them.

Few prescribers were using the national STGs or other sources of independent drug information. One hospital specialist even stated that the STGs for referral hospitals were not suitable for such hospitals because the drugs were "too simple" and that “some recommended drugs were not on the EML." It was mentioned that Cuban doctors, responsible for much of the clinical teaching of Timorean medical students, follow their own STGs.

The STGs seen during the visit were - for Referral Hospitals - in English (which few people are able to use) and for PHC - in Portuguese. It is not clear whether any of these STGs are also in Indonesian. At district level, many nurses mentioned that they

would like to have the STGs in Indonesian and Tetum. Most Cuban doctors only speak Spanish so STGs would need to be translated into Spanish as well if one wanted Cuban doctors to follow them.

Education and Information

Undergraduate education
Pharmacology is taught to undergraduate pre-clinical level medical students and prescribing is taught by individual specialists in the National Referral Hospital and during clinical attachments to Cuban doctors (part of Cuban aid program) in district hospitals. The DOP/MOH clinical guidelines aimed at primary and referral hospital care are not used by the Faculty of Medicine in the National University. Even though some of the faculty had been involved in the development of the national STGs, they appeared to be not much used. There is also little teaching on clinical pharmacology and Cuban doctors tend to use their own STGs. One Timorese specialist stated *"Even though I am a specialist in the National Referral Hospital, I do not teach medical students because that is under the control of the Cuban program"*. Thus, medical students are not being encouraged to prescribe as per DOP/MOH STGs and any prescribing principles learnt as pre-clinical undergraduates are likely to be undermined by later clinical studies and work with senior consultants.

Continuing Professional Development
Continuing Professional Development (CDP) is adhoc and not mandatory. There is some organized training in the national referral hospital for in-service staff. Medical students are assigned to Cuban doctors for training. The MOH vertical disease control programs run refresher training for district level staff from time to time. However, there is virtually no CPD on general prescribing – for general prescribers (mainly clinical nurses and doctors) who see the majority of patients. The Timor-Leste Medical Association, established in 2005 with 176 members including 10 specialists, mentioned that they are working on an induction course for new doctors. The Timor-Leste Pharmacy Association is not yet officially established and is searching for start-up funds and premises.

Independent Drug Information
Sources of independent drug information are few. There is no Drug Information Centre (DIC) run by MOH or the National Referral Hospital.

Public Education
Apart from some general messages that were disseminated on World Health Day in April 2011 on rational use of antibiotics, which few prescribers had encountered, there have been no public education campaigns on rational drug use. Some health staff felt that patient demand was a problem and that relevant messages could be spread to the community such as "don't take antibiotics without seeing a health worker first" or "medicines are not needed for simple coughs and colds" or "ask your doctor whether your child really needs more than 2 medicines".

Supervision and training for district level staff
While there are visits by district staff to health facilities in their jurisdiction, there is very little supervision of drug management or prescribing. Some prescribers felt the need for more training and support with regard to prescribing. One CHC Chief Nurse

stated *"I have had no training since I finished my 6-month clinical nursing course in 2007"*. Supervision by one unit may sometimes result in unforeseen consequences in another unit as expressed by one pharmacy technician who stated "*We have a lot of soon-to-expire erythromycin so we are pushing it to the dispensary and we will finish it in a few days"*. The desire to avoid expiry resulted in some patients receiving erythromycin unnecessarily.

Drug and Therapeutic Committees (DTC)

There is no national DTC and there are no DTCs in any of the referral hospitals or districts. Respondents from National Referral Hospital mentioned that the list of drugs for local purchase was decided by the Hospital Director after receiving requests from the various specialty departments. One specialist from the National Referral Hospital remarked that doctors no longer had any power, stating *"One year ago doctors were relieved as Heads of Department. Now doctors can only approach the Hospital Director through the nurses"*. Therefore they could no longer decide anything!

Private prescribers/dispensers

Many public sector doctors and nurses also see patients privately after hours. In one pharmacy shop review of the prescriptions showed that there was high use of injections, unlike in the public sector. One respondent mentioned that the average private consultation fee in Dili was 3 USD and that the drugs prescribed often cost around 10 USD. It was mentioned and observed that antibiotics were freely available over-the-counter (OTC) even though a letter had been sent by MOH/DOP to all pharmacies that they should not be issued OTC. Furthermore, antibiotics were one of the higher through-put items. Record review revealed that in one shop, 29% of the items sold were antibiotics and in another shop 95% of amoxicillin was sold without prescription.

Possible Solutions

1. Monitor drug use including:
    - ABC analysis of consumption /distribution data both centrally and in each referral hospital and district to identify high consumption drugs and to make comparisons between districts and between primary and hospital care;
    - adherence to the NEML (in referral hospitals);
    - Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above);
    - Annual reporting of consumption data and prescription audit by each hospital and district to MOH which should analyse and publish the results;
    - Establishing a unit or strengthen the Department of Pharmacy to be able to analyse reports on drug consumption and prescription audit sent by districts and hospitals.

2. Implement national STGs, for both primary care and hospitals, including:
    - Updating the STGs involving all specialties;
    - Translating the STGs into all relevant languages including Tetum and Indonesian;

- Disseminating the STGs to all doctors and nurses;
- Incorporating the STGs into both undergraduate and postgraduate CPD curricula.

3. Establish functional DTCs in all referral hospitals with an obligation to:
   - monitor drug use;
   - develop their own formulary from within the NEML, monitor compliance and justify non-EML use;
   - coordinate CPD in their institutions;
   - report annually to MOH on their activities so enabling MOH to know what is and is not going on and what needs to be done (requires MOH capacity to review these reports).

4. Encourage Continuing Professional Development for general prescribing by:
   - Collaborative efforts of Department of Pharmacy, INS, Faculty of Medicine UNTL, Timor-Leste Medical Association, Cuban Doctor Program;
   - Incorporating prescription audit and feedback and ethics into CPD.

5. Develop core pharmaceutical messages and disseminate to the public through the community health workers attached to each primary health care facility and through the media, e.g. does my child need more than one drug?

Medicines Regulation

The pharmaceutical sector consists of 11 importers, 25 pharmacy shops and an unknown number of products on the market. There are no local manufacturers.
There is a draft Drug Act of 26 May 2010. This act is not yet approved by Parliament. At the time of writing it was being reviewed by the Ministry of Health legal team. The draft Act contains a comprehensive set of drug regulations requiring implementation by a full Drug Regulatory Authority. However, currently, there is no drug regulatory authority and the DOP undertakes some regulatory functions as well as other functions such as supervising drug management in health facilities and developing the NEML and national STGs.

The DOP's main regulatory function is to coordinate inspection visits to drug outlets and approval of drugs for importation in collaboration with the Commission for Regulation of Pharmaceuticals Activities (CRAF). CRAF is a committee appointed by the Ministry of Health based on decree law No. 12/2004 of 26 May to decide upon what drugs can be imported into the country, to control the sale of narcotics and to recommend issuance of licenses for drug outlets. It is chaired by the DG MOH and has member representatives from SAMES and the DOP and also from the Customs, Police, Trade and Justice Departments. Actual licenses to outlets are issued by the Ministry of Trade, Commerce and Industry on recommendation of CRAF. The MOH issues licenses to health professionals.

The DOP aims to visit every district at least once a year but in practice does not have the budget or staff (only 6) to do this. Although CRAF has a budget (which is larger than that of DOP) that can be used for inspection visits, the procedure for accessing

these funds is lengthy requiring approval from MOH. Last year two trips were organized and 3 shops were closed down, licenses confiscated and fined for selling controlled psychotherapeutic drugs illegally. Illegal drugs are mostly non-EML drugs, narcotics and psychotherapeutic drugs. SAMES is able to import whatever drug products it likes provided the molecule and formulation are on the NEML or permission has been granted by MoH.

Regulation of outlets and drug schedules

Although by law a diploma pharmacist or a pharmacy assistant should always be present on the pharmacy premises to supervise dispensing, often they are not. While there are no official drug schedules, there is a rule that antibiotics should only be sold with prescription, DOP/MOH having sent out a letter to this effect in 2011. However, such drugs can be bought over the counter easily. By contrast, narcotics are strictly controlled only SAMES being allowed to import them.

Regulation of drug importation

SAMES is able to import all NEML drugs without any license. For non-EML drugs ordered by the referral hospitals, approval by CRAF is required. All drugs imported by the private sector must have an import license. CRAF will grant a license for importation on the basis of adequate documentation concerning GMP and certification of the product - indicators for quality. There is no system of drug registration based on dossier evaluation with regard to safety and efficacy. Nobody was able to provide information on how many drugs are actually on the market. However, the Customs department stated that they could provide a list of all products that had been imported during 2010-11 from their electronic database. More than 50 brands of multivitamins were observed in one pharmacy in Dili.

Other regulatory functions

There are few drug promotional activities and no monitoring of them. There is no pharmacovigilance program, no drug testing laboratory or quality testing of drugs. The private sector is small and currently there are no price controls. SAMES stated that there is a requirement for them to buy more cheaply than the private sector.

Possible Solutions

1. Work towards getting the new Drug Act approved by Parliament. This requires the Department of Pharmacy pro-actively to explain the Drug Act to all stakeholders.

2. Establish a mandated, independent Drug Regulatory Authority:
   - Appoint sufficient staff and provide adequate funding;
   - Train staff for certain specialist activities such as dossier evaluation for drug registration.

3. Draft standard operating procedures (SOPs) for all procedures.

4. Establish a process of drug registration that takes full account of the efficacy, safety and quality of drug products:
   - Establish criteria for registration;
   - Establish a committee with technical competence to judge applications;
   - Maintain and publish a list of all registered products.

5. Start a unit within the DRA dedicated to monitoring drug promotional activities, starting with pre-approval of adverts for medicines and package inserts.

6. Start a unit within the DRA dedicated to monitoring ADRs.

7. Develop and publish drug schedules for OTC and prescription-only medicines.

Medicine Policies and Health system issues

There is an extensive public health care system where patients can receive free health care. While there are reports of stock-outs of drugs, only rarely do patients go without medicines since other drugs are substituted. The various medicine policies that may impact on drug use and are in place, are summarized in table 3.

Table 3: Medicine Policies in place in Timor-Leste

Drug Policy	State of implementation
National Medicines Policy	Official document 2010, with some aspects implemented, but many aspects not implemented.
Monitoring the use of medicines	Little monitoring of consumption centrally or locally. Some indicator studies on prescribing done by DOP.
Essential Medicines List	National List 2010 followed by SAMES.
Standard Treatment Guidelines	National STGs for PHC and referral hospitals published in 2010 but insufficient distribution.
Formulary	No national Formulary.
Generic Policies	SAMES buys generic or branded generic products
Regulation of drug promotion	No regulation of promotion.
Monitoring of ADRs	No monitoring of ADRs.
Payment for medicines	All drugs received free of cost in public facilities.
Health Insurance	None.
Revenue from medicines	Never used to pay salaries in the public sector.
Medicine Pricing policies	No strict pricing policies used in either the public or private sectors.
Undergraduate medical training	National EML and STGs are not part of the curricula.
Continuing medical education	Very little CPD on prescribing.
Medicines Information Centre	No national medicines information centre.
Public education on medicines use	No public education campaigns on medicines use done in past 2 years except some limited messages on antibiotic use sent out on World Health Day in 2011.
Drug - Therapeutic Committees	None.
National Strategy for containing antimicrobial resistance	No National strategy to contain antimicrobial resistance. Antibiotics frequently available over-the-counter without prescription.

Coordination and Management

There is a national medicines policy (NMP) document published in 2010 which attempts to describe a full set of pharmaceutical polices. While some aspects of the national drug policy have been implemented, many have not. One of the possible reasons for non-implementation of many parts of the NMP may be the existing MOH structure and the lack of any particular department or division to ensure coordination between all the concerned departments/directorates within not only the MOH, but also with other relevant ministries such as the Ministries of Education and Finance.

The central MOH structure consists of five national directorates, which oversee services in 13 districts and 6 hospitals. The national directorates are: National Community Health Services, Hospitals, Planning and Policy, Human Resources and Administration and Logistics. In addition to the national directorates there are other bodies such as the partially independent national drug supply agency SAMES (which is accountable to both the MOH and the MOF) and National Institute for In-Service Training. Within the Directorate of National Community Health Services are the Departments of Pharmacy, Communicable diseases, Non-communicable diseases, Mental health, Nutrition, Maternal child health, Oral health, Environment and Health promotion. The Department of Pharmacy (DOP) is thus quite low in the administrative hierarchy and this will make it difficult to attract more staff and resources and also to coordinate drug policy across departments.

The responsibility for drug management is divided between SAMES (responsible for procurement and distribution) and the DOP (responsible for storage, use and reordering in the districts and hospitals). Unfortunately, coordination and sharing between these two bodies is not optimal and their systems are not harmonized. Many functions required to ensure rational use of medicines are undertaken by different departments without much coordination. Thus, the DOP updates the PHC guidelines and is responsible for quality of care at the primary care level, but it is the Hospital Directorate that is responsible for hospital care and would be responsible for encouraging DTCs, implementation of STGs for hospitals and hospital quality improvement systems. The MOH vertical disease control programs undertake refresher training for health workers with regard to their specific areas and the INS undertook clinical nurse training up until 2008 or so. However, no unit is in overall charge of training and supervision with regard to general prescribing, continuing professional development or organizing public education on medicines use. The DOP is overworked having only 6 staff to cover both drug management and regulatory tasks. The lack of infrastructure in the pharmaceutical sector means that the same people may serve on various committees, such as procurement, NEML selection, “registration” and CRAF and this may be problematic in terms of lack of time and conflict of interest for individual members.

It was suggested that one way to overcome this problem would be to elevate the Department of Pharmacy to a Directorate of Pharmacy to be guided by an independent broad-based steering committee that is answerable directly to the Minister of Health. The Directorate of Pharmacy would act as the executive within the MOH to carry out the recommendations of the steering committee which would, in turn, provide the level authority required to bring together all the relevant MOH

departments and directorates and other Ministries. It was mentioned that liaison with the Cabinet of Health Research and Development (CHRD) could provide post-graduate students to collect the information needed by the MOH as part of their in-service graduation theses.

Possible Solutions

1. Establish a permanent, independent, statutory committee, with wide membership of all the major stakeholders and including laypersons and professional bodies, to advise the Minister of Health on Pharmaceuticals.

2. Establish an Executive Division in the MOH to carry out the statutory committee recommendations – Directorate of Pharmacy?
   - To coordinate action between SAMES, other MOH Directorates and other Ministries, etc;
   - To be responsible for promoting rational use of drugs including: NEML, STGs, DTCs, monitoring drug use, CPD, Medicines Information Centre, public education;
   - To liaise with the Cabinet of Health Research and Development (CHRD) to provide post-graduate students to collect the information needed by the MOH as part of their in-service graduation theses and research studies;
   - To update the National Medicines Policy to be more specific and to include an implementation plan and time line;
   - Department of Pharmacy should be elevated to be a Directorate of Pharmacy with more resources - so as to be better able to coordinate drug policy;
   - Increase capacity in pharmaceutical skills with regard to all aspects of drug management, regulation and policy through scholarships in the field of pharmacy.

3. Update the National Medicines Policy so as to be more specific and with provision for implementation. This would require:
   - A sub-committee of the statutory committee to draft it;
   - An implementation plan and time line to be included;
   - Incorporation into the national health plan and regulations.

Workshop

At the end of the mission, a 1-day workshop was held on February 16th 2012 with 69 national stakeholders to discuss the consultant's findings and to develop recommendations. The participants in the workshop can be seen in annex 2. The consultant's presentation at the workshop can be seen in annex 3.

Objectives of workshop

- Review the WHO fact finding results
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems
- Develop plan to:
  - implement recommendations, and
  - incorporate recommendations into the national health plan for sustained implementation and follow up

Agenda

Morning

- Presentation of the findings by the WHO consultant and discussion of the findings with identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations for implementation
  - include practical steps and the human and financial resources needed

Afternoon

- Presentation of group work with plenary discussion and finalization of recommendations
  - Road map for MOH, stakeholders and WHO to follow

Group work instructions

- Each group to draft recommendations with practical steps including:
  - Who will do it?
  - How many staff?
  - Budget?
- 4 groups, each one to discuss one topic as specified below:
  - Drug supply and selection
  - Promoting rational drug use
  - Drug regulation
  - National structure and drug Policy

There was a lively discussion and the stakeholders agreed with the most of the consultant's findings and recommendations. During the workshop, recommendations were agreed by consensus in plenary discussion. Following the workshop, the recommendations were edited (for language and coherence) and circulated to all the stakeholders. The following conclusions and recommendations were agreed by all stakeholders and incorporate all comments from the workshop participants.

Conclusions and Recommendations

A. Drug Supply

1. Institute pre-printed standardized forms of stock control, harmonized between SAMES and DOP, to manage stock and undertake quantification. This should include:
   - Bin cards with recording of stock coming in and going out and stock balance;
   - Order forms with accurate estimates of past consumption and specific instruction on how to estimate need.

2. Establish a feasible system for managing and monitoring expired drugs locally.

3. Train all pharmacy technicians and assistants in stock management, quantification and how to supervise nurses managing drug stocks.

4. Once a standardized stock-control system is instituted with standardized forms, start a process of extending an electronic logistics drug management inventory system from the central level at SAMES to the district centres and hospitals in order to:
   - improve stock management and quantification;
   - enable monitoring of drug consumption in the public sector.

5. Make it a requirement for drug distribution and consumption data to be published annually and therefore available to all planners:
   - SAMES to publish an annual report on drug distribution, to include various analyses including ABC analysis and distribution by district & hospital;
   - Districts and Department of Pharmacy to publish annual reports on drug consumption.

6. Ensure that every district health office/district hospital employs a pharmacy technician and train such staff to supervise stock management and quantification and monitor drug consumption in all facilities under their care including CHCs, HPs and SISCa clinics.

7. Require all secondary or tertiary level hospitals to employ a pharmacist to:
   - manage drug procurement, quantification and distribution;
   - act as the secretary to the hospital Drug and Therapeutics Committee (DTC);
   - monitor drug consumption and undertake prescription audit and to report the results to the DTC.

8. Establish a technical working group led by the Department of Pharmacy and including SAMES and all relevant programs of MOH, to improve coordination and communication with regard to medicines management.

B. Drug Selection

9. Ensure consistency between the NEML and other lists such as that used by SAMES.

10. Establish Drug and Therapeutic Committees or Hospital Specialist Boards to provide guidance on what specialist drugs are "reasonable" for non-EML purchase (which should not be greater than 10% of the budget).

11. Continue to regularly update the NEML, publish the selection criteria, widely disseminate it to all facilities and include it into pre-service and in-service training curricula in order to further sensitize doctors to the utility of following the NEML.

C. Promoting rational drug use

12. Monitor drug use including:
    - ABC analysis of consumption /distribution data both centrally and in each referral hospital and district to identify high consumption drugs and to make comparisons between districts and between primary and hospital care;
    - adherence to the NEML (in referral hospitals);
    - Prescription audit and feedback targeting the gross areas of potential misuse as identified through monitoring of consumption (described above);
    - Annual reporting of consumption data and prescription audit by each hospital and district to MOH which should analyse and publish the results;
    - Establish a unit or strengthen the Department of Pharmacy to be able to analyse reports on drug consumption and prescription audit sent by districts and hospitals.

13. Implement national STGs, for both primary care and hospitals, including:
    - Updating the STGs involving all specialties;
    - Translating the STGs into all relevant languages including Tetum and Indonesian;
    - Disseminating the STGs to all doctors and nurses;
    - Incorporating the STGs into both undergraduate and postgraduate CPD curricula.

14. Establish functional DTCs in all referral hospitals with an obligation to:
    - monitor drug use;
    - develop their own formulary from within the NEML, monitor compliance and justify non-EML use;
    - coordinate CPD in their institutions;
    - report annually to MOH on their activities so enabling MOH to know what is and is not going on and what needs to be done (requires MOH capacity to review these reports).

15. Encourage Continuing Professional Development for general prescribing by:
    - Collaborative efforts of Department of Pharmacy, INS, Faculty of Medicine UNTL, Timor-Leste Medical Association, Cuban Doctor Program;
    - Incorporating prescription audit and feedback and ethics into CPD.

16. Develop core pharmaceutical messages and disseminate to the public through the community health workers attached to each primary health care facility and through the media, e.g. does my child need more than one drug?

D. Drug regulation

17. Work towards getting the new Drug Act approved by Parliament. This requires the Department of Pharmacy pro-actively to explain the Drug Act to all stakeholders.

18. Establish a mandated, independent Drug Regulatory Authority:
    - Appoint sufficient staff and provide adequate funding;
    - Train staff for certain specialist activities such as dossier evaluation for drug registration.

19. Draft standard operating procedures (SOPs) for all procedures.

20. Establish a process of drug registration that takes full account of the efficacy, safety and quality of drug products:
    - Establish criteria for registration;
    - Establish a committee with technical competence to judge applications;
    - Maintain and publish a list of all registered products.

21. Start a unit within the DRA dedicated to monitoring drug promotional activities, starting with pre-approval of adverts for medicines and package inserts.

22. Start a unit within the DRA dedicated to monitoring ADRs.

23. Develop and publish drug schedules for OTC and prescription-only medicines.

E. National Structure & Drug Policy

24. Establish a permanent, independent, statutory committee, with wide membership of all the major stakeholders and including laypersons and professional bodies, to advise the Minister of Health on Pharmaceuticals.

25. Establish an Executive Division in the MOH to carry out the statutory committee recommendations – Directorate of Pharmacy?

- To coordinate action between SAMES, other MOH Directorates and other Ministries, etc;
- To be responsible for promoting rational use of drugs including: NEML, STGs, DTCs, monitoring drug use, CPD, Medicines Information Centre, public education;
- To liaise with the Cabinet of Health Research and Development (CHRD) to provide post-graduate students to collect the information needed by the MOH as part of their in-service graduation theses and research studies;
- To update the National Medicines Policy to be more specific and to include an implementation plan and time line;
- Department of Pharmacy should be elevated to be a Directorate of Pharmacy with more resources - so as to be better able to coordinate drug policy;
- Increase capacity in pharmaceutical skills with regard to all aspects of drug management, regulation and policy through scholarships in the field of pharmacy.

26. Update the National Medicines Policy so as to be more specific and with provision for implementation. This would require:
    - A sub-committee of the statutory committee to draft it;
    - An implementation plan and time line to be included;
    - Incorporation into the national health plan and regulations.

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Annex 1: Persons met and places visited during the situational analysis:

NO	DATE	DEPARTMENT/ STAKEHOLDERS	NAME	DESIGNATION
1	06-Feb-12	WHO	Dr Jorge Mario Luna	WHO Country Representative
			Dr Rajesh Pandav	Health Policy Advisor
			Mr Leoneto Soares Pinto,Lic.SP	NCD, Health Promotion and Mental Health Focal Point
2		Pharmacy Department, MoH	Mr Antonio Ximenes Lic SP	Head of Pharmacy Department
			Mr Stanley Chindove	SAMES and Pharmacy Dept MoH Advisor
3		National Community Health Service Directorate, MoH Directorate, MoH	Mr Antonio Ximenes Lic SP	Head of Pharmacy Department
			Teofilio J.K Tilman, Lic.SP	Head of Mental Health Dept
			Apolinario Guterres, Lic.SP	Head of Health Promotion & Education
			Albertina Gusmao	Rep. Oral Health Dept
			Caetano da Costa	Rep. Communicable Disease Dept.
			Pascoal da Costa	Rep. Maternal Child and Health Dept.
			Duarte Ximenes,SKM,MM	Rep. Nutrition Dept.
4	07-Feb-12	Hospital Directorate	Dr Ana Maria Magno	Dead of Hospital Department, MoH
5		SAMES	Dr Domingos Alves	SAMES Director
			Mr Edwardo Estoque	SAMES Management and Finance Advisor
			Mr Stanley Chindove,	SAMES and Pharmacy Dept MoH Advisor
			Mr Teodoro de Jesus	Director for Procurement
			Mr Antonio Oqui,Lic.SP	Director for Quality Assurance
			Mr Cipriano Madeira, SE	Director for Finance
			Mr Octavio Fernandes	Director for Warehousing and Distribution
			Ms Aida Abreu Duca	Director for Administration
		Pharmacy Association	Mr Teodoro de Jesus	President
			Antonio Oqui,Lic.SP	Member

			Stanley Chindove,	SAMES and Pharmacy Dept MoH Advisor
6		INS	Mr Francisco Salguiro,Lic.SP	Act Director and Director for Administration
			Ms Ivonia Soares,Lic.SP	Director for Training Center
7	**08-Feb-12**	Customs, Ministry of Finance	Ms Brigida da Costa	Customs National Director
			Mr Alejandro Garcia	Lead Custom Advisor
8		National Hospital Guido Valadares, Dili	Mr Rui Exposto	Hospital Administrator
			Dr Aniceto Cardoso, Pediatric MKes	Hospital Clinical Director
			Ms Regina Ceuk Bere	Hospital Pharmacy Dept
9		Dili District Health Service (DHS Dili)	Ms Natalia de Araujo,SKM	Dili DHS Director
			Ms Mariana Soares	Dili District Pharmacy Officer
10		Community Health Center (CHC) Formosa	Ms Carolina	Pharmacy Technician
			Dr Vitalina Vilanova	General Doctor
11		Private Pharmacy in Dili	Mr Dedy Setyo	Manager Pharmacy Moris Foun
12	**09-Feb-12**	Baucau District Health Service (DHS Baucau)	Mr Leonel Guterres	Deputy Director of Baucau DHS
			Mr Fernando da Costa	
13		Referral Hospital Baucau	Dr Liborio da Costa	Genera Director
			Dr Alberto	Clinical Director
			Mr George Correia	Head of Clinical Support
			Mr Geronimo Freitas	Head of Pharmacy Department
14	**10-Feb-12**	CHC Venilale	Mr Domingos R. da C. Guterres	Head of CHC and Clinical Nurse
			Ms Sandra F. dos Reis	Pharmacy Assistant
15		CHC Laga	Mr Geronimo da Costa Ximenes	Head of CHC and Clinical Nurse
			Ms Cristalina Fonceca	Pharmacy Assistant
16	**11-Feb-12**	Private Pharmacy Lospalos	Ms Luisa da Costa	Owner One Pharmacy
			Mr Costantino Lopes	DHS Lospalos Pharmacy Officer
17	**13-Feb-12**	Lospalos DHS	Mr Julio Perreira	DHS Lospalos Director
			Mr Constantino	DHS Lospalos Pharmacy Officer
		Health Post MAUPITIN	Ms Herlina	In-charge HP and Midwife

		CHC Lospalos/Lospalos Hospital / Level 4	Ms Gina Ximenes	Pharmacy Assistant
			Mr Lorenco da Costa	OPD Registration & Senior Nurse
18	**14-Feb-12**	Health Post Com, Lautem	Ms Domingas	Nurse & In-charge IMCI
		CHC Lautem	Mr Martinho Alves	Senior Nurse, in-charge IMCI
			Mr Gonsalos	Nurse & In-charge IMCI
			Ms Joanita	Pharmacy Technician
			Mr Jose	Pharmacy Technician
		Private Pharmacy Baucau	Mr Aleixo	Owner of Bonita Farma Pharmacy
19	15-Feb-12	National Univeristy, Dean Faculty of Meicine	Dr Joao Martins	Dean of Faculty
			Mr Jose Deonisio, SE	Deputy of Dean
			Dr Ana	Medicine Director
20		Medical Assosiation	Dr Artur Cortereal SPOG	Secretary General
			Dr Domingas Sarmento	Finance Section

Annex 2: Participants of National Workshop organized by MOH in collaboration with WHO, Dili, Feb 16th 2012

No	Name	Organization	Designation
1	Isabel Maria Gomes, Lic SP	MoH, DNSC	National Director
2	Leão Borges, MPH	MoH, Director NALA	National Director
3	Agostinha Amaral, AMKep, SKep	MoH, Hospital Directorate	In-Charge
4	Dr Domingos da Silva	MoH, INS	National Director
5	Ivonia de Jesus dos Santos, SKM	MoH, INS	Training Directorate
6	Dra Carmen Valdes	UNTL	Director Medicine
7	Lorencho Carvalho	Custom, Ministry of Finance	Director
8	Augusto Tolan, SKM	DHS Oecuse	Head of DHS
9	Victor Soares Martin, SKM	DHS Bobonaro	Head of DHS
10	Bernardino Amaral da Silva, Lic.SP	DHS Covalima	Head of DHS
11	Alberto Martins Chang, Lic.SP	DHS Manufahi	Head of DHS
12	Hilario Raamos da Silva	DHS Ainaro	Head of DHS
13	Pedro Paulo Gomes, Lic SP	DHS Liquiça	Head of DHS

14	Francisco Soares	DHS Manatuto	Head of DHS
15	Leonel Gutteres	DHS Baucau	Deputy of DHS
16	Apolinario Soares	DHS VIqueque	Deputy of DHS
17	Antonio Ximenes, Lic SP	MoH, Head of Department	Pharmacy
18	Mislisa Vital, Lic SP	MoH, Head of Department	Maternal & Child Health
19	Luis Celestino, Lic Ed, MPH	MoH, Head of Department	NCD
20	Teofilio J.K. Tilman, Lic.SP	MoH, Head of Department	Mental
21	Marianao C. Soares	MoH, Head of Department	District Coordination
22	Ivo Ireneu da C. Freitas	MoH, Head of Department	Partnership
23	Apolinario Guterres, Lic SP	MoH, In-charge	Health Promotion
24	Domingos Perreira	MoH, In-charge	CDC, TB
25	Duarte Maubuti	MoH, In-charge	Nutrition
26	Dr Aniceto Cardoso Barreto, SpA. Mkes	National Hospital	Director Clinic
27	Dr Alberto Guterres	Referral Hosp Baucau	Director Clinic
28	Moises de Andrade, Lic. SP	Referral Hosp Maubesi	Director Clinic
29	Dr Adilia O.F. Moniz	Referral Hosp Maliana	Director Clinic
30	Aida Abreu	SAMES	Director Administration
31	Octavio Fernandes	SAMES	Director Warehouse
32	Dr Avelino Guterres, MpH	MoH	Advisor
33	Dr Jaime d. Sarmento	MoH	Advisor
34	Eduardo Estofe	SAMES	Advisor
35	Stanley Chindove	SAMES &MoH	Advisor
36	Dr Rajesh Pandav	WHO & MoH	Health Policy Advisor
37	Vitorino da Costa Araujo	MoH, Unit Office	Oral Health

38	Albertina Gusmão	MoH, Unit Office	Oral Health
39	Osvaldo Castelanos	MoH, INS	Coordinator BMC
40	Constantino dos Santos	DHS Lautem	Pharmacy Technician
41	Fernando A. Sarmento	DHS Baucau	Pharmacy Technician
42	Mateus Vicente	DHS Manatuto	Pharmacy Technician
43	Mariana F. da Silva	DHS Dili	Pharmacy Technician
44	Costodio P.Soares	DHS Liquiça	Pharmacy Technician
45	Geronia G. Fernande	DHS Ermera	Pharmacy Technician
46	Paulo S. Faria	DHS Aileu	Pharmacy Technician
47	Ezequil S. dos Reis P	DHS Manufahi	Pharmacy Technician
48	Natalia P. Martins	DHS Ainaro	Pharmacy Technician
49	Domingas Gutteres Lopes	DHS Maliana	Pharmacy Technician
50	Emelito da Cruz	DHS Covalima	Pharmacy Technician
51	Maria Liezeti da Cunha	DHS Oecuse	Pharmacy Technician
52	Jeronimo Freitas	Referral Hosp Baucau	Pharmacy Technician
53	Bendito P.B. D. Jesus Cabral	Referral Hosp Maubesi	Pharmacy Technician
54	Francisco Guterres	Referral Hosp Covalima	Pharmacy Technician
55	Ernesto Ati	Referral Hosp Maliana	Pharmacy Technician
56	Haris Sanjaya	Private Pharmacy Foho Osan Mean	Staff
57	Ida	Private Pharmacy Foho Osan Mean	Staff
58	Dedy Irawan	Private Pharmacy Moris Foun	Manager
59	Joaquim Pinto	UNTL	Lecture

60	Nina Soares	World Bank	
61	Sherin Varkey	UNICEF	
62	Chet Chaulagai	HIP	
63	Dr Domingas Angela Sarmento	WHO	National Officer
64	Cornelio d S.	AUSAid	
65	Marion Kelly	AUSAid	
66	Dr Teodoro Ximenes	USAID	
67	Dr Costodio de Jesus	AMTL	
68	Dr Angela Bismark	UNFPA	
69	Narsico	MoH	Translator

Annex 3: Slide presentation given by consultant to stakeholders in the 1-day workshop

Medicines supply and use in Timor Leste

WHO mission: 6-17 February 2012

Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Agenda of the workshop

- Presentation by WHO with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
  - include practical steps and the human and financial resources needed
- Presentation of group work with plenary discussion and finalization of recommendations
  - for MOH, WHO and partners to follow

Background

- **Irrational use of medicines in all countries of region**
  - Increasing demand for medicines but limited budget in Timor Leste
- **July 2010 regional meeting in SEARO attended by 9 countries, including Timor Leste**
  - Recognised the need for a comprehensive health system approach to promote rational use of medicines
  - Recommended undertaking a national situational analysis to identify the major problems and possible solutions in order to develop national action plan
- **Regional Resolution: SEA/RC64/R5**
  - Recommended undertaking a national situational analysis
- **Situational analysis**
  - WHO fact finding mission, 6-17 February, 2012
  - Workshop to develop recommendations for national plan of action, to incorporate into national health plan

Mission 6-17 February, 2012

- **6 Feb:** visit to WHO; Dept of Pharmacy; All departments in National Community Health Directorate
- **7 Feb:** Dept of hospitals; SAMES, Pharmacy Assoc; INS
- **8 Feb:** Customs Dept, National Referral Hospital, a Community Health Centre (CHC) & private pharmacy in Dili district;
- **9 Feb:** Baucau District Hospital
- **10 Feb:** CHCs in Venilale & Laga sub-districts
- **11 Feb:** Private pharmacy in Lospalos
- **13 Feb:** Health Post (HP) & "District" hospital in Lospalos
- **14 Feb:** Com HP, Lautem CHC, private pharmacy in Baucau
- **15 Feb:** Faculty of Medicine UNTL & Timor Leste Medical Association in Dili
- **16 Feb:** Workshop
- **17 Feb:** Debriefing with DG MOH

Objectives of the workshop

- Review the WHO fact finding results
- Identify the main priority problems to be addressed
- Formulate recommendations to resolve / address the problems
  - for use by MOH, WHO, partners

Mission findings

- Extensive health care system, with substantial infrastructure, trained health care personnel in difficult terrain, but…
- Serious problems in the pharmaceutical sector concerning:
  - Drug supply, selection, use, regulation, policy, information and coordination, but…
- Sufficient resources and capacity to address some of the problems

Drug supply (1)

- **Complaints of stock-outs in all health facilities**
  - Half of key medicines in stock in one recent study
  - All facilities had some items out of stock & also some items expired
- **Slow procurement process**
  - Delay of 2011 funds from MOF (until Aug 2011) & then MOH (until Oct 2011) and
  - Delay of 5 months in clearance from the port (Aug – December 2011) so …
  - Some 2011 drugs only arrived in early 2012
- **Drug Quantification**
  - SAMES does all quantification based on past distribution figures as a proxy for consumption
  - No accurate data or standardized method for doing quantification in districts or hospitals
  - No allocation of budget/drug quantities according to population and case-mix

Health worker views on drug supply

- **Chief of District Health Services**
  - *SAMES sometimes takes 2 months to send the order and often they send only part of what was ordered. Sometimes they send drugs that were not ordered particularly short-dated drugs.*
- **Hospital Pharmacy Technician**
  - *Monitoring expired drugs on the ward is not my job, it is the job of the nurses.*
- **District Health Office Pharmacy Technician**
  - *I should visit Health Posts quarterly but there is often no transport and anyway I do not have enough time as I frequently have to go to Dili to collect emergency supplies.*
- **Health Post Nurse**
  - *I put zero balance (stock-out) in the regular order form even if there is some stock and a larger request than actually needed in order to ensure that SAMES will send some medicine.*

Drug supply (2)

- **Poor inventory control in public facilities**
  - Manual inventory control system with few standardized forms or registers used
  - No collation of consumption at district level and mismatch of "consumption" data between SAMES & Dept Pharmacy in 2010
  - "Pull" system with frequent emergency orders, often monthly & "pushing" of near-expired drugs down the system sometimes
  - 1-2 pharmacy technician/asst in district health office & hospital – but unable to supervise drug management & monitor consumption
  - Expired drugs found mixed with in-date drugs in some hospital stores & wards with no systematic recording/collation by district and central level of quantities & cost
- **Higher procurement prices with emergency orders**
  - Prices for many medicines higher than private sector e.g…
  - In Jan 2012 National Hospital emergency order invoice, higher prices than private sector resulted in 5000 USD (26%) greater cost
  - Imagine 26% of the total 2012 budget …. > USD 1 million ! … this could happen if purchasing power is decentralised

Top 20 drugs by value (USD) 2011, SAMES

	Drug Name	Value		Drug Name	Value
1	Amoxycillin 250mg	196,966	11	Albumin Solution	24,800
2	Griseofulvin 500mg	114,462	12	Ciprofloxacin 250mg	23,400
3	Cotrimoxazol 480mg	95,380	13	Amoxy/Clav 625mg	22,050
4	Erythromycin 250mg	77,696	14	Promethazine 25mg	21,950
5	Ceftriaxone 1gm inj	42,675	15	Ranitidine 150mg	21,608
6	Ibuprofen 400mg	41,130	16	Surgical Spirit	20,067
7	Cloxacillin 250mg	40,080	17	Beclomethasone 250 mcg/dose	19,892
8	Cloxacill.125mg/5ml	33,394	18	Multivitamin tab	19,738
9	Halothane 250ml	21,147	19	Haemacell solution	19,038
10	Paracetamol 500mg	25,300	20	Morphine 10mg inj	16,650

Total of top 20 drugs: 903,425 USD – nearly 20% annual SAMES budget

Health worker views on drug supply

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- **Health Post Nurse**
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Possible solutions for supply & selection

- **SAMES to publish annual report on drug consumption**
- **Develop standardized reporting forms/registers for all drug management processes in facilities and districts**
- **Electronic inventory mgt system to be extended to level of the district & to all hospitals receiving drugs from SAMES**
  - Better estimation / forecasting of drug need and stock control
  - Consumption analysis for feedback to planners & prescribers
- **Train pharmacy technicians & assistants in all district health offices & hospitals on drug management & supervision**
  - to supervise drug management in all district hospitals, CHCs, HPs & SISCA (outreach) clinics
  - to monitor drug consumption, undertake prescription monitoring & report to Department of Pharmacy & SAMES
- **Stricter adherence to the National EML (NEML)**
  - Ensure consistency between NEML & SAMES e.g. OBH, captopril
  - Establish DTC &/or specialists boards to provide guidance on "reasonable" specialist drugs for non-EML purchase in hospitals

Rational Drug Use

- Why is it important to avoid over-use?
  - Contributes to stock-outs
  - Wastes resources
    - Can you afford to waste drugs with limited budget?
  - Causes increased antimicrobial resistance, so
    - Newer more expensive antibiotics must be used
    - Increased hospitals stays of patients, which is more costly
  - Causes more adverse drug reactions and adverse drug events
    - Significant morbidity
    - Costly to treat

Drug use observed

- 90% of patients buying drugs in pharmacies do not have a prescription
- 29% of drug items sold in one pharmacy were antibiotics & 95% of amoxycillin sold in another pharmacy had no prescription
- 21% of prescriptions in one pharmacy contained injections
- SISCa clinics mainly for promotion/prevention & basic primary care but more drugs/patient are being prescribed in SISCa than in CHCs and HPs
- Doctors prescribe more antibiotics for non-pneumonia ARI than nurses – 63% vs 26% observed in one CHC, 57% vs 43% in another CHC
- Doctors & nurses do not think that there is any problem of polypharmacy, or overuse of antibiotics or vitamins

Drug use – current situation

- **Little monitoring of drug use or prescription audit**
  - 2 surveys in last 5 years, last one in 3 districts in 2011
- **Few prescribers using any Standard Treatment Guidelines or other sources of independent drug info**
  - Few copies available and no training on use
- **No national Drug Information Centre**
- **No Drug & Therapeutic Committees or QC in hospitals**
- **Prescribing taught at undergrad pre-clinical level but undermined by clinical studies and later work**
- **No nationwide public education on medicines use**
  - Except World Health Day on Antimicrobial Resistance
- **Continuing Professional Development adhoc**
  - DHO/MOH training mostly from vertical disease control programs aimed at staff working for their program & not covering general prescribing
  - Continuing Medical Education not followed by many prescribers

Health worker views on drug use

- **CHC Chief Nurse**
  - *I have had no training since I finished my 6-month clinical nursing course in 2007.*
- **Hospital Pharmacy Technician**
  - *We have a lot of soon-to-expire erythromycin so we are pushing it to the dispensary and we will finish it in a few days.*
- **HP Nurse**
  - *We have the Standard Treatment Guidelines for Primary Care in Portuguese but it would be easier for us if it were in Tetum or Indonesian.*
- **Referral Hospital Senior Consultant**
  - *The Standard Treatment Guidelines marked for referral hospitals are not appropriate because the medicines are too simple.*

Drug use indicator survey

Drug use indicator	Hosp n=3	CHC n=4	HP n=3	SISCa n=2	Private pharmacy n=3
Av.no.drugs/patient	2.9	2.4	2.2	2.8	2.1
% patients with ABs	52%	42%	59%	75%	27%
% non-pneum with ABs	88%	69%	77%	-	-
% patients with INJs	1.0%	0%	1.5%	-	0%-21%
% patients with VITs	56%	45%	33%	45%	21%
% generic drugs	96%	97%	100%	98%	53%
% NEML drugs	95%	98%	95%	100%	61%
% pres drugs dispensed	100%	100%	100%	100%	100%
Av.cost/Px (USD)	-	-	-	-	5.14

Possible solutions for improving use

- **Monitor drug use**
  - Consumption analysis & prescription audit by district & hospital
- **Implement Standard Treatment Guidelines**
  - Update & disseminate to every doctor & nurse
  - Incorporate into undergraduate curricula & pre-service training, Continuing Professional Development & in-service training
- **Establish Drug & Therapeutic Committees (DTC)**
  - to monitor drug use, encourage Continuing Professional Development, & report annually on activities to MOH
- **Continuing professional development (CPD)**
  - incorporate prescription audit & feedback and ethics into CPD
- **Public Education**
  - Core pharmaceutical messages through Community Health Volunteers & media e.g. *does my child need more than one drug?*

Drug regulation

- **No Drug Regulatory Authority**
  - Department of Pharmacy has 6 staff to coordinate some regulatory functions with CRAF
  - Commission for Regulation of Pharmaceuticals (CRAF) is responsible for: (1) approving all importation of drugs, (2) making recommendation for drug outlet licences, (3) control of narcotics
  - Draft 2010 new Drug Act still under review by government
- **Current situation**
  - No technical registration of drugs
  - Unknown number of products with many brands on the market so difficult to control e.g. >50 brands of multivitamins in one pharmacy
  - Prescription-only drugs available Over-The-Counter (OTC) & often dispensed by unqualified shops assistants
  - No monitoring of drug promotional activities e.g. pre-approval of adverts or package inserts
  - No pharmaco-vigilance
  - No quality control of drugs in the market

Possible solutions for coordinating structure and national policy

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies …**
- **Executive Division in MOH to carry out the statutory committee recommendations – Directorate of Pharmaceutical Services?**
  - To coordinate action between various departments, including SAMES, Drug Regulatory Authority, etc
  - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CPD, Drug Info Centre, public education
  - Could liaise with Cabinet of Health Research & Development (CHRD) to provide post-grad students to collect info needed by the MOH as part of their in-service graduation theses & research
  - To update the National Drug Policy to be more specific and to include an implementation plan and time line

Possible solutions for improving regulation

- **Work towards getting the new Drug Act approved by parliament**
- **Establish a fully resourced Drug Regulatory Authority to implement the new Drug Act**
- **Draft Standard Operating Procedures for all processes**
- **Establish a process of technical drug registration for all drugs (OTC & prescription-only)**
  - Criteria for registration
  - Technically competent committee
  - Maintain and publish list of registered products
- **Start system to monitor Adverse Drug Reactions**
- **Start system for pre-approval of adverts & package inserts**
- **Develop & publish drug schedules for OTC and prescription-only drugs**

Group work

- **Each group to draft recommendations with practical steps including:**
  - Who will do it?
  - How many staff?
  - Budget
- **Groups**
  - Drug supply and selection
  - Promoting rational drug use
  - Drug regulation
  - National structure and drug Policy

Coordination and management

- **Drug policy 2010 comprehensive**
  - but inadequately implemented …and is it realistic?
- **MOH Structure:**
  - DG MOH with 5 national directorates, 13 districts, 6 hospitals.
  - Dept Pharmacy (DOP) under the Directorate of Community Health Services & has difficulty to coordinate drug policy across departments
- **Different units look after different functions:**
  - Coordination between Dept Pharmacy & SAMES is sub-optimal e.g. unshared information, different consumption data, non-harmonised management system
  - Dept Pharmacy overworked – has to deal with district drug management as well as regulation
  - Which MOH unit is in overall charge to coordinate pharmaceutical services? E.G. Implementing STGs, monitoring drug use, procuring drugs, establishing DTCs, coordinating CPD/CME & implementing public education programs?
- **Same members serve on various sub-committees e.g. NEML selection, drug "registration" and CRAF, drug procurement, etc**
  - Lack of time and conflict of interest for members?