

Karnataka, India

Pharmaceuticals in Health Care Delivery

Mission Report 16-26 July 2013

August 2013

Dr. Kathleen A Holloway

Regional Advisor in Essential Drugs and Other Medicines,
World Health Organization, Regional Office for South East Asia

in collaboration with

Dr Madhur Gupta, Technical Officer - Pharmaceuticals,
WHO India Country Office, New Delhi.

Contents

Programme Agenda	3
Acronyms	5
Executive Summary	6
Terms of Reference	9
Background	9
Medicines Supply	10
Medicines Selection and consumption	17
Medicines use	21
Medicines Regulation	31
Medicine Policy and health system issues	35
Workshop	40
Conclusions and Recommendations	41
References	45
Annex 1: Persons met during the mission	47
Annex 2: Participants in the workshop	50
Annex 3: Consultant’s slide presentation given in workshop	52

Programme Agenda

Tuesday, July 16th

Morning: Principal Health Secretary and senior MOH officials with Dr Kathleen Holloway and Dr Madhur Gupta (WHO India);
Afternoon: State Drug Controller in Karnataka.

Wednesday, July 17th

Morning: St John's medical college hospital;
Afternoon: Karnataka Drug Logistics Warehousing Society (KDLWS) and Bangalore-Urban District Warehouse.

Thursday, July 18th

Morning: Abbigere PHC & Kadugondanhalli CHC in Bangalore-urban district;
Afternoon: Bangalore Medical College & Hospital and private pharmacy.

Friday, July 19th

Morning: Mandya Medical College & district hospital; private pharmacy;
Afternoon: Tubineakere PHC & Arakere CHC in Mandya district.

Saturday, July 20th

Morning: Sri Narshima Raja General hospital in Kolar district; private Pharmacy;
Afternoon: Kurudmale PHC & Mulbagel hospital (upgraded CHC) in Kolar district.

Sunday, July 21st

To Mysore; meeting with president of the Pharmacy Council.

Monday, July 22nd

Morning: JSS Medical College hospital & clinical pharmacy department;
Afternoon: Mysore Medical College & Hospital; Mysore KDLWS district warehouse.

Tuesday, July 23rd

Morning: KC General Hospital in Bangalore-urban district; private Pharmacy;
Afternoon: Karnataka State Pharmacy Council.

Wednesday, July 24th

Morning: private pharmacy; Director Health Services MOHFW;
Afternoon: Karnataka Medical Council; Karnataka Medical Association.

Thursday, July 25th

Morning: NGOs & other senior advisors including Karnataka Knowledge Commission, Karnataka Drug Action Forum, Society for Community Health, Awareness, Research and Action (SOCHARA); Karnataka Drug & Chemists Association.
Afternoon: Karnataka Drug Logistics Warehousing Society

Friday, July 26th

Workshop for national stakeholders

Morning: Report preparation;
Afternoon: Presentation of findings by Dr. K.A.Holloway;
Plenary discussion of findings and recommendations

Saturday, July 27th

Morning: Departure to Delhi

Acronyms

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
AHW	Auxiliary Health Worker
ANM	Auxiliary Nurse Midwife
CHC	Community Health Centre
CPD	Continuing professional development
CME	Continuing medical education
CMHO	Chief Medical and Health Officer
CMO	Chief Medical Officer
DCD	Drug Control Department
DHS	Department of Health Services
DIC	Drug Information Centre
DHO	District Health Officer (doctor)
DPHO	District Public Health Office
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
E-DDMS	Electronic Drug Distribution & Management System
EDL	Essential Drug List
EML	Essential Medicines List
HA	Health Assistant
HQ	Headquarters
HP	Health Post
IPD	Inpatient department
IRs	Indian Rupees
KDLWS	Karnataka Drug Logistics & Warehousing Society
MO	Medical Officer (doctor)
MOF	Ministry of Finance
MOH	Ministry of Health
MOHE	Ministry of Health Education
MOHFW	Ministry of Health & Family Welfare
MTC	Medicines and Therapeutic Committee
NABL	National Accreditation Board for Laboratories
NGO	Non-governmental organization
NDP	National Drug Policy
NRHM	National Rural Health Mission
OPD	Outpatient department
OTC	Over-the-counter
PHC	Primary Health Care Centre
KCDA	Karnataka Chemists and Druggists Association
KMC	Karnataka Medical Council
KPC	Karnataka Pharmacy Council
RUM	Rational use of medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
VEN	Vital Essential Non-Essential – method for classifying drug importance
WHO	World Health Organization

Executive summary

A visit was made by WHO to Karnataka during July 16-26, 2013. The programme was arranged in agreement with the central MOHFW, the Karnataka Department of Health and Family Welfare, the State Drug Controller and the Karnataka Drug Logistics & Warehousing Society (KDLWS) and in collaboration with the WHO Country and Regional Offices. The TOR were to undertake a situational analysis of the pharmaceutical situation, focusing on health care delivery, and to conduct a half-day workshop with stakeholders to discuss the findings and develop a roadmap for state action. Visits were made to public health facilities and private pharmacies in the three districts, the KDLWS, the major MOHFW departments (including the Drug Regulatory Authority), the pharmacology departments at Bangalore & Mysore Medical Colleges, the clinical pharmacy department in JSS Medical College Hospital, St John's Medical College Hospital, the Karnataka Medical Council, Karnataka Pharmacy Council, Karnataka Medical Association, Karnataka Drug & Chemists Association. In addition a group of NGOs were met including Karnataka Knowledge Commission, Karnataka Drug Action Forum, Society for Community Health, Awareness, Research and Action (SOCHARA).

It was found that Karnataka has an extensive health care system with trained health care personnel. The Karnataka government started in 2002 the KDLWS which operates supplies drugs free of cost to patients in government health facilities. This scheme resulted in a great improvement in access to essential medicines over the previous system operated by the Government Medical Stores. There remain, however, a number of challenges 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 the problems.

Drug Supply and selection

Medicines are supplied to all public district facilities by the KDLWS which was established in 2002, since when access to essential medicines has improved. The KDLWS has none of its own staff and relies on staff deputed from other sections of the MOHFW, but the staff are too few for the workload. Procurement is done by e-bidding and relies on technical evaluation prior to financial evaluation. Quality control is in-built into the procurement process. An electronic management Drug Distribution Management System allows for efficient stock management at central and warehouse levels but does not extend down to the level of health facility where stock-outs were found. The IT software used by the state has some positive features like Indent, Order, Passbook, Stock Balance and Stock Use, and it is user-friendly, but the software updating is not done regularly. A 'push-pull' system is used with drugs being sent according to prior indenting (quantification) and allocation from warehouse to facility but also with some demand from health facilities to the district warehouses for extra stock. Warehouses receive medicines directly from the suppliers who have the contract to supply drug products. While most essential drugs were available in the facilities visited, there was evidence of stock-outs from both facilities and warehouses. Quantification of drugs is based upon last year's consumption and senior staff estimates but is inaccurate due to a lack of a systematic method and not taking into account stock-out periods. Stock management was good in many public

facility pharmacy outlets, but could be improved for emergency drugs on the wards for inpatients. There is an Essential Medicines List (EML) 2011, updated in 2013, which the KDLWS follows. Not all stakeholders outside the KDLWS were aware of amount of work that KDLWS undertakes to run an efficient drug supply system, nor were all aware of the process of updating the EML.

It was recommended that the KDLWS: become a corporation to have greater autonomy to hire staff and a larger budget; publish an annual report on drug procurement and distribution and its activities; extend the electronic drug distribution management system down to the level of the health facility; review the method of quantification for annual need; review how emergency drugs are managed on the wards; and update the EML in a more transparent way using a web-based process and monitor adherence to it. It was recommended that all medical college hospitals establish DTCs and develop evidence-based formulary lists, in compliance with the EML.

Drug use

A number of prescribing surveys conducted in India have been published but few in Karnataka. The consultant observed prescribing that showed very high use of injections and high use of antibiotics for upper respiratory tract infection. Few prescribers knew of the State standard treatment guidelines (STGs) developed by the KDLWS in collaboration with the Pharmacy Council. Some hospital specialists felt the STGs were not applicable to them. There was over-crowding in many OPDs and some doctors were seeing over 100 patients per day which is not conducive to good prescribing. 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 does not include much on rational use of medicines, although there are many stakeholders, such as local NGOs and branches of the local Pharmacy Council and Medical Association who run CME and could play a role in promoting rational use of medicines. Although most hospitals had procurement committees which are focused on stock availability and local purchase, few had DTCs which oversee prescribing. Prescription audit is not done. Public education on safe effective medicines use through the network of Ashas has not been done.

It was recommended that prescribing patterns be monitored to identify specific prescribing patterns that need changing and that staff workload be analysed in order to redistribute workload and decrease overcrowding in the outpatient departments. Supervision should be targeted, in a non-confrontational way, to poorly performing prescribers/facilities and focused on targeted required behaviour changes, as identified from prescription audit. Other interventions recommended include: strengthening Drug and Therapeutic Committees (DTCs) in all hospitals and requiring them to monitor prescribing and report annually to MOHFW; distributing updated guidelines and incorporating them into undergraduate and Continuing Professional Development (CPD) curricula; and developing public education programs on safe and prudent medicines use to be delivered through the Ashas, media, schools, etc.

Drug Regulation

The State Drug Control Department (DCD) manages a pharmaceutical sector of about 100,000 registered products, 247 manufacturers, more than 6,000 wholesalers and more than 22,000 registered drug retail shops. There is a manpower shortage in the DRA, with only 453 staff in post (out of 709 sanctioned posts) thus limiting its ability to inspect all the registered drug outlets regularly. There are checklists but not formal SOPs for all processes. All processes are being computerized and the DCD is operating an E-governance system to ensure transparent and timely action in five service areas covering the issue of licenses and samples for drug testing. In the case of substandard drugs, depending upon the findings of Government Analyst, the actions of suspension, cancellation of licenses and prosecution are taken as per the guidelines of 40th Drugs Consultative Committee (DCC) meeting proceedings. Dispensing in some private pharmacy shops is done by unqualified persons contrary to regulations and prescription-only drugs are often sold without prescription. There are many brands for the same active pharmaceutical ingredient available on the market so making regulation of the market very difficult. A pharmacovigilance program is managed by the medical colleges which are linked with the National Coordination Centre of the Pharmacovigilance Programme of India (PVPI) and WHO collaborating centre on ADR monitoring at Uppsala Monitoring Centre, Sweden . The DCD has limited ability to monitor pharmaceutical drug promotion due to resource constraints. The DCD has three drug testing laboratories and tests more than 6000 samples per year, with an aim to increase this to 12,000 samples per year.

It was recommended that the manpower shortage be rectified as a matter of urgency, that the Standard Operating Procedures (SOPs) be established for all various procedures and committees, that drug schedules be enforced more strictly, and that a unit be established to monitor drug promotion activities.

Coordination

Many important functions such as monitoring of medicines use, supporting DTCs, updating and distributing STGs, coordinating CPD, ensuring incorporation of EML and STGs into CPD and undergraduate curricula and public education on safe and prudent medicines use are currently not done.

It was recommended that a multidisciplinary mandated independent statutory committee reporting directly to the State Minister of Health and Family Welfare be established and that an executive unit, possibly in the Department of Health and Family Welfare, be established to carry out the recommendations of the statutory committee, including prescription audit and coordination of the implementation of strategies to improve use.

Terms of Reference

The objectives were:

- (1) to meet senior officials of the Karnataka Ministry of Health and Family Welfare and Karnataka Drug Logistics Warehousing Society.
- (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 half-day workshop with Karnataka State stakeholders to validate the findings of the situational analysis and to develop recommendations for future use by MOHFW, KDLWS, WHO and stakeholders in planning.

Background

This mission was undertaken to conduct a State situational analysis with regard to the pharmaceutical sector in order to aid MOHFW 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. The recommendation was reaffirmed during the Regional Consultation on Effective Management of Medicines in Bangkok 23-26 April 2013. This mission was undertaken during 16-26 July, 2013, 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 half-day workshop with 18 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.

Karnataka has an extensive health care delivery system. The Karnataka Drug Logistics and Warehousing Society (KDLWS) was established in 2002 with the assistance of the European Union and with the aim to supply essential medicines free of charge to patients in government health facilities. This scheme has resulted in increased access of the population to essential medicines. Nevertheless there remain some concerns that medicines are sometimes out of stock and also that there is 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

The Karnataka Drug Logistics and Warehousing Society (KDLWS) was established in 2002 with assistance of the European Union and registered under the Karnataka Registration Act 2003. The KDLWS replaced the Government Medical Stores and supplies all government health facilities with drugs, which are provided free of cost to patients. Unlike the previous Government Medical Stores the KDLWS does not supply government medical college hospitals, which are under the Ministry of Medical Education and which have retained their autonomy for the purchase of medicines. With the advent of free drugs scheme in 2002 plus the advent of the National Rural Health Mission in 2005, access to essential medicines at government health facilities has improved although there are still some reports of stock-outs and patients having to buy their medicines in private retail pharmacies.

The KSLWS operates an HQ in Bangalore, where there 6 departments covering administration, procurement, logistics, quality control, finance and accounts and IT, and 57 staff. There are also 14 medical warehouses, each one serving 2 or sometime 3 districts, and each being staffed by one in-charge, 1 chief pharmacist, 2 junior pharmacists, 1 data operator and 2 attendees. Currently a further 13 warehouses are planned and construction is now starting. An electronic drug management information system operates in the HQ and district warehouses but not at health facility level. The IT software used by the state has some positive features like Indent, Order, Passbook, Stock Balance and Stock Use, and it is user-friendly, but the software updating is not done regularly. Only medicines from the Essential Medicines List (EML) are supplied. The annual turnover of drugs was about 120 crore rupees in 2012 and this year (2013) it will be about 140 crore. Drugs are dispensed free of charge in all the public health facilities, although the patients must pay a small registration fee of Rs 2-5 (outpatients) and Rs 10 (inpatients) per visit in some facilities. A print-out of various KDLWS procedures was available but no annual report or booklet of SOPs could be provided.

The State Government has allocated a drug budget for each facility according to the type of facility and number of beds, but not according to patient attendance or staffing, which varies hugely even between same type facilities. Primary health centres (PHCs) have 5-6 beds, Community Health Centres (CHCs) 30-100 beds, and district hospitals 350-400 beds. Most of the facility budgets are directly transferred to the KDLWS to undertake procurement and distribution of essential medicines but some is allocated to local purchase. The approximate allocations in INR are as in table 1 below:

Table 1: Budget allocation for drugs to district health facilities

Facility type	KDLWS	Local budget to be used as decided by the Arogya Raksha Samitee	
		NRHM*	Use fees
District hospital	79-90 lakhs	5.0 lakhs	From registration fees from OPD/IPD plus diagnostic tests plus GOI projects
Taluk hospital	25-30 lakhs	5.0 lakhs	
CHC	4-6 lakhs	2.5 lakhs	
PHC	2 lakhs	1.75 lakhs	

1 lakh = 100,000; *Budget only partially used for drugs

There are eleven Medical College hospitals and 7 super-specialty institutes in Karnataka and they provide tertiary referral services as well as much primary care for the populations living nearby. The Medical Colleges and hospitals come under the jurisdiction of the Ministry of Medical Education and not under the Ministry of Health and Family Welfare. Each of these institutions develops their own formulary list and undertakes their own procurement.

KDLWS is a registered society, headed by the Additional Director of Logistics who reports to the Commissioner of Health and Family Welfare who, in turn, reports to the Principal Secretary of Health and Family Welfare of the Ministry of Health and Family Welfare. The status of being a Society allows KDLWS to purchase drugs more efficiently, with less administrative constraints than if it were a government department, even though funds for drug purchase come through the MOHFW from the MOF. Competitive bidding (which has succeeded in purchase of all items) has replaced rate contracts (which only succeeded in purchase of some items so necessarily resulting in decentralized procurement). Purchase preference is given to Pharmaceutical Public Sector Undertakings (PSUs) and Small Scale Industries (SSIs) provided they match the technical and financial bids of other bidders in the procurement process. These changes have been achieved by amendment of the KTPP Act, which allows KDLWS to go online for all procurement of drugs and other items with more than Rs 50 Lakhs estimated value. These facts account for much of the improved drug availability in health facilities since the purchase of drugs is not subject to the lengthy delays that occurred during the time of the Government Medical Stores.

With regard to staffing and policy making, KDLWS is much like other government departments. There is a policy that KDLWS should have no staff and that all personnel should be deputed from the District Health Offices or other MOHFW departments. Of the annual drug budget, 1.6% (Rs 2.25 crore) is allocated for staff salaries, both deputed regular staff and contract temporary staff. Thus the warehouse in-charge and the chief pharmacist are deputed from other health facilities and the other staff, such as junior pharmacists, attendees and IT operator in the warehouses is all temporary, on a contract basis. In one warehouse visited, the in-charge was also working in the district hospital and the chief pharmacist had been on deputation from another facility for 3 years. The lack of staff in general, the lack of regular staff dedicated specifically to the KDLWS, and the reliance on contract staff is likely to contribute to stock-outs. The two warehouses visited were piled high to the ceiling with drugs and there was lack of information on stock levels at facilities. Were the KDLWS to be a Medical Services Corporation, it would have greater autonomy to hire staff.

Procurement

Drug procurement is done through an e-tendering process according to a strict written protocol. Tendering is done once a year for most products based on the last 1-2 year's consumption and an estimation of need by each health facility. The bidding process follows two processes – technical evaluation first, followed by financial evaluation for only those suppliers that pass the technical evaluation. Technical evaluation is done

by the Tender Scrutiny Committee which includes the Director of Health Services as Chairman, Additional Logistics Director of KDLWS as member Secretary and the Drug Controller as a member as well as staff from the procurement unit of KDLWS. Recommendation is then made to the Tender Accepting Authority, chaired by the Principal Secretary, to open the financial bid. Decision is then made on which bids to accept based on lowest (L1 price) and also comparison of prices on the open market. The detailed tender document for 2013-2014 was shared with the consultant.

Criteria to pass technical evaluation cover both supplier and supply criteria and include:

- Supplier must be a manufacturer or importer,
- Supplier annual turnover of more than 5 crore,
- Production of the product by the supplier for more than 3 years,
- Supplier not blacklisted by any Medical Services Corporation or other State/central government procurement agency in India,
- GMP certificate for the product,
- Agreement to supply products with 80% of the shelf-life remaining on delivery and with labeling and packaging, which should include the KDLWS logo and words “not for sale”,
- Agreement to supply half products within 60 days and the remaining products within a further 60 days. Delays of 1-15 days incur a 3% penalty, 16-30 days a 5% penalty, more than 30 days a 10% penalty or cancellation, blacklisting and forfeiture of deposit.

All accepted bids must be accompanied by an Earnest Money Deposit of 1 lakh. In addition, a bank guarantee against default at 5% of the value of the amount to be supplied must be made by the successful supplier at the time of contract. In the procurement documents it is also explained that 0.5% of the value of the medicine will be required to undertake QA testing and that this will be deducted by KDLWS from their bills for products supplied, so the manufacturers may boost the prices quoted to take this into account. While the tendering process is underway the technical evaluation committee also undertakes a market survey to assess the prices of good quality products in the market.

Once the bids are submitted on-line by a specified date, the Tender Scrutiny Committee opens the technical part of all bids, undertakes a technical evaluation and presents the results to the Tender Accepting Authority which decides which suppliers and products have passed the technical evaluation. Results of those suppliers and their products that pass and fail are then placed on the web and a few days given for failing suppliers to appeal. The Appellator assesses all grievances. The Tender Scrutiny Committee reassesses their bids and re-discusses with the Tender Accepting Authority. Once the list of suppliers and products that have passed the technical evaluation is finalized, the Tender Accepting Authority gives permission to open on-line the financial bids of only those suppliers and products that pass the technical evaluation.

The products that qualify with the lowest price (L1) are chosen, provided that their prices are equivalent to or lower than those found in the market survey. For a product where the quoted price is higher than that of the market survey, the supplier is invited to negotiate with the purchase committee. However, if he cannot equal the price, a

retendering for that product is initiated. Other suppliers that match the lowest (L1) price or are the second (L2) and third (L3) lowest prices are also identified as they may be approached for purchase should the first L1 supplier fail to supply all products on time. In 2012, two manufacturers were blacklisted. In recent years, four manufacturers and ten products have been black listed for failing quality testing (URL: <http://stg2.kar.nic.in/healthnew/>).

Quality assurance (QA)

There is a strict quality assurance system. Once drugs arrive at the district warehouses directly from the suppliers, in addition to requiring a certificate of analysis from the manufacturer, the consignment is placed under 'quarantine'. A sample of each newly arrived product is sent to the QA unit in KDLWS for quality testing. Once the samples arrive, they are each given a code and all trace of the manufacturer or trade names are erased from the sample. A sample is then chosen for each product and sent for testing in a private empanelled laboratory. Upon receipt of a certificate of quality from the laboratory (and decoding the sample codes to match the lab results with the product names) new consignments are taken out of quarantine and may be used. If any sample fails, the sample is again tested in the government drug testing laboratory. If the sample again fails, then KDLWS will reject the products and the supplier will be asked to replace the complete batch of products.

Testing is according to Indian Pharmacopoeial standards or in their absence according to British or US Pharmacopoeias. In order to get results within 2 weeks all samples are sent to private empanelled laboratories (since the government one does not have capacity). This strict attention to quality should mean that few people can complain of poor quality drugs. However, it was found that some stakeholders were unaware of the drug quality testing undertaken by the KDLWS and were still maintaining that the quality of drug was poor.

Drug Quantification

The method of quantification is unclear. It appears to be based on the previous year's consumption plus some adjustments based on estimations made by individual facilities and some additional percentage. However, the government provides a drug budget based on a fixed allocation per facility according to its number of beds (which may not correspond to actual need). In theory, quantification should be done by the facilities first, then data compiled centrally and final quantities agreed by the Needs Assessment Committee, which has 15 members, including hospital superintendents and chaired by the Commissioner of Health and Family Welfare. However, this year, the Needs Assessment Committee met late - in July 2013 three months after the start of the fiscal year - before quantification had been done by each health facility. Furthermore, initiation of e-tendering has already started. On discussing with warehouse and health facility staff, it appeared that no standard formula is used for estimating need and stock-out periods are not taken into account. In theory 3 months buffer stock is required but, in practice, this appears to not be followed by many facilities and warehouses.

This lack of systematic method is not likely result in accurate estimates according to need. Underuse or over use in past years will lead to under- and over-estimates respectively. Easy availability of drugs may lead to over-demand and irrational over-use of medicines and/or frequent stock-outs, all of which may distort expected trends. If the actual amounts needed differ substantially from what is quantified this may result in future procurement difficulties. It may be wise to review the current system of quantification and institute a formula for calculating need based on past consumption *adjusted for stock-out periods* plus buffer needed minus the balance.

Distribution

Distribution takes place from the supplier who has the procurement contract for that product directly to 14 district warehouses twice per year. Each warehouse sends in a request which is processed by the KDLWS logistics unit which then informs the manufacturers to which warehouse they must deliver the products. KDLWS has an electronic drug distribution management system (DMMS), which is extended to the level of district warehouse so allowing redistribution of stock between districts. However, the DMMS is not extended to the level of hospitals, CHCs or PHCs which rely on paper systems and between which redistribution of stock is not so easy. The DMMS does allow tracking by the warehouse of the quantity of budget allocation used by each facility. There is no patient information on the DMMS. It was unclear whether there was a limitation in the DMMS electronic system or whether warehouse staff were unable fully to use the DMMS. This was highlighted by the fact that warehouse staff when asked to demonstrate stock availability on the DMMS were only able to show stock level for drugs that were in stock but not for drugs that were out of stock (zero stock). By contrast, the KDLWS headquarters was able immediately to demonstrate which drugs were out of stock in every warehouse (see section on availability below).

A buffer stock of 3 months in all warehouses and facilities is required but it was observed that this is not followed. The distribution system is a mix of both push and pull. Once stock is received in the warehouse, stock is distributed to the health facilities according to their allocation. Thus most facilities receive supplies twice yearly. There is also some demand from facilities to the KDLWS warehouse for stock that is in low supply. PHCs mentioned they requested emergency stock 1-2 times per year but district hospitals stated that they requested drugs monthly. It was mentioned that some facilities do not know when their supplies will come and there is no schedule for staggered delivery. Both warehouses and facilities complained that they were not always sent what they asked for. It was mentioned centrally that about 5% of medicines expired or were short-dated and had to be replaced.

The records and storage of medicines appeared adequate in most facility stores and outpatient dispensaries. In contrast, drug stores in hospital wards were less systematically organized and, sometimes, drugs were stored in loose boxes in the nurses' room. In addition there is a shortage of nurses. Staff shortages and poorly organized ward drug storage may lead to adverse drug events.

Local purchase

Some drug budget is available for local purchase. This comes from an allocation from the National Rural Health Mission (NRHM). In addition, there are extra funds from fees for registration and diagnostic tests that can be used for local purchase. Local purchase may be done if KDLWS does not have stock of required EML drugs or for non-EML drugs if justified by the prescribing doctor. For district facilities, EML drugs are generally, though not exclusively, purchased, as decided by the medical officer. For tertiary hospitals non-EML products are purchased as decided by the Medical Superintendent after discussion with his/her medical staff. Though district facilities generally followed the EML, there was no restriction on what EML drugs could be purchased based on facility-type, i.e. no categorization of drug by facility type was observed. By contrast, tertiary hospitals use local purchase mainly for non-EML drugs. Large hospitals also have cooperative shops operated by Medical Relief Societies for sales of non-EML drugs. Local budget is administered by the health facilities themselves with approval of the Arogya Raksha Samitee. Most local procurement is for less than 1 lakh for which a tendering process is not needed and procurement can be done on a quotation system. Any purchase using government funds must follow the financial rules and amounts of more than INRs 5000/- require 3 quotes.

Drug Availability

It was observed that very few of the facilities visited complained of any stock-out of medicines. The number of items out of stock in government facilities visited ranged from 0 to 23 (although in the case of the one health facility with 23 items out of stock, they mentioned that 8 items had been received that day). In most cases staff mentioned that there was always an alternative item that could be used so that no patients went without and, indeed, the average number of drugs prescribed and dispensed to outpatients was observed to be 2.4. However, most doctors in CHCs and hospitals mentioned that they sent about 10% of patients to purchase medicines from outside private pharmacies mostly because the medicines do not belong to the EML.

Review of the stock-out status of the KDLWS on 25.7.2013 using the electronic DMMS revealed a significant number of stock-outs on that day. Overall, 24% of items were out of stock in 80% or more of the warehouses and only 23% of items were available in all warehouses.

A number of community members and other stakeholders stated that stock-outs were a problem. One NGO, Logistimo in Bangalore, was operating an electronic drug management information system in all 74 health facilities of Chamarajanagar district. A review of stock-out status on 25.7.2013 using this electronic system, which can be managed centrally and at long-distance, revealed significant stock-outs, with half of facilities having a stock-out of many of the selected drugs chosen for this exercise (table2). It was also found that 89% of the items mentioned in table 2 as being out of stock at the facilities were in-stock in the district warehouse. With a shortage of staff, no standard method for quantification, no common electronic management information system operating at district warehouses and facilities and with the late procurement process this year, such stock-outs are likely.

Table 2: Facilities with stock-out of selected drugs in Chamarajanar district 25.7.2013

Drug name	% Facilities (n=74)	Drug name	% Facilities (n=74)
Amoxicillin 500mg	50.0%	Metformin	46.0%
Amoxicillin 250mg	59.5%	Metronidazole 200mg	87.8%
Amoxicillin 125mg	51.3%	Metronidazole 400mg	35.1%
Albendazole 400mg	48.7%	Metronidazole inj.	48.7%
Albendazole susp.	55.4%	Paracetamol 500mg	23.0%
Atropine inj	48.7%	Paracetamol syrup	59.5%
Dicofenac 50mg	20.3%	Phenobarbitone 30mg	33.8%
Diclofenac inj. 75mg	45.0%	Phenobarbitone 60mg	36.5%
Iron-Folic large	51.4%	Phenytoin 100mg	50.0%
Iron-Folic small	78.4%	Tetracycline 250mg	90.5%
Ringer Lactate 500ml	90.5%	Tetracycline 500mg	48.6%

Possible Recommendations

1. KDLWS should become a corporation:
 - a. Greater autonomy and budget and power to hire staff.
2. KDLWS to produce annual report on procurement and distribution:
 - a. ABC analysis, per-capita allocation, comparison across districts;
 - b. Number of samples failing quality testing and number of batches replaced;
 - c. % of stock that expires and % short-dates stock that is replaced.
3. KDLWS to extend electronic drug distribution management system to level of all district health facilities:
 - a. Better estimation / forecasting of drug need and stock control.
4. Develop and publish formal SOPs for all processes in the KDLWS, with time-frames, and covering drug selection, quantification, procurement & distribution.
5. Review system of quantification:
 - a. Introduce a standard method based on past consumption, adjusted for stock-out periods plus buffer stock minus stock balance;
 - b. Train all the staff in drug quantification and procurement and supply chain concepts.
6. Review storage systems for drugs on inpatient wards.
7. Hire more staff in each warehouse and review the policy of KDLWS only having permanent staff through deputation.

Medicines Selection and Consumption

Karnataka published its Essential Medicines List (EML) in booklet form 2011. The 2011 EML contains 361 drug items (excluding disinfectants). The EML is revised annually prior to quantification (indenting) and purchase. It was mentioned that this year 951 drugs were suggested and 465 selected. However, the EML of 2013 is only printed as an indent booklet for quantification of drugs by health facilities and the number of drugs (excluding disinfectants) appears to have increased by 2 items to a total of 363. There was no categorization of drugs by facility level mentioned in either the 2011 EML booklet or the 2013 facility indent book. The health facility staff were not familiar with any rules concerning categorization of drugs by facility although lower level facilities often did not all select all drugs on the list saying that they had no need of them.

The KDLWS is responsible for coordinating development of the EML through the State Therapeutics Committee, which decides annually upon the Essential Medicines that should be included in the list of medicines to be purchased by the KDLWS. Selection is based upon the National EML of India and the State EMLs of Rajasthan and Tamil Nadu and the technical opinion of 21 specialist sub-committees. The State Therapeutics Committee consists of 14 members, including the Director of Health and Family Welfare, Director of Medical Education, Project Director of Reproductive and Child Health, the Drug Controller, the Additional Director of KDLWS, Senior Supervisor of KDLWS, the President of Karnataka State Society for Rational Use of Drugs, Directors of some government medical colleges, the most senior physician of KC General Hospital and the most senior pharmacist working in Bangalore. In addition invitees may include representation of the Drug Information Centre of the Karnataka State Pharmacy Council and a superintendent of a major hospital, a district surgeon, a district health and family welfare officer, the superintendent of TB and Communicable Disease Hospital and the superintendent of the Leprosy Hospital. A notification of the constitution of the State Therapeutic Committee from 2005 was shared with the consultant. However, it is not clear whether recent committees have had this membership. The State Pharmacy Council said that they had not been involved and also mentioned that pharmacists were generally not involved in the committee and that the selection of medicines was not always evidence-based.

While district facilities are only supplied EML drugs from KDLWS, it is not clear to what degree the EML is followed in overall use. Most government hospitals mentioned stocking about 350 items. In one district hospital, the formulary list contained 296 drug items (less items than the EML), of which 60 (20%) were non-EML items. Of these 60 items, 7 items were non-EML formulations and 53 were non-EML items. The majority of the non-EML items were antibiotics, analgesics, and ophthalmic and Ear, Nose and Throat products. It was observed that nearly all drugs prescribed in the outpatients belonged to the EML and most drugs observed in district facility stores were EML drugs. Thus it appears that purchase of non-EML drugs by hospitals is low and that patients must purchase non-EML drugs if required. Since separate prescriptions are written for outside non-EML drug purchase the size of this problem is unknown, although doctors mentioned sending out about 10% of patients to purchase non-EML drugs from outside pharmacies. Of two cooperative generic pharmacies visited in hospital compounds, both sold non-EML drugs to hospital

patients and one of them was observed to sell many non-EML antibiotic injections for use by inpatients.

Despite all best efforts, many doctors may not be aware of the process of drug selection for the EML and the reasons for inclusion or exclusion of new drugs. While some specialist doctors would like more drugs to be included in the EML arguing that their patients have more complicated refractory conditions, others accepted that in the public sector they must send some of their patients outside to purchase non-EML medicines. It appeared that many doctors regarded the EML as a basic set of drugs that could be afforded by the state, rather than a set of essential drugs that could cover the majority of the health care conditions.

Increased transparency of the process and sensitization of senior specialist doctors could be achieved by making the process web-based and including all reasons for inclusion or exclusion of drugs on the web. Application for adding new drugs should be on-line and open to specialists, with a requirement to include the evidence and justification for why a new product is better than an existing one.

Table 3 shows an ABC analysis of drugs purchased by KDLWS during 2012-13. This analysis only covers medicines and excludes medical devices and disinfectants. It can be seen that a large proportion of these top 28 drugs by value are antibiotics and some products such as vitamin B Complex and paracetamol which are frequently used in outpatient care for simple diseases. It can also be seen that only EML drugs have been supplied.

Table 3: ABC Analysis of Drugs purchased during 2012-2013

Drug Name		Value	Drug Name		Value
1	Paracetamol 500mg	49,204,726	15	Cefotaxime 1gm inj	16,227,214
2	Diclofenac 75mg inj	43,755,092	16	Albendazole 400mg	14,790,853
3	Ciprofloxacin 500mg	32,746,868	17	Ibuprofen 400mg	13,103,839
4	Diclofenac 50mg	31,296,461	18	Gentamicin 80mg inj	13,004,885
5	Ringer Lactate 500ml	30,466,765	19	Ranitidine 150mg	11,718,190
6	Cefadroxil 500mg	26,275,443	20	Silver sulphadiazine	11,600,589
7	Amoxycillin 500mg	25,969,922	21	Ofloxacin 200mg	11,585,586
8	Phenobarbitone 60mg	25,951,040	22	Omeprazole 20mg	10,681,465
9	Dextrosaline 500ml	25,438,653	23	Vitamin B Complex	10,546,774
10	Normal saline 500ml	23,818,493	24	Phenobarbitone 30mg	10,353,561
11	Ceftriaxone 1gm inj	20,111,034	25	Snake venom serum	10,032,728
12	Rabies vacc 2.5 iu/ml	18,690,056	26	Rabies vacc 2.5iu/0.5ml	9,172,598
13	Vitamin A 2 iu cap	18,190,620	27	Cotrimoxazole 960mg	9,144,374
14	5% Dextrose 500ml	17,651,545	28	Cotrimoxazole susp.	7,900,576
Total value of top 28 drugs (8% items) cost 50% budget					

One can also see that three of the top 4 drugs are analgesics which consumed 11.5% of the budget (paracetamol tablets 4.5%, diclofenac injection 4% and diclofenac tablets 3%). Nine of the top 28 items were antibiotics and it was found that overall antibiotics consumed 22% of the budget. Further analyses should be done to see what proportion of the budget is consumed by various therapeutic groups and also to see what actual products within therapeutic categories are the highest by value. In this way one may target different drugs for investigation of whether use is appropriate or not.

The medical colleges develop their own formulary lists, the process coordinated by the medical superintendent in liaison with heads of departments in the hospital. While the two government medical college hospitals said they stocked about 350 drug items, the two private medical college hospitals visited stocked 2000-3000 items, with around 600 active pharmaceutical ingredients. Table 4 shows an ABC analysis of drugs purchased by JSS Medical College Hospital during Jan – Jun 2013.

Table 4: Top 25 medicines consumed at JSS Hospital Mysore during Jan-June 2013 by cost

ITEM NAME	BY QUANTITY	BY COST VALUE	% of Total Purchase *
PIPERCILLIN + TAZOBACTUM	12472	3335884	5.93
MEROPENAM	5028	2232025	3.97
IMIPENAM + CILASTAIN	1837	1608746	2.86
CEFOPERAZONE + SULBACTUM 1.5GM	7027	1351535	2.4
PANTOPRAZOLE INJ	37035	1135291	2.02
AZTREONAM 1GM INJ	2400	1020000	1.81
CEFTRIAZONE + TAZOBACTUM	8240	915964	1.63
ENAXAPARIN (LMWH)	3276	867042	1.54
CEFOPERAZONE + SULBACTUM 1GM	6574	748453	1.33
CEFTRIAZONE + SALBACTUM 1.5GM	7142	704766	1.25
CEFTRIAZONE 1GM	14871	547284	0.97
NETILMICIN 300MG INJ	1980	532800	0.95
TRAMADOL INJ	27141	509447	0.91
IRON SUCROS	2006	470937	0.83
EDARAVONE	1389	457287	0.81
AMOXYCILLIN + CLAVULANIC ACID	23575	450107	0.8
CEREBRO PROTEIN HYDROLYSATE 60	720	442846	0.78
FERROUS FURAMATE + FOLIC ACID	60220	401953	0.71
PARACETAMOL IV	3344	396832	0.7
CEFIXIME 200MG TAB	31560	393355	0.7
PROTEIN POWDER	3000	375000	0.67
PANTOPRAZOLE + DOMPERIDONE	54046	333469	0.59
HUMAN ALBUMIN	120	324000	0.58
PANTOPRAZOLE 40MG TAB	58520	316714	0.56
METHYLCOBALAMINE + COMBINATION	30650	306500	0.54

*Total Amount Medicines Purchased during Jan-2013 to June – 2013 was INR 562,45,018

Less than 1% of the items consumed about 36% of the budget. About half of the top 25 items are antibiotics and more than half of the items are not on the KDLWS EML. Such information was not available from government medical college hospitals.

Possible Recommendations

1. KDLWS to produce annual report on consumption:
 - a. ABC analysis, per-capita consumption, comparison across districts.
2. Revise the EML annually in a more transparent way with categorization of drugs by level of facility:
 - a. Have web-based process and strict criteria for inclusion of new medicines in the EML;
 - b. Publish the EML in booklet form and distribute it to all health facilities and medical colleges.
3. Include the EML and how it is formed in pre-service and in-service training curricula in order to sensitize doctors and medical students as to its utility and use.
4. Monitor adherence to the EML:
 - a. Will require review of local hospital procurement and also exiting patient interviews to see the number of outside prescriptions given for non-EML drugs (since non-EML drugs are written on separate prescriptions from those prescriptions containing EML drugs for dispensation in the government facility);
 - b. Should be done Drug and Therapeutic Committees in all teaching hospitals and may also be done district health offices in some of their large hospitals.
5. All Medical College Hospitals should develop evidence-based formulary lists.
6. Government medical college hospitals should:
 - a. consider developing a harmonized formulary list;
 - b. monitor drug consumption (e.g. ABC analysis and prescription audit to monitor compliance with the formulary list); and
 - c. consider purchasing their drugs through the KDLWS for economies of scale.

Medicines Use

Prescribing in India

There have been a number of studies of drug use in public health facilities done since 2000 in India. Table 5 summarizes the baseline data from these studies. In addition, it has been found that drugs are not labeled when dispensed (Chaudhury et al 2005, Karande et al 2005, Rishi et al 2003) and that up to 20-70% of patients may not know how to take their medicines (Chaudhury et al 2005, Karande et al 2005, Rishi et al 2003, DSPRUD 2002). Although the majority of patients seek health care in the private sector relatively few studies of drug use have been done in the private sector. Some studies have shown greater use of medicines in the private sector as compared to the public sector (Kumar et al 2008, Bhatia & Cleland 2004) although this has not been shown in other studies (Indira K 2004). Different types of private sector provider are likely to have widely varying prescribing and dispensing patterns.

Table 5: Summary of baseline drug use in public sector primary care in India as reported in studies conducted during 2000-2009*

Reference	Year of survey	Av. no. drug/Px	% Px with ABs	% Px with INJs	% generic drugs	% EML drugs	% Px with VITs	% viral URTI given AB
Malhotra et al 2001, N.India	2000	1.9			30	90		
DSPRUD 2002, Orissa	2001	2.4-2.7	63-78	8-13		77-92		
Chaudhury et al 2005, Delhi	2001	2.4	49-55		49-96	94-100		
Bhatia & Cleland 2004, S.India	2001			34				
Rishi et al 2003, Uttaranchal	2001	3.7	77	7	51		60	
Karande et al 2005	2001	2.9	40	0.2	73	90		53
Indira K 2004	2003	3.5	71	25				76
Kumar et al 2008, Uttar Pradesh	2003		79	3				
WHO 2009, Thatta/Mumbai	2002-3		43-49					
WHO 2009, Chandy/Vellore	2003, 2005		46					
Biswas et al 2007, Bangalore	2004		56					
Bhunja et al 2009, S.India	2007			22				
Singh et al 2010	2007	2.5	44	21	28	84		

Px=prescription; AB=antibiotic; INJ=injection; EML=Essential Medicines List; VIT=vitamin; URTI=upper respiratory infection;

*Data extracted from the WHO database on medicines use, updated to 2009.

Very few of these studies have been done in association with interventions to improve the use of medicines and even fewer have been evaluated for their impact (using adequate study design). Training to improve dispensing resulted in an increased dispensing time from 24 to 114 seconds, increased drug labeling from 0% to 100% and improved patient knowledge on how to take their medicines from 58% to 97% (Chaudhury et al 2005). Interactional group discussion between prescribers and patients resulted in 11% decreased injection use (Bhunias et al 2009).

Prescribing in Karnataka

The consultant undertook a rapid prescribing survey in the outpatient departments in 11 public facilities (serving mostly acute patients), 2 private medical college hospitals and 5 private pharmacies (serving acute and chronic patients). In each public facility and the two private medical college hospitals 30 prescriptions in the OPD pharmacy were examined. In private pharmacies (2 generic cooperative shops and 3 commercial shops), 30 patient bills were examined. In some district facilities, where OPD doctor registers were well maintained, treatment could be matched against diagnosis. In most facilities, injections were written on a separate prescription from oral drugs so injection rate could only be calculated by dividing the total number of injections given in OPD by the total OPD patient attendance. In two facilities the method was checked by cross-checking patient numbers on both injection and oral medication prescriptions. The results are shown in table 6.

Table 6: Prescribing survey undertaken by the WHO consultant

Drug use indicator	Referral hospital n=2*+2**	District hospital n=3	CHC n=3	PHC n=3	Private Drug Retailer n=5
Average no.drugs / Px	2.4	3.1	3.4	3.2	1.9
% Px with antibiotics	25	37	45	23	27
% URTI cases given antibiotics	-	67	78	64	-
% Px with injections	6	30	57	77	23
% Px with vitamins	23	16	16	2	17
% drugs prescribed by generic name	72*/21**	83	90	87	2
% prescribed drugs belonging to the EML	98*/54**	99	100	100	36
% drugs dispensed	92	98	100	100	100
Average cost/Px (IRs)	256**				376

Px = prescription; *government and **private medical college hospitals

It can be seen, by comparing tables 5 (literature review) and 6 (WHO consultant's survey), that the average number of drugs prescribed per patient is slightly lower (better) than what has been described elsewhere although we do not know the influence of stock-outs on this finding. Antibiotic use in upper respiratory tract infection is similar to what has been described elsewhere but injection use is much higher (worse). Prescribing of EML drugs and by generic name in the government sector is higher (better) than described elsewhere and also higher than in private facilities.

While one might expect a greater number of medicines to be prescribed on average to hospital patients who have more complex conditions, this was not the case here and may be due to patients receiving prescription for outside purchase. Care was taken to select primary care type patients as far as possible but inevitably included more complex cases. The proportion of patients prescribed antibiotics is highest in the district hospitals and CHCs probably because these facilities are seeing most patients with acute infections. Lower rates of antibiotic use seen in the tertiary referral hospitals reflect the higher proportion of chronic cases and lower proportion of acute cases as compared to what is seen in primary health care. Of particular concern is high use of antibiotics in patients with upper respiratory tract infections (URTI) – which has been seen elsewhere. In estimating use of antibiotics in URTI effort was made to exclude lower respiratory tract infection cases from the analysis. Higher rates of vitamin use (B Complex and multivitamins) were seen in the higher level facilities and retail shops.

Injection use was extremely high in district OPD facilities and was highest in the lower level facilities. Most of these injections were diclofenac injection which consumed the second highest amount (4%) of the drug budget (table 3). Most patients did not need an injection and such use risks harm to patients (side-effects) and is wasteful. Doctors said patients demanded injections and that they would return the next day if not given one. However, it was observed that a number of patients were returning the next day anyway to get a repeat injection! High injection use and effective interventions to reduce such use have been seen in other Indian states (Bhunja et al 2010).

Other very common examples of inappropriate prescribing included the following:

- Ranitidine or omeprazole to counter diclofenac or ibuprofen or even paracetamol!
- Metronidazole and a fluoroquinolone for acute diarrhoea
- Use of newer generation antibiotics such as cefadroxil and cefixime rather than the older antibiotic for upper respiratory tract infection cases even in PHCs

Ranitidine, omeprazole, cefadroxil, ciprofloxacin, ciprofloxacin and amoxicillin were all used extensively in OPD prescribing as well as vitamin B Complex and all were in the top 8% of drugs consuming half the drug budget (table 3).

In most of the public facilities visited, the OPD was overcrowded. Doctors were seeing about 50-70 patients per day on average. Some generalist doctors stated that they saw up to 120 patients per day. There was quite some degree of variation but all the doctors seeing more than 50 patients per day complained of overwork. Even, so a number of doctors, more at the hospital level and less at PHC level, see private patients in the evening time.

Prescribers seeing more than 50 patients per day will be constrained by overly short consultations from making proper diagnoses and this may contribute to irrational overuse of medicines. It will also constrain communication with patients. In one facility visited, doctors saw about 30 patients per day and it was mentioned by several senior public health staff that there was unequal workload between facilities and even within facilities (since patients sometimes prefer one doctor to another). Even though the problem of unequally distributed staff is recognized, the districts have limited power to redistribute staff, this being controlled centrally. They may sometimes depute staff from one less busy facility to a busier one. A medical superintendent mentioned that prescribing could not be improved until the overcrowding in OPD was solved. A further problem was non-alignment of specialist doctors with equipment. In the facilities visited, there were cases of a surgeon, gynaecologist, dentist and anesthetist placed in CHCs without an operating theatre or equipment. One mentioned: “We are wasted here because we cannot do what we are trained for”.

Dispensing

Dispensing was generally done by pharmacy assistants (or a nurse in PHCs) under the supervision of a pharmacist. In most hospitals and busy CHCs one staff member may have to dispense medicines to over 250 patients per day. It was observed that the patient-dispenser contact time was often less than one minute, sometimes only a few seconds, so allowing little time to give patients proper instruction on how to take their medicines. There was no labeling whatsoever of medicines in any facility visited. Although patients keep their prescriptions, instructions on how to take medicines are not written in a manner that may be read by patients. It is likely therefore that a substantial number of patients do not know how to take their medicines on leaving the facility and do not take them properly at home. It would be worth conducting a study on this in different facilities in order to assess the size of the problem and then take action to correct the problem. It was also observed that a number of patients returned to the prescriber to ask how to take their medicines, so contributing to the overcrowding in the OPD.

Traditional Practitioners

AYUSH doctors were available in some facilities visited. In one CHC the AYUSH doctor was seeing patients in the busy OPD and prescribing allopathic medicines as well as Ayurveda medicines. She mentioned that she had received 18 months of training in allopathic medicines and that she was generally expected to help out in the busy OPD and prescribe allopathic as well as ayurvedic medicines. In another district hospital, there was a separate unit for AYUSH doctors. Here, they were not expected to see patients requiring allopathic medicines and the number patients seen was much less, being 20-30 per patients per doctor. It was mentioned that the 18-month training given to AYUSH doctors on allopathic medicines has recently been cut – yet they confirmed that AYUSH doctors are expected to prescribe allopathic medicines as well as AYUSH ones in many facilities. In another district hospital, it was found that AYUSH interns were helping in the OPD, being assigned to one allopathic doctor each.

Private prescribing

The five private pharmacies observed served very different customers. Table 7 shows the rapid prescribing survey broken down by type of private pharmacy.

Table 7: Prescriptions dispensed in private retail pharmacies

Drug use Indicator	Private retail shops n=3	“Generic” shops n=2
Average no. drugs / patient	1.90	1.95
% patients given antibiotics	16.7	41.6
% patients given injections	8.7	43.6
% patients given vitamins	16.6	17.1
% drugs prescribed by generic name	1.4	4.6
% prescribed drugs belonging to EML	28.9	47.2
Average drug cost per patient (IRs)	464.57	243.99

All prescriptions dispensed from private pharmacies showed low levels of EML drugs and prescribing by generic name as compared to public facility prescriptions. “Generic” shops (inside hospital compounds) tended to dispense injections, particularly antibiotics, and other non-EML medicines to inpatients in public hospitals. Despite selling more injections, the drug cost per patient is lower in “generic” shops as compared to the other private pharmacies. Private shops outside hospital compounds tended to serve customers with prescriptions from private practitioners as well as selling medicines directly to customers.

Standard Treatment Guidelines (STG)

There is a Karnataka State Standard Treatment Guidelines published in 2005 by the KDLWS in association with the Karnataka Pharmaceutical Council. The STGs are aimed at primary health care. Most doctors at district level did not know of the STGs and none were found in consultation rooms. Few doctors seemed to be using any other STGs or other sources of independent drug information. Some doctors in tertiary hospitals stated that they used national specialist protocols and that general STGs were not for them.

Drug and Therapeutic Committees (DTC)

All Government Medical College hospitals have a “pharmacy” committee, chaired by the Medical Superintendent, to develop the hospital formulary, discuss drug stocks and to decide on purchase of medicines (which they undertake independently using budget allocated by the Department of Medical Education). However, few of them seem to have a Drug and Therapeutics Committee with wider activities such as monitoring or prescriptions, coordinating CME on medicines or monitoring ADRs. CME is organized by the Scientific Committee and each department must run a program at least once per year as well as other internal programs. Pharmacovigilance is conducted by the pharmacology department in some medical colleges designated as

ADR monitoring centres under the Pharmacovigilance Programme of India. However, pharmacologists have little input into the medical college hospitals and do not contribute to deciding the formulary in most cases.

The two private medical colleges visited had more active DTCs with involvement of pharmacologists and clinical pharmacists and some prescription audit as well as active pharmacovigilance programs. In JSS Medical College, Mysore, the Head of Department of Clinical Pharmacy is the Member Secretary of the DTC and there is an active program of drug utilization review mainly of inpatients with feedback to physicians.

There were no DTCs in any of the district hospitals or District Public Health Offices visited. All respondents mentioned that the list of drugs for local purchase was decided by the facility in-charge and approved by Chairman of the *Arogya Raksha Samitee*. In the larger district hospitals, the medical superintendent would decide purchase in liaison with his/her medical colleagues. There was no need to get permission from higher government authorities.

Education and Information

Undergraduate education

The pharmacology faculty teaches prescribing principles to undergraduate pre-clinical medical students. However, prescribing skills during the clinical years are taught by the specialists with very little input from the faculty of pharmacology. Thus, what they learn in the pre-clinical years is likely to be undermined by their clinical studies and later work with senior consultants. Pharmacy diplomas and degrees often do not cover clinical pharmacy skills, including supply chain management, prescription audit, evidence-based selection of medicines, etc. Few institutions offer training in clinical pharmacy which covers these skills. However, JSS Medical College does have an active clinical pharmacy department which is teaching these skills through various post-graduate programs. Few medical schools have clinical pharmacy departments, although the Indian Pharmacy Council is recommending that all have medical schools should have such a department which should be based in the teaching hospital rather than the medical school (unlike pharmacology departments).

Continuing Professional Development (CPD) / Continuing Medical Education (CME)

CDP is organized with the teaching hospitals for in-service staff. The MOHFW vertical disease control programs run refresher training for district level staff from time to time and this may be organized through the State Institute of Health and Family Welfare. The Medical Association of Karnataka has been running CME sessions through local branches regularly, often fortnightly, for the last 25 years. Most, though not all, of their sessions are aimed at specialists as there is a separate Family Physician Association for GPs. Some lectures are organized by the specialist societies. However, for general practice prescribing outside of teaching hospitals, continuing medical education (CME) is adhoc and not mandatory, neither is it followed by many prescribers, nor does it include much on prescribing or rational use of medicines. It was mentioned that the Pharmacy Council had conducted CME on

drugs and prescribing and that such CME could be left to them. However, this is unlikely to sufficiently engage the doctors who are the people who must decide what drugs should be prescribed. It was further mentioned that for many doctors CME consists only of lectures accompanied by dinners sponsored by the pharmaceutical industry. While CME is adhoc or minimal for many prescribers, daily visits by pharmaceutical representatives are common in the private sector.

Karnataka Branch of the Indian Medical Council (IMC)

The Karnataka branch of the IMC administers the rules set out at the central level. They register all doctors practicing in the state, inspect all medical colleges (40 in Karnataka) and investigate complaints against doctors, mostly for asking too much money from patients or clinical negligence. Every year they investigate complaints and have about 200 court cases. Currently, there are about 100,000 members of whom 65,000 are actively practicing, mostly in the private sector. Previously registration was for life, but a new system of re-registration started in January 2013 whereby over 5 years, 30 hours of CME, approved by the local branch of the Medical Council, must be undertaken by every doctor to get re-registration. Two days for 5-6 hours will be recognized as 4 hours CME and one day of 5-6 hours as 2 hours of CME. Central guidelines are followed with regard to whether CME sessions may be recognized for any credits. All CME sessions must have adequate content and must not be sponsored by the pharmaceutical industry. The Medical Council has an auditorium for CME sessions but is not, itself, involved in delivering any CME sessions for doctors.

Karnataka Branch of the Indian Pharmacy Council (IPC)

The Karnataka branch of the IPC administers the rules set out at the central level. They register all pharmacists practicing in the state (with direct communication of this information electronically to the Drug Control Department, DCD), inspect all pharmacy colleges and investigate complaints against pharmacists, mostly complaints brought by the DCD for not being present in the pharmacy while medicines are dispensed. Currently, there are 46,000 pharmacists registered in Karnataka, most of them working in the private sector. The Karnataka branch of the IPC does organize CME refresher training sessions for pharmacists in each district per year. These sessions cover drug storage, patient counseling, regulatory affairs, drug pharmacology (side-effects, interactions, etc) and dispensing. The council also runs a Drug Information and Research Centre (DIRC), which was started 14 years ago and which receives 30-50 queries per month. The DIRC publishes a quarterly Newsletter with information on pharma topics of public importance, drug interactions, new drugs and banned drugs. The DIRC Newsletter has an accreditation from the International Society of Drug Bulletins. In addition the council has published a number of books including Handbook of PharmaSOS and Drug Usage in Special Populations e.g. Pediatrics and Geriatrics and Pregnancy and Lactation.

Karnataka Medical Association

The Karnataka branch of the IMA has 13,000 members (mostly specialists) and runs the Karnataka Medical Journal and fortnightly CME programs (mostly on Sundays) through some local branches. It also runs a fully digitalized library, which is used by postgraduates of the medical colleges and also medical students as well as by

members. A major benefit to members is the ability to avail themselves of cheaper accommodation run by the IMA in different cities. The Family Physician Association is smaller and separate from the IMA. A scientific committee decides the topics but general prescribing topics are generally not covered.

Karnataka Drug and Chemists Association

The Karnataka Drug and Chemists Association has 26,000 members. They also organize their own CME programs running one training program per district every 2 years. During these sessions they inform their members about new drugs and laws. Sometimes they invite staff of the Drug Control Department to these meetings.

Independent Drug Information

Sources of independent drug information are few. Some teaching hospitals were receiving journals and producing newsletters but this is not generally the case elsewhere. There is no Drug Information Centre (DIC) in the state run by MOHFW, only by the Karnataka State Pharmacy Council. The Department of Clinical Pharmacy, JSS Medical College at Mysore, also runs a drug information centre and a Poison Information Centre.

Public Education

District-level PHCs have sub-centres attached to them. In each sub-centre is an ANM and under her are 6-19 Ashas, one per 1000 population. Ashas are local women selected by their communities to undertake health work. They are given training every year and they generally undertake work with regard to women and children's health. They are reimbursed according to how many activities they undertake including bringing pregnant women for delivery in hospital and bringing children for vaccination, etc. They also have a small quantity of drugs which they can use to treat simple illness in the community. Much public education with regard to maternal child health, treatment of childhood illness, vaccination, etc has been undertaken by Ashas. The topics taught by Ashas are decided by MOHFW and so far these workers have not generally been used to spread messages on the proper use of medicines to the community, although many people felt this would be good to do as patient demand for drugs is high. Relevant messages could include:

- *“don't take antibiotics without seeing a health worker first”*
- *“medicines are not needed for simple coughs and colds”*
- *“injections can be dangerous and should only be used for immunization or serious illness in hospital.”*

Monitoring and Supervision

Supervision with regard to prescribing seems to be minimal. If it is done at all it is only to check whether the prescription is properly written and signed. Even in government tertiary hospitals, specialist departments do not appear to be undertaking any drug utilization review, or if they are, it is not reported to the DTC or hospital superintendant. Only in the two private medical colleges was any prescription audit

done, mostly on inpatients. In JSS medical college, the clinical pharmacy ran an active drug utilization review program on inpatients with active feedback to the clinicians and the DTC. Other prescription audit, particularly of OPD prescribing, is not generally done.

Monitoring could be done with minimal time and effort as shown by the consultant who undertook a rapid OPD prescribing survey. Monitoring and supervision to promote rational use of medicines is likely to work best if:

- doctors are approached as friends and collaborating partners rather than in any confrontational way;
- clearly defined behaviours for change are focused on one at a time.
- similar messages are sent out to both prescribers and the community at the same time.

For example, one might say to doctors that their help is needed to reduce the number of injections prescribed for simple primary care conditions in order to save drug costs and reduce potential for adverse events. Other messages might be not to prescribe ranitidine simply to counteract diclofenac or ibuprofen and not to prescribe combination analgesic products for mild pain. One could send out similar messages through the Ashas to the community, stating that fewer medicines are better for simple illness, that injections should only be used for inpatients or immunization, etc. The DDMS could be expanded to allow prescription entry. This has been done in Rajasthan successfully but does have cost implications since a data-entry staff member is needed to do this at each institution. Nevertheless, there would be benefits in terms of safer drug use and savings from reducing unnecessary use. Furthermore, by adding the doctors name to the prescription entry one would have the information for targeting supervision and feedback plus information on doctor workload (which could be used to plan and justify staff redistribution).

Hospital Quality of Care

KC General Hospital is one of five government general hospitals in Karnataka working towards accreditation with National Accreditation Board for Hospital Standards and Health Care Providers (NABH). In the first phase government provides training to staff and infrastructural support including building modernization of the Operating Theatre and laboratory and other equipments. For accreditation there must be good documentation of practices. In KC hospital, there was a Citizen Charter, a DTC and a printed formulary list, though no prescription audit had been done. Another benefit of being accredited is the right to have junior doctors. There is a great shortage of staff and currently AYUSH interns were being used to help in the OPD.

In JSS Medical College in Mysore, an active department of clinical pharmacy with 11 staff, has been established. This college has an active postgraduate training program in clinical pharmacy, covering: drug utilization review; drug information services; poisons information services; ward round participation; treatment chart review; therapeutic intervention; patient counseling; ADR detection, reporting and monitoring; design of cancer chemotherapy regimens and patient referrals. In addition they offer community services, including: home medicines review (in old age homes

and through a community pharmacy); participation in the immunization program; and health screening services. All these activities go towards improving the quality of care with regards to management of medicines. All students are taught these skills, which enable them, as pharmacists, to contribute to the clinical health care team and promote more rational safe use of medicines.

Possible Recommendations

1. Monitor drug use:
 - a. Prescription audit using diagnosis;
 - b. Consider adding prescription data to the electronic DMMS;
 - c. Identify specific inappropriate practices that one wants to change e.g. overuse of injections, overuse of antibiotics in upper respiratory tract infection, ranitidine to 'counter diclofenac', vitamins;
 - d. Should be done by all teaching hospitals and district health offices.

2. Analyse prescriber workload:
 - a. Necessary to reduce over-crowding in the OPD;
 - b. Could be done easily if prescription data was entered into a revamped electronic Drug Distribution and Management System (DDMS);
 - c. Lobby central level for redistribution of staff and matching of expertise with equipment.

3. Make doctors your friends in improving use:
 - a. "Help us to make the free drug supply system sustainable by avoiding use of unnecessary drugs and injections."

4. Standard Treatment Guidelines:
 - a. Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines;
 - b. Disseminate to every doctor and incorporate into CPD;
 - c. Introduce the STGs in all medical colleges.

5. Drug and Therapeutic Committees (DTC):
 - a. Establish DTCs in every hospital and require them to monitor drug use, encourage CPD, and report annually on activities to MOHFW;
 - b. Encourage hospitals to work towards the NABH accreditation process which will, in turn, encourage the setting up of functional DTCs to oversee quality use of medicines and undertake prescription audit.

6. Continuing professional development (CPD):
 - a. IMA/IMC should continue to establish a credit system;
 - b. prescription audit and feedback and ethics should be incorporated into CPD run by the IMA/IMC and the State Institute of Health and Family Welfare;
 - c. help from the Pharmacy Council may be sought for CME on prescribing but the Medical Association and/or Council should be involved to ensure full engagement by the medical profession.

7. Medical and pharmacy education needs to include more focus on the management of medicines:
 - a. Clinical pharmacy departments should be established in all medical schools;
 - b. All AYUSH doctors should be trained in prescribing allopathic medicines or they should not prescribe them in at all.

8. Public Education:
 - a. Core pharmaceutical messages e.g. *does my child need more than one drug? Injections can be dangerous and should only be used for immunization or serious illness in hospital* - through Ashas and the media and with the help of local NGOs.

Medicines Regulation

The Karnataka State Drug Regulatory Authority (DRA), is known as the Drug Control Department (DCD) and is under the Ministry of Health and Family Welfare. The DCD implements the Drug and Cosmetics Act of 1940 and rules there under that apply throughout India in all States. They also implement the Drug Prices Control Order of 1995 and the Drug and Magic Remedies (Objectionable advertisements) Act of 1954. The DCD has three wings – enforcement/administration, drug testing laboratory and pharmacy education. Altogether the DCD has a staff of 709 sanctioned posts but unfortunately, only 453 posts are filled. It was mentioned that 77 new posts are being created and that new staff are being appointed to fill vacant posts. Most regulatory processes are done in accordance with checklists but not formal SOPs.

The pharmaceutical sector consists of 247 manufacturing units, more than 6000 wholesalers, more than 22,000 retail pharmacies, and more than 75,000 products on the market. In addition they regulate 178 blood banks and 147 blood storage centres. One Assistant Drug Controller heads the drug regulatory actions in each of the 30 districts in the state.

E-Governance

The Drug Control Department has a website: <http://drugs.kar.nic.in> and is in the process of computerizing all functions. A system called E-Governance operates, under the Karnataka Guaranteed Services Act 2011, in which five services of the DCD are delivered to citizens within a stipulated time (SAKALA). These services include licenses for drug sales, manufacturing, blood banks, and laboratories, and sampling for drug testing – all of which are computerized. Under SAKALA during 2012-2013, out of 9453 license applications, 9182 were granted and 99 rejected. Information on the daily availability of blood is also available on the DCD website. The DCD also launched the Karnataka Pharmaceutical Policy 2012, which is a policy aimed at supporting the pharmaceutical industry. In addition, the DCD coordinates a state committee that decides on annual quantities of morphine to be supplied to 16 licensed hospitals. The DCD produces an annual performance report and administrative report – from which much of the information in this report was taken.

Regulation of drug outlets

Licences are granted to all outlets which should be inspected at least annually. Manufacturing plants are inspected for GMP compliance annually. However, due to lack of staff it is difficult inspect all drug outlets, such as wholesale and retail shops, as regularly as the DCD would like. In 2012-13 (up to March 2013), the DCD carried out 23,690 inspections and took 2,476 punitive actions. Blood Banks are inspected jointly by the DCD and local NGOs to increase transparency. Most punitive action consisted of suspension or cancelled retail pharmacy licenses due to absence of the pharmacist from the premises or selling of prescription-only medicines.

There are prescription-only drug schedules but, in practice, many prescription-only drugs are available over-the-counter (OTC). A new H1 schedule has been notified by the Drug Controller General of India at the federal level to ensure that various drugs such as new generation antibiotics and second-line TB drugs are not available OTC. However, in practice, this new H1 schedule is yet to be enforced. A special inspection drive is undertaken once every 3 months to check and control the sale of psychotropic and habit-forming drugs.

Drug Testing Laboratory

There are three drug testing laboratories with 187 staff (136 technical). The drug testing laboratory in Bangalore is well equipped and has six sections, covering Pharmaceutical chemistry I and II, pharmacology, pharmacognosy, biochemistry, bacteriology and high-tech, as well as an animal house. The other two laboratories (in Hubli and Bellary) are functioning with 4 sections but are due to be expanded. The laboratories are unable to analyse vaccine, sera, blood and blood products. The Bangalore laboratory is in the final stages of NABL accreditation

Every 3 months, the DCD works with local NGOs (to increase transparency) to make a random selection of samples for testing. During 2012-13 (until March 2013), 6,335 drug samples from the market were tested of which 287 failed quality standards and 77 cases face prosecution. If any sample fails quality testing, an automatic SMS is sent out to all outlets for recall. The software allowing such recall is also used in Maharashtra and Gujarat states. It is proposed to increase the number of samples analysed to 15,000 in the coming year.

In the case of substandard drugs, depending upon the findings of Government Analyst, the actions of suspension, cancellation of licenses and prosecution are taken as per the guidelines of 40th Drugs Consultative Committee (DCC) meeting proceedings.

Drug Registration

While the Federal Drug Controller is responsible for the registration of new molecules/drug products in the India, State Drug Regulatory Authority provides product permission for me-too products – a new product for a molecule and

formulation already on the market. Once such a product is registered in one state it may be marketed throughout India. The product permission given for such a drug usually lasts for 5 years or till the licence/s granted are valid and then need renewal.

The number of drug products on the market is unknown but may be up to 100,000. There are hundreds of different branded generics for commonly used medicines such as paracetamol, amoxicillin, etc. It is recognized that regulating a market with so many products is extremely difficult and the federal drug controller issued an order in Oct 2012 that no more trade names were to be allowed in the registration of me-too drugs. However, it is not clear whether the companies registering products by generic name will be able to use their own trade names, which will not be permitted.

Availability of multiple brands is not only a problem for the DCD to regulate; it may also be dangerous for the patients. Large sections of the community still use the private sector, going from one doctor to another or from one pharmacy shop to another, seeking medicines. Many people do not understand that products with different brand names may contain the same drug. Furthermore, the generic name is often less legible than the brand name since the letters are more spindly than the letters used for brand names which are generally in bold font. Also the generic name may be spread across several tablets/capsules in strip packages whereas the brand name is not. Thus, when strip packages are cut to dispense individual tablets/capsules, the generic name often cannot be read. The use of different brands containing the same API may lead to instances of drug poisoning.

Price control

In practice the prices of only 74 drugs belonging to the national EML at the time of the original drug price control order are regulated. Of these 74 drugs only 38 are currently used. A new price control mechanism has fixed the prices allowed for all essential drugs (on the 2011 EML) at the average of the leading brands in the market. Since these prices are often quite high, many people feel that there is no real price control. KDLWS buys these drugs at well below the upper limit of price control imposed by government.

Pharmacovigilance

Pharmacovigilance is undertaken by pharmacology departments within various Medical Colleges, which report all ADRs to the national coordination centre at Indian Pharmacopoeia Commission, Ghaziabad, which then sends them to the WHO collaborating centre for ADR monitoring at Uppsala, Sweden. Most medical colleges have only just started doing ADR monitoring and causal investigation is limited. Bangalore Medical College started ADR monitoring in 2011 and 140 ADRs have been uploaded to VIGIFLOW so far.

The pharmacology department at St John's Medical College (private) set up their own pharmacovigilance program in 2010 and became a member of the national pharmacovigilance program in 2011. Since 2010 they have detected 204 ADRs. Since undertaking active surveillance on the hospital wards and in the dermatology clinic,

they have detected 32 ADRs (over 3 months) and 56 ADRs (over 5 months) respectively. The clinical pharmacy department at JSS medical college (private) has been monitoring ADRs for many years and has reported 7266 ADRs to the national centre and Uppsala since 2008. Furthermore, they operate a system of feedback to prescribers and decide and document action to be taken.

The Drug Controller mentioned that ADRs are not always reported to the DCD and no information is received from the national centre. He recommended feedback be given by the national centre so that appropriate regulatory action may be taken. While causality assessments (by the concerned ADR monitoring centre) and signal reviews (by the national signal review panel under the Indian Pharmacopoeia Commission) need to be completed before appropriate regulatory action can be taken, cases of lack of efficacy which may be due to sub-standard quality, could be investigated by the regulatory authority in order to enforce quality as per the Drug and Cosmetics Act.

Drug promotion

It was mentioned that there is some monitoring of advertisements of OTC medicines aimed at the public in newspapers, but other drug promotional activities are not monitored. No pre-approval of advertisements is required.

Pharmacy Education

Unlike other State Drug Regulatory Authorities, the Karnataka DCD has administrative control over the Government College of Pharmacy at Bangalore, which has an intake of 50 diploma and 50 degree students annually. In addition the college has 32 post graduate students. The DCD is entrusted with conducting the examination of students for the Diploma in Pharmacy Course as per the regulations of the Pharmacy Council of India. There is a Board of Examining Authority, with the Principal of the Government College of Pharmacy as Chairman and Deputy Drug Controller as Member Secretary.

Possible Recommendations

1. Strengthen the DCD:
 - a. More inspectors – to ensure an adequate number of inspectors to inspect all outlets regularly;
 - b. Standard operating procedures and guidelines for all procedures.
2. Continue to Strengthen Drugs Testing Laboratories:
 - a. Fill all posts so more samples can be processed;
 - b. Expand services to 12,000 samples per year.
3. Start unit to monitor drug promotional activities:
 - a. Develop monitoring of promotional activities and adverts.

4. Implement drug schedules more strictly:
 - a. Focus on implementation of the new H1 schedule to ensure that certain prescription-only drugs e.g. new antibiotics are not sold without prescription.
5. Continue computerization of all processes:
 - a. E-governance and guaranteed services.
6. Pharmacology departments undertaking pharmacovigilance to inform the State Drug Controller concerning ADR monitoring, so that appropriate regulatory action may be taken:
 - a. Investigation of cases of poor efficacy which may be due to sub-standard quality;
 - b. Regulatory action after causality assessments (by the concerned ADR monitoring centre) and signal reviews (by the national signal review panel under the Indian Pharmacopoeia Commission) have been completed.

Medicine Policies and Health system issues

There is an extensive public health care system and the free drug scheme administered by the KDLWS has improved access to medicines since its inception in 2002. However, there are still problems of distribution with stock-outs and also irrational use of medicines.

There is no state stand-alone medicines policy (NMP) document that describes a full set of pharmaceutical policies. The Drug Control Department has produced the Karnataka Pharmaceutical Policy 2012 but this only covers the pharmaceutical industry. There is a Karnataka State Integrated Health Policy 2003 with a mission which states that:

The State will provide improved access to good quality health care and promote an enabling environment for development of the health sector, It will endeavor to provide quality health care with equity, which is responsive to the needs to the people and is guided by principles of transparency, accountability and community participation (MOHFW 2003).

One of the goals of the health policy mentioned is improved access to safe and quality medicines at affordable prices and one component of the policy is entitled Rational Drug Policy. Within this component mention is made of:

- support of the essential medicines concept with regular updating of a state EML and standard treatment guidelines;
- measures to increase efficiency, economy and transparency in drug procurement, storage and distribution;
- strengthening of drug control enforcement; and
- implementing strategies to promote rational use of medicines.

(MOHFW 2003)

A task Force on Health and Family Welfare produced a report in 2002 with many recommendations to promote rational use of medicines including that: all hospitals should have a DTC; the EML and STGs should be regularly updated; educational programs for providers be encouraged; drug information be promoted; pharmacovigilance be undertaken and consumer organizations be involved in public education about drugs (Task Force HFW 2002).

In 2013 a State Public Health Charter was published by the Mission Group on Public Health, part of the Karnataka Knowledge Commission. The mission group included several government officials, including the Principal Secretary of Health, as well as a number of academics and representatives from the NGO sector. This Charter states that the Karnataka State will continue to develop a comprehensive, integrated public health system that will continue to emphasize values of equity, quality and integrity as emphasized by the earlier Task Force. It further states that e-governance will be adopted at all levels of the health system.

The Charter highlights barriers to access to medicines and recommends:

1. scaling up government expenditure on drugs;
2. strengthening drug supply by making the KDLWS an autonomous corporation, having one warehouse per district and a having a stronger drug management information system for stock management;
3. promoting rational use of medicines by following the EML and STGs in all public facilities and by allocating 1% of the drug budget on public education;
4. improving the state medicine regulatory system;
5. strengthening the state-level capacity-building efforts by allocating 2% of the medicines budget to capacity building efforts particularly with regard to the supply chain management system and its workforce;
6. building a strong monitoring and evaluation system including continuous prescription audit of public health facilities.

Thus, there is strong documentation making similar recommendations to the suggested solutions already made in this report.

The various medicine policies that may impact on drug use and that are in place are shown in table 8. This information is adapted to Karnataka state from the findings of this mission and from a report sent by the central MOH for all India to WHO Geneva in 2011.

Table 8: Medicine Policies in place in Karnataka according to the WHO Pharmaceutical Surveys in 2007 and 2011 and the consultant visit in 2013

Drug Policy	State of implementation
State Medicines Policy	State Integrated Health Policy 2003 plus State Public Health Charter 2013, which covers policies for the public sector but not the private sector. Some of the policies are being implemented.
Monitoring the use of medicines	Monitoring of drug consumption is done centrally by KDLWS but very little prescription audit is done.
Essential Medicines List	State EML 2011, recently revised in 2013. KDLWS strictly follows the EML
Standard Treatment Guidelines	State STGs published in 2005 covering but not updated since and not used by practitioners
Formulary	No Karnataka state formulary booklet but a Handbook of PharmaSOS published by the Pharmacy Council
Generic Policies	Generic prescribing policy in the public sector
Regulation of promotion of medicines	Government regulation only but DCD has very little capacity to monitor promotion and does not undertake any pre-approval for drug adverts
Monitoring of ADRs	Done by the various medical colleges and reports sent to the national centre in Ghaziabad
Payment for medicines	All medicines are received free of cost in public health care facilities.
Health Insurance	Public health insurance does not cover a significant proportion of the population.
Revenue from medicines	Never used to pay salaries in the public sector
Medicine Pricing policies	KDLWS buys drugs at prices lower than the maximum prices set by the Centre for essential drugs. No pricing policies for non-essential drugs.
Undergraduate medical training	Training by the pharmacology faculty on prescribing only occurs in the pre-clinical years.
Continuing medical education	Little non-commercially funded CME. Some CPD provided to district level staff by MOHFW vertical disease control programs and by the professional bodies
Medicines Information Centre (MIC)	Karnataka Pharmacy Council runs a medicine information centre.
Public education on medicines use	No public education campaigns on safe medicines use done by government in the past 2 years
Drug and Therapeutic Committees (DTCs)	DTCs exist in some medical college hospitals but they only develop a formulary for purchase and review stock levels. Other hospitals only have purchase committees for local drugs.
State Strategy for containing antimicrobial resistance	No state strategy on antimicrobial resistance. Antibiotics frequently available over-the-counter without prescription.

Coordination and Management

The Ministry of Health and Family Welfare is responsible for overall health care delivery and the Ministry of Medical Education is responsible for the education of all health professionals.

The senior most person in the MOHFW is the principal Secretary who reports to the Minister of Health and Family Welfare. Under the Principal Secretary are the Commissioner for the National Rural Health Mission (NRHM), the Drug Controller, the Commissioner for Health and Family Welfare and the Commissioner for Food Safety. Under the Commissioner of Health for Health and Family Welfare are the Additional Director of Logistics in charge of KDLWS, the Director of Health and Family Welfare, the Director of State Institute for Health and Family Welfare, and the Director of AYUSH. Under the Director of Health of Health and Family Welfare are more than 16 joint directorates, including planning, medical (hospitals), TB, Leprosy, communicable diseases, public health, health education, ophthalmology, etc

Many aspects of the state public sector integrated health policy have been implemented. Some objectives concerning drug procurement and distribution policies, use of the EML, prescribing drugs dispensed from public facilities by generic name have been achieved in primary and secondary facilities. This has been due to the KDLWS only purchasing EML drugs. Nevertheless the investment in the KDLWS has been insufficient to ensure that all essential medicines are always available to patients. Other objectives, particularly concerning rational use of medicines, have not been achieved. One of the reasons for non-achievement is the lack of coordination between the various stakeholders, including various departments within the Department of Health and Family Welfare and also between the MOHFW and other Ministries such as the Ministry of Medical Education. Such liaison requires high political support.

Promoting rational use of medicines requires effective management of the whole pharmaceutical sector. This, in turn, requires liaison with many departments and ministries. Other relevant Ministries include Medical Education (health worker undergraduate training), Finance (drug budget), Public Services Commission (Human Resource Allocation), Trade and Industry (Pharmaceutical Manufacturers), Chemicals and Fertilizers (Drug Prices) and the Drug Regulatory Authority. Other relevant departments in the MOHFW include those responsible for the Asha system for public education, hospital care and the health management information systems, amongst others. Which department in the MOHFW will coordinate amongst all these entities?

WHO recommends that countries or states have a high level multidisciplinary body accountable to the most senior health official possible to advise the Minister of Health or Chief Minister on pharmaceutical issues and to coordinate policy (WHO 2007). Such bodies need an executive in the MOHFW to carry out their directives. What is the situation in Karnataka? Could the KDLWS or the Department of Health and Welfare fulfill some of these functions to ensure the safe and rational use of medicines in the public sector?

Possible Recommendations

- Establish a permanent, independent, state statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOHFW), in Karnataka, under the chairmanship of the Principal Health Secretary, to advise the Chief Minister of Karnataka on Pharmaceuticals.
- Establish an Executive Division in the MOHFW to carry out the statutory committee recommendations – Department of Health & Welfare or KDLWS?
 - a. To coordinate action between various departments and ministries, including the Ministry of Medical Education with regard to undergraduate training of health professionals;
 - b. To be responsible for promoting rational use of drugs including: EML, STGs, DTCs, monitoring drug use, CPD, public education on medicines.

Workshop

At the end of the mission, a half-day workshop was held on July 26th with 18 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.

Agenda

- Presentation of the findings by the WHO consultant;
- Plenary discussion of the findings with identification of main problems and possible solutions.

Discussion

There was a lively discussion and the stakeholders agreed with the many of the consultant's findings and most of the consultant's 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

The free distribution of drugs in government health facilities run by the KDLWS started in 2002 has improved availability of essential medicines in public health but there are still some stock-outs and problems of distribution. There is still a challenge of irrational use of essential medicines for which a coordinated approach involving many different stakeholders is needed.

A. Drug Supply

1. KDLWS should become a corporation:
 - a. Greater autonomy and budget and power to hire staff.
2. KDLWS to produce annual report on procurement and distribution:
 - a. ABC analysis, per-capita allocation, comparison across districts;
 - b. Number of samples failing quality testing and number of batches replaced;
 - c. % of stock that expires and % short-dates stock that is replaced.
3. KDLWS to extend electronic drug distribution management system to level of all district health facilities:
 - a. Better estimation / forecasting of drug need and stock control.
4. Develop and publish formal SOPs for all processes in the KDLWS, with time-frames, and covering drug selection, quantification, procurement & distribution.
5. Review system of quantification:
 - a. Introduce a standard method based on past consumption, adjusted for stock-out periods plus buffer stock minus stock balance;
 - b. Train all the staff in drug quantification.
6. Review storage systems for drugs on inpatient wards.
7. Hire more staff in each warehouse and review the policy of KDLWS only having permanent staff through deputation.

B. Drug Selection

8. KDLWS to produce annual report on consumption:
 - a. ABC analysis, per-capita consumption, comparison across districts.
9. Revise the EML annually in a more transparent way with categorization of drugs by level of facility:
 - a. Have web-based process and strict criteria for inclusion of new medicines in the EML;

- b. Publish the EML in booklet form and distribute it to all health facilities and medical colleges.
- 10. Include the EML and how it is formed in pre-service and in-service training curricula in order to sensitize doctors and medical students as to its utility and use.
- 11. Monitor adherence to the EML:
 - a. Will require review of local hospital procurement and also exiting patient interviews to see the number of outside prescriptions given for non-EML drugs (since non-EML drugs are written on separate prescriptions from those prescriptions containing EML drugs for dispensation in the government facility);
 - b. Should be done Drug and Therapeutic Committees in all teaching hospitals and may also be done district health offices in some of their large hospitals.
- 12. All Medical College Hospitals should develop evidence-based formulary lists.
- 13. Government medical college hospitals should:
 - a. consider developing a harmonized formulary list;
 - b. monitor drug consumption (e.g. ABC analysis and prescription audit to monitor compliance with the formulary list); and
 - c. consider purchasing their drugs through the KDLWS for economies of scale.

C. Promoting rational drug use

- 14. Monitor drug use:
 - a. Prescription audit using diagnosis;
 - b. Consider adding prescription data to the electronic DMMS;
 - c. Identify specific inappropriate practices that one wants to change e.g. overuse of injections, overuse of antibiotics in upper respiratory tract infection, ranitidine to 'counter diclofenac', vitamins;
 - d. Should be done by all teaching hospitals and district health offices.
- 15. Analyse prescriber workload:
 - a. Necessary to reduce over-crowding in the OPD;
 - b. Could be done easily if prescription data was entered into a revamped electronic Drug Distribution and Management System (DDMS);
 - c. Lobby central level for redistribution of staff and matching of expertise with equipment.
- 16. Make doctors your friends in improving use:
 - a. "Help us to make the free drug supply system sustainable by avoiding use of unnecessary drugs and injections."

17. Standard Treatment Guidelines:
 - a. Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines;
 - b. Disseminate to every doctor and incorporate into CPD;
 - c. Introduce the STGs in all medical colleges.

18. Drug and Therapeutic Committees (DTC):
 - a. Establish DTCs in every hospital and require them to monitor drug use, encourage CPD, and report annually on activities to MOHFW;
 - b. Encourage hospitals to work towards the NABH accreditation process which will, in turn, encourage the setting up of functional DTCs to oversee quality use of medicines and undertake prescription audit.

19. Continuing professional development (CPD):
 - a. IMA/IMC should continue to establish a credit system;
 - b. prescription audit and feedback and ethics should be incorporated into CPD run by the IMA/IMC and the State Institute of Health and Family Welfare;
 - c. help from the Pharmacy Council may be sought for CME on prescribing but the Medical Association and/or Council should be involved to ensure full engagement by the medical profession.

20. Medical and pharmacy education needs to include more focus on the management of medicines:
 - a. Clinical pharmacy departments should be established in all medical schools;
 - b. All AYUSH doctors should be trained in prescribing allopathic medicines or they should not prescribe them in at all.

21. Public Education:
 - a. Core pharmaceutical messages e.g. *does my child need more than one drug? Injections can be dangerous and should only be used for immunization or serious illness in hospital* - through Ashas and the media and with the help of local NGOs.

D. Drug regulation

22. Strengthen the DCD:
 - a. More inspectors – to ensure an adequate number of inspectors to inspect all outlets regularly;
 - b. Standard operating procedures and guidelines for all procedures.

23. Continue to Strengthen Drug Testing Laboratories:
 - a. Fill all posts so more samples can be processed;
 - b. Expand services to 12,000 samples per year.

24. Start unit to monitor drug promotional activities:
 - a. Develop monitoring of promotional activities and adverts.

25. Implement drug schedules more strictly:
 - a. Focus on implementation of the new H1 schedule to ensure that certain prescription-only drugs e.g. new antibiotics are not sold without prescription.
26. Continue computerization of all processes:
 - a. E-governance and guaranteed services.
27. Pharmacology departments undertaking pharmacovigilance to inform the State Drug Controller concerning ADR monitoring, so that appropriate regulatory action may be taken:
 - a. Investigation of cases of poor efficacy which may be due to sub-standard quality;
 - b. Regulatory action after causality assessments (by the concerned ADR monitoring centre) and signal reviews (by the national signal review panel under the Indian Pharmacopoeia Commission) have been completed.

E. National Structure & Drug Policy

28. Establish a permanent, independent, state statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOHFW), in Karnataka, under the chairmanship of the Principal Health Secretary, to advise the Chief Minister of Karnataka on Pharmaceuticals.
29. Establish an Executive Division in the MOHFW to carry out the statutory committee recommendations – Department of Health & Welfare or KDLWS?
 - a. To coordinate action between various departments and ministries, including the Ministry of Medical Education with regard to undergraduate training of health professionals;
 - b. To be responsible for promoting rational use of drugs including: EML, STGs, DTCs, monitoring drug use, CPD, public education on medicines.

References

- Bhatia J, Cleland J. "Health care of female outpatients in south-central India: comparing public and private sector provision", *Health Policy and Planning*, 2004; 19(6): 402-409.
- Bhunia R, Hutin Y, Ramkrishnan R, Ghosh PK, Dey S, Murhekar M. Reducing use of injections through "Interactive group discussions": a randomized controlled trial. *Indian Pediatrics*; Vol. 47: 409-414.
- Biswas R, Dineshan V, Narasimhamurthy NS, Kasthuri AS. Integrating hospital-acquired lessons into community health practice: optimizing antimicrobial use in Bangalore. *Journal of Continuing Education in the Health Professions* 2007; 27(2): 105-110.
- Chaudhury RR, Parameswar R, Gupta U, Sharma S, Tekur U, Bapna JS. Quality medicines for the poor: experience of the Delhi programme on rational use of drugs. *Health Policy and Planning*, 2005; 20:124-36.
- Delhi Society for Promotion of Rational Use of Drugs New Delhi. *Evaluation of the Orissa Drugs System*. 2002.
- Drugs Control Department. *Performance report 2012-2013 (up to 31.3.2013)*, Ministry of Health and Family Welfare, Government of Karnataka 2013.
- Drugs Control Department. *Annual Administrative report of the Drugs Control Department, Karnataka State 2012-2013 (up to 31.3.2013)*. Ministry of Health and Family Welfare, Government of Karnataka 2013.
- Government of India. *The Drugs and Cosmetics Act, 1940 (23 of 1940) with The Drugs and Cosmetics Rules 1845 as amended by the second amendment Rules 2011 & 2012 & 3rd, 4th, 5th amendment rules 2012 and the Drug Control Act 1950*. Universal's New Delhi 2013.
- Indira K. APR Project: *A survey on antibiotic prescribing pattern and related factors in primary and secondary health care settings 2002-2004*. Indian Clinical Epidemiology Network INDIACLEN, 2004.
- Karande S, Sankhe P, Kulkarni M. Patterns of prescription and drug dispensing. *Indian J Pediatr*. 2005; 72(2): 117-121.
- Kumar R, Indira K, Rizvi A, Rizvi T, Jeyaseelans L. Antibiotic prescribing practices in primary and secondary health care facilities in Uttar Pradesh, India. *Journal of Clinical Pharmacy and Therapeutics*, 2008; 33: 625-634.
- Karnataka government. *Karnataka State Integrated Health Policy*. Department of Health and Family Welfare, Government of Karnataka 2003.
- Karnataka government. *Karnataka Pharmaceutical Policy 2012*. Drugs Control Department, Ministry of Health and Family Welfare, Government of Karnataka 2012.

Karnataka Government. *Karnataka State Standard Treatment Guidelines 2005*. Karnataka Drug Logistics and Warehousing, Health and Family Welfare Department, and Karnataka Pharmacy Council, Bangalore, Karnataka, India.

KDLWS. *Essential Drug List 2011*. Karnataka Drug Logistics and Warehousing Society, Bangalore India.

Karnataka Jnana Aayoga, *Towards a community orientated public health system development in Karnataka*. Mission Group on Public Health, Karnataka Knowledge Commission, Government of Karnataka, 2013.

Karnataka State Pharmacy Council. *Handbook of PharmaSOS*. 5th Edition. Drug Information and Research Centre, Karnataka State Pharmacy Council. 2012.

Karnataka State Pharmacy Council. *Drugs usage in special population – paediatrics and geriatrics*. 4th Edition. Drug Information and Research Centre, Karnataka State Pharmacy Council 2012.

Malhotra,S, R S Karan, P Pandhi, S Jain. Pattern of use and pharmaco-economic impact of antihypertensive drugs in a north Indian referral hospital: *European Journal of Clinical Pharmacology*, 2001; 57: 535-540.

Rishi RK, Sangeeta S, Surendra K, Tailang M. Prescription audit: experience in Garhwal (Uttaranchal), India. *Tropical Doctor*, 2003; 33(2):76-9.

Singh I, Mittal R, Shafiq N, Bharati B, Nigah KR, Pandhi P, Chaudhary RR, Malhotra S. A drug utilization study to provide background data for bringing amendments in the drug dispensing policy of a pediatric referral center. *Pharmacoepidemiology and Drug Safety*, 2010; 19:393-399.

Task Force on Health and Family Welfare: *Towards equity, quality and integrity in health: final report of the Task Force on Health and Family Welfare*. Task Force on Health and Family Welfare, Government of Karnataka. 2002.

WHO. *Community-based surveillance of antimicrobial use and resistance in resource-constrained settings: report of five pilot projects*, WHO/EMP/MAR/2009.2. Thatte U et al Chapter 4 and Chandy S et al Chapter 3, World Health Organisation, Geneva, 2009.

WHO. World Health Assembly Resolution, WHA60.16. *Progress in the rational use of medicines*. World Health Organisation, Geneva, 2007.

WHO/SEARO. Regional Committee for South East Asia Resolution, SEA/RC64/R5. *National Essential Drug Policy including the rational use of medicines*. World Health Organisation, Regional Office for South East Asia, New Delhi, India, 2011.

WHO, *Promoting rational use of medicines: report of the inter-country meeting New Delhi, India, 13-15 July 2010*. SEA-Drugs-161. World Health Organisation, Regional Office for South East Asia, 2010.

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

	Name	Affiliation
1	M. Madan Gopal I.A.S	Principal secretary to Government, Health and Family Welfare Department, Room No 105, 1st Floor, Vikasa Soudha, Bangalore-560001
2	V.B. Patil I.A.S	Commissioner Health & Family Welfare and Ayush Services, 3rd Floor, IPP Building, Anandarao Circle, Bangalore-560009
3	Dr. B.N. Dhanya Kumar	Director, Health & Family Welfare Services, Anandarao Circle, Bangalore-560 009.
4	B.S. Japali	Joint secretary to Government Health and Family Welfare Department, 1st Floor, Vikasa Soudha, Bangalore-560001
5	Dr. A.R. Aruna,	Director State Institute of Health and Family Welfare, Magadi Road. Bangalore- 560023
6	Dr. B. R Jagashetty	Drugs Controller for the state of Karnataka, Drugs Control Department Bangalore.
7	Sri. Raghurama Bhandary	Additional Drugs Controller, for the state of Karnataka, Drugs Control Department Bangalore.
8	Dr. Vadivelu N	Deputy Drugs Controller, Drugs Control Department Bangalore.
9	Smt. Parvathi Anand Gowdar	Chief Scientific Officer, Drugs Control department Bangalore.
10	Sri. Vijayakumar Gogi	Director Nature Cure, AYUSH Department.
11	Dr G Vinkatsh	Secretary, Medical Education, Government of Karnataka
12	Dr A Chandrashekarappa	Chief, Karnataka Drug Logistics Warehousing Society (KDLWS)
13	Dr. G. Srinivas,	Chief Supervisor, KDLWS, Bangalore
14	Dr K Sreedhara Murthy	Chief Supervisor, KDLWS, Bangalore
15	D. Sridhara Murthi	IPO, KDLWS, Bangalore

16	Amaresh Tumbagi	Assistant Drug Controller, Drugs Control Department
17	Mrs Sudha Swamy	Superintendent, Drug Testing Laboratory, Government of Karnataka, Bangalore
18	Dr. Gurumurthy Parthasarathi	Professor & Head, Department of Clinical Pharmacy, JSS College of Pharmacy & JSS Medical College Hospital (private), Ramanuja Road, Mysore - 570 004,
19	Dr Ravi M.D.	Paediatrician, JSS Medical College Hospital, Mysore
20	Dr. Narahari	Associate Professor of Medicine, JSS Medical College Hospital (private), Ramanuja Road, Mysore - 570 004
21	Dr B Suresh	Vice Chancellor, JSS university, Mysore-570 015, Karnataka and President of India Pharmacy Council
22	Sri. Bhagavan P.S	Registrar Karnataka State Pharmacy Council Stage, Vijayanagar, Bangalore
23	Dr Gundu Rao D.A.	President Karnataka State Pharmacy Council Stage, Vijayanagar, Bangalore
24	Dr Ravi Narayan	Community Health Advisor, Centre for Public Health & Equity, Society for Community Health, awareness, Research & Action, Bangalore
25	Dr Thelma Narayan	Director, SOPHEA, Karnataka Task Force Member, Bangalore
26	Dr Prakash Rao	Drug Action Forum, Karnataka, & Family Physician, Bangalore
27	Sri. Anup Akkihal	Logistimo, Bangalore
28	Dr Yuvaraj Yu Vi	Project Coordinator CHLP, SOCHARA, Bangalore
29	Sri.Teena Xevier	SOCHARA, Bangalore
30	Dr Naveen I Thomas	Coordinator, Aalamba: towards fullness of life..., an initiative of headstreams, Bangalore
31	Dr P Baregowda	Suvarna Arogya Suraksha Trust, Health & FamilyWelfare Dept. Bangalore
32	Dr Gopal Gabary	SOCHARA, Bangalore
33	Dr Prem Pais	Dean and Professor of Medicine St John's Medical College & Hospital (private), Bangalore
34	Dr Dennis Xavier	Head of Dept Pharmacology, St John's Medical College, Bangalore
35	Dr Padmini Devi	Pharmacology Department, St John's Medical College, Bangalore
36	Dr Rajnani M	Bangalore-urban District Health Officer
37	Narahari	Junior Health Inspector, Bangalore-urban

		district
38	Mr Ravi Shankhar	District Program Management Officer, Bangalore-urban district
39	Dr Renuka Prasad	Medical Officer, Abbigere PHC, Bangalore-urban district
40	Ms Suchitra C	Pharmacist, Abbigere PHC,
41	Ms C.B. Martha	Nurse, Abbigere PHC
42	Dr Mangala	Administrative Medical Officer, Kadu Gondanahalli CHC, Bangalore-urban district
43	Mr Ranganath E.S.	Pharmacist, Kadu Gondanahalli CHC Bangalore-urban district
44	Dr R.A. Chandraprabha	Medical Superintendent, KC Government General Hospital, Bangalore-urban district
45	Dr Vimila Patil	Resident Medical Officer, KC General Hospital
46	Narasimhu Muti	Pharmacist, KC General Hospital
47	Dr D Raviprakash	Dean, Bangalore Medical College, Bangalore
48	Dr Narayana Reddy	Prof Pharmacology, Bangalore Medical College (BMC), Bangalore
49	Dr Geeta A	Prof Pharmacology, Bangalore Medical College
50	Dr Shiva Swamy	Medical Superintendent, Victoria Hospital, BMCRI, Bangalore
51	Dr Ranganett	Prof/Head of Dept Community Medicine, BMCRI, Bangalore
52	Mohan Kumar K.A.	Pharmacist, Janatabazaar Generic Drug Stores, near Victoria Hospital, Bangalore
53	Dr Shashikala	District AIDS prevention & control officer, Mandya district
54	Dr Verrabhadrappa	Taluk Health Officer, Mandya district
55	Dr Nagabushan	Pharmacologist, Mandya Medical College
56	Dr K.M. Shivakumar	Medical Superintendent, Mandya Institute of Medical Science & Teaching Hospital, Mandya
57	Mr Srinivasa	Pharmacist, Sri Srinivasa Medicals, Mandya
58	Dr Chandra Shekhar	Medical Officer, Tubineakere PHC, Mandya district
59	Dr R.G. Anupama	Dental Health Officer, Arakere CHC, Mandya district
60	Dr S Henalathe	AYUSH Medical Officer, Arakere CHC, Mandya district
61	B Oenkatesh	Pharmacist, Arakere CHC
62	K.T. Suresh Babu	Senior pharmacist, Sri Narshima Raja (SNR) Government General Hospital, Kolar district
63	Malini	Senior Pharmacist, SNR Government General Hospital, Kolar district
64	Hakeen Munavey	OPD pharmacist, SNR Government General Hospital, Kolar district
65	Dr S.G. Narayana Sung	District Surgeon, SNR Government General Hospital, Kolar district
66	Dr Shashi Kanth Ans	District Health & Family Welfare Office, Kolar

		District
67	Dr S.S.Shankhar Kumar	Paediatrician, SNR Government General Hospital, Kolar district
68	Dr Shivana	Gynaecologist, SNR Government General Hospital, Kolar district
69	Dr Murli	AYUSH Officer, SNR Government General Hospital, Kolar district
70	Mr Venkat Reddy	Pharmacist, TAPCMS Ltd, Janatha Bazaar Medicals, Kolar
71	Dr G Manjunath	Medical Officer, Kurudmale PHC, Kolar district
72	?	Mulbagel Hospital, upgraded CHC, Kolar district
73	Dr Basavanna P.L.	Prof Pharmacology, Mysore Medical College (MMC), Mysore
74	Dr Hema N.G.	Prof Pharmacology, Mysore Medical College, Mysore
75	Dr B.G.Sagar	Medical Superintendent, Krishna Rajendra (K.R) Hospital (attached to MMC), Mysore
76	Mr Desh Pande	Chief Pharmacist, K.R. Hospital, Mysore
77	Dr G.M. Vamadeva	District Surgeon and physician, Mysore District
78	Mr Maruthi (father & son)	Pharmacist-owner, Maruthi Medicals, Bangalore
79	Mr G. Ramnath	Pharmacist-owner, Residency pharmacy, Bangalore
80	Mr. G.N.Bhanu Prakash	Karnataka Chemists & Druggists Association, Bangalore
81	Mr Indraneel Sinha	Executive, PlasmaGen Biosciences & member of Karnataka Pharmacy Council, Bangalore
82	Mr K.S.Prasad	Director, Abhinava Bio-Sciences Private Ltd, Bangalore

Annex 2: Participants of Workshop on Medicines Supply and Use, Bangalore, Karnataka, India, 26 July 2013

SN	Name	Affiliation
1	M. Madan Gopal I.A.S	Principal secretary to Government, Health and Family Welfare Department, Room No 105, 1st Floor, Vikasa Soudha, Bangalore-560001
2	V.B. Patil I.A.S	Commissioner Health & Family Welfare and Ayush Services, 3rd Floor, IPP Building, Anandarao Circle, Bangalore-560009
3	Dr. B.N. Dhanya Kumar	Director, Health & Family Welfare Services, Anandarao Circle, Bangalore-560 009.
4	B.S. Japali	Joint secretary to Government Health and Family Welfare Department, 1st Floor, Vikasa Soudha, Bangalore-560001
5.	Dr. A.R. Aruna,	Director State Institute of Health and Family Welfare, Magadi Road. Bangalore- 560023
6	Dr. B. R Jagashetty	Drugs Controller for the state of Karnataka, Drugs Control Department Bangalore.
7	Sri. Raghurama Bhandary	Additional Drugs Controller, for the state of Karnataka, Drugs Control Department Bangalore.
8.	Dr. Vadivelu N	Deputy Drugs Controller, Drugs Control Department Bangalore.
9	Smt. Parvathi Anand Gowdar	Chief Scientific Officer, Drugs Control department Bangalore.
10	Sri. Vijayakumar Gogi	Director AYUSH Department. Nature Cure,
11	Dr. G. Srinivas,	Chief Supervisor, KDLWS, Bangalore
12	D. Sridhara Murthi	IPO, KDLWS, Bangalore
13	Dr. Gurumurthy Parthasarathi	Professor and Head Department of Clinical Pharmacy, JSS College of Pharmacy and JSS Medical College Hospital, Ramanuja Road, Mysore - 570 004,
14	Dr. Narahari	Associate Professor of Medicine, JSS Medical College Hospital, Ramanuja Road, Mysore - 570 004
15	Sri. Bhagavan P.S	Registrar Karnataka State Pharmacy Council Stage, Vijayanagar, Bangalore
16	Sri. Anup Akkihal	Logistimo, Bangalore
17	Dr Yuvaraj Yu Vi	Project Coordinator CHLP, SOCHARA, Bangalore
18	Sri. Teena Xevier	SOCHARA, Bangalore

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

Medicines supply and use in Karnataka, India

WHO mission: 16-26 July 2013

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 MOHFW, WHO and partners to follow

Background

- **Lack of access to medicines in many SEAR countries**
 - Government of India plans for Universal Health Coverage
- **Irrational medicines use in all SEAR countries**
- **Regional SEARO meeting of 9 countries, July 2010**
 - Recognised the need for a comprehensive health system approach
 - Recommended undertaking a national situational analysis to identify the major problems and possible solutions
- **WHO Resolution SEA/RC64/R5, September 2011**
 - National essential drug policy including rational use of medicines
 - Requested WHO to undertake national situational analyses
- **Regional consultation 23-26 April 2013 to report progress to WHO Regional Committee in Sept 2013**
 - Recommended countries to do situational analyses 2 yearly
- **Situational analysis in Karnataka**
 - WHO fact finding mission, 16-26 July, 2013
 - Workshop to develop recommendations for future state action

Mission 16-26 July, 2013

- **16 July:** visits to Health Secretary; State Drug Controller
- **17 July:** visits to St John's Med College; KDLWS HQ & warehouse
- **18 July:** visits to CHC & PHC in Bangalore Urban District; Bangalore Medical College Hospital & generic retail pharmacy;
- **19 July:** visits to Mandya Medical College & district hospital; CHC; PHC; and retail pharmacy
- **20 July:** visits to Kolar district hospital; CHC; PHC; & generic retail pharmacy
- **21 July:** to Mysore
- **22 July:** visits to JSS Medical College Hospital; Mysore Medical College & Hospital; KDLWS Mysore warehouse
- **23 July:** visits district hospital in Bangalore Urban District; retail pharmacy; Karnataka Pharmacy Council
- **24 July:** visits to retail pharmacy in Bangalore; Director of Health Services MOHFW; Medical Council, Medical Association
- **25 July:** Meeting with Karnataka Drug Action Forum
- **26 July:** workshop

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 MOHFW, Karnataka State Drug Logistics and Warehousing Society (KDLWS), Drug Controller, WHO, partners

Mission findings

- Extensive health care system, with substantial infrastructure, trained health care personnel
- KDLWS supplies all medicines in public sector except Medical College Hospitals
- Some problems in the pharmaceutical sector concerning:
 - Drug supply, selection, use, regulation, policy, information and coordination, but...
- Sufficient resources & capacity to address the problems
 - Will require effort by MOHFW as well as KDLWS

Drug supply: availability

- **Drug availability in PHCs, CHCs, District hospitals**
 - Most public facilities visited reported availability of most items.
 - All use their local budget (from registration fees, diagnostic fees or NRHM) to purchase emergency items out of stock in KDLWS or not supplied by KDLWS
 - Local purchase done 6-12 times/year (hospitals), 1-2 times/year (PHCs)
 - 0-14 items out of stock in facilities visited but all out-of-stock items could be substituted by other items
 - 15 items out of stock in one warehouse visited
 - 5 patients in 1 hospital complained they could not buy non-EML drugs prescribed for inpatients & 1 patient had been begging at the hospital gates for the past week
- **Drug Availability in tertiary referral hospitals**
 - Limited selection of about 350 medicines available in government hospitals but 2000-3000 products available in private hospitals

Drug supply: KDLWS procurement

- Annual e-tendering with technical & then financial evaluation
- Technical evaluation:
 - GMP certificate for the product
 - Supplier annual turnover of 5 crore
 - Production of the product by the supplier for more than 3 years
 - Supplier not blacklisted
 - Agree to supply half annual quantity in 60 days & the remaining half in a further 60 days. Delays of 1-15 days incur a 3% penalty, 16-30 days a 5% penalty, and >30 days a 10% penalty, or cancellation, blacklisting & forfeiture of deposit
 - 80% of shelf-life remaining on delivery
 - KDLWS logogram on packaging
- Earnest Money Deposit (1 lakh) and Security Deposit (5%) against supply default
- Quality testing of every batch (0.5% drugs costs included in quote). Two failed batches results in blacklisting
- 2 companies black listed for contravening technical criteria 2012

% facilities without drugs in Chamarajanagar district 25.7.13

Drug name	% Facilities (n=74)	Drug name	% Facilities (n=74)
Amoxicillin 500mg	50.0%	Metformin	46.0%
Amoxicillin 250mg	59.5%	Metronidazole 200mg	87.8%
Amoxicillin 125mg	51.3%	Metronidazole 400mg	35.1%
Albendazole 400mg	48.7%	Metronidazole inj.	48.7%
Albendazole susp.	55.4%	Paracetamol 500mg	23.0%
Atropine inj	48.7%	Paracetamol syrup	59.5%
Diclofenac 50mg	20.3%	Phenobarbitone 30mg	33.8%
Diclofenac inj. 75mg	45.0%	Phenobarbitone 60mg	36.5%
Iron-Folic large	51.4%	Phenytoin 100mg	50.0%
Iron-Folic small	78.4%	Tetracycline 250mg	90.5%
Ringer Lactate 500ml	90.5%	Tetracycline 500mg	48.6%

- 89% of the above medicines were available in the relevant warehouse
- **In Karnataka overall**, only 23% of items were in stock in all warehouses & 24% of items were out of stock in $\geq 80\%$ warehouses

Drug supply: KDLWS distribution

- **Push/pull distribution system**
 - Drugs supplied from manufacturers to 14 warehouses twice yearly
 - Warehouses should have 3 months buffer stock
 - Warehouses supply 3-6 monthly to hospitals & facilities
 - Facilities have budget which can partially be used for drug purchase (annually 1 lakh per PHC/CHC & 5 lakhs per district hospital)
- **Quantification**
 - based on previous year's consumption and estimates by Chief Medical Officers, which may not reflect actual need
 - No standard method used
- **Electronic Drug Distribution Management System**
 - Covers district warehouses but not facilities
 - Allows review & adjustment of drug requests according to stock balance and redistribution of drugs between districts
 - Includes info on amount of budget allocation used in each facility
 - No patient information on prescribing or diagnosis

Karnataka Drug Logistics Warehousing Society (KDLWS)

- Established 2002 with assistance of the European Union and registered under Karnataka Registration Act in 2003
 - Replaced the Government Medical Stores
 - Unlike the Government Medical Stores, KDLWS does not supply the Medical College Hospitals which are under the Ministry of Medical Education & retained their autonomy for purchase
 - Resulted in improved access to essential drugs in facilities
- Supplies IRs 140 crore essential medicines/year to all government facilities (excluding medical college hospitals)
- 14 district warehouses (piled high with drugs) & 13 more being built
- KDLWS has no warehouse staff:
 - in-charge & chief pharmacist deputed by the DHOs; 2 junior pharmacists, 1 data operator & 2 attendees are contract staff
- 6 technical departments under Additional Director (Logistics)
 - Administration, Procurement, Logistics, Quality Control, Finance & Accounts, and IT

Drug supply: possible solutions

- **KDLWS to become a corporation**
 - Greater autonomy, larger budget, power to hire staff
- **Annual report by KDLWS on consumption & activities**
 - ABC analysis, per-capita consumption, comparison across districts
 - Number samples failing quality testing & number batches replaced
 - % of stock that expires; % short-dated stock that is replaced
- **Extend electronic DDMS system to level of facility**
 - Better estimation / forecasting of drug need and stock control
- **Review system of quantification**
 - Introduce method based on past consumption adjusted for stock-out periods and buffer need minus stock balance
 - SOPs for process of selection and quantification with time-line
- **Hire more staff**
 - May need more than 1.5% of drug budget for staff

Drug selection

- **State Essential Medicines List (EML) 2011**
 - State Therapeutic Committee decides on EML based on EMLs of India, Tamil Nadu and Rajasthan and 21 specialist sub-committees
 - 375 drug items in 2011
 - Categorisation by level of facility not published
 - State Needs Assessment Committee (SNAC) decides on quantities to purchase, adjusting the amounts requested by facilities
 - KDLWS then does e-tendering & procures and supplies EML drugs
 - Processes for 2013-14 late & unclear:
 - SNAC in July 2013 before any quantification done by districts
 - 2012-13 buffer stock currently being used to supply facilities
 - About 10% patients referred for non-EML drugs in district hospitals
- **Medical College Hospitals**
 - Decide their own formulary list & purchase individually
 - Ministry of Medical Education supplies budget for govt colleges
 - Unknown number of patients referred outside to purchase drugs

KDLWS 2012-13: Top 28 (8%) drug items cost 50% budget

Paracetamol 500mg	49,204,726	Cefotaxime 1gm inj	16,227,214
Diclofenac 75mg inj	43,755,092	Albendazole 400mg	14,790,853
Ciprofloxacin 500mg	32,746,868	Ibuprofen 400mg	13,103,839
Diclofenac 50mg	31,296,461	Gentamicin 80mg inj	13,004,885
Ringer Lactate 500ml	30,466,765	Ranitidine 150mg	11,718,190
Cefadroxil 500mg	26,275,443	Silver sulphadiazine	11,600,589
Amoxycillin 500mg	25,969,922	Ofloxacin 200mg	11,585,586
Phenobarbitone 60mg	25,951,040	Omeprazole 20mg	10,681,465
Dextrosaline 500ml	25,438,653	Vitamin B Complex	10,546,774
Normal saline 500ml	23,818,493	Phenobarbitone 30mg	10,353,561
Ceftriaxone 1gm inj	20,111,034	Snake venom serum	10,032,728
Rabies vacc 2.5 iu/ml	18,690,056	Rabies vacc 2.5iu/0.5ml	9,172,598
Vitamin A 2 iu cap	18,190,620	Cotrimoxazole 960mg	9,144,374
5% Dextrose 500ml	17,651,545	Cotrimoxazole susp.	7,900,576

Possible solutions for selection

- **Government Medical College Hospitals**
 - Should develop evidence-based EMLs (rather than purchase lists)
 - Should consider purchasing drugs through KDLWS to allow economies of scale
- **Regularly revise the KDLWS EML**
 - Have web-based process & strict criteria for inclusion of new medicines in the EML
 - Should classify drugs by facility type
- **Prescription audit to monitor adherence to the Essential Medicines List (EML)**
 - Drug & Therapeutic Committees (DTCs) in teaching hospitals & District Health Offices (DHOs) should start

Drug use indicator survey

Medicines (drug) use indicator	Referral hospital n=2*+2**	District hospital n=3	CHC n=3	PHC n=3	Drug Retailer n=5
Av.no drugs/patient	2.4	3.1	3.4	3.2	1.9
% patients given ABs	25	37	45	23	27
% URTIs given ABs	-	67	78	64	-
% patients given INJs	6	30	57	77	23
% patients given VITs	23	16	16	2	17
% generic drugs	72*/21**	83	90	87	2
% EML drugs	98*/54**	99	100	100	36
% drugs dispensed	92	98	100	100	100
Av.cost/Px (IRs)	256**	-	-	-	376

*government medical college hospitals; **private medical college hospitals

Drug use

- **Monitoring of prescribing not generally done**
- **KDLWS STG 2005 but few prescribers use it**
- **Many doctors do private practice in the evenings**
 - Sometimes receive pharmaceutical representatives in clinics
- **Prescribing taught at undergrad pre-clinical level but**
 - undermined by later work, little focus on primary care cases
- **DTCs only in tertiary hospitals**
 - Generally only discuss drug availability and procurement
 - One hospital working towards NABH (hosp accreditation)
- **CME adhoc & includes little on prescribing, but...**
 - Medical Council making 30 hours CME in 5 years compulsory
 - Medical Association runs continuing Med Ed (CMEs) in all districts
 - Pharmacy Council runs CMEs, Drug Info Centre & Drug Bulletin
 - State Institute of Health & Family Welfare runs training programs
- **No state-wide public education on medicines use**

Prescribing problems in primary care patients

- **Poor documentation**
 - Doctors outpatient (OPD) registers sometimes not filled in properly & often include no information on drug use
- **Separate prescriptions given for oral & injectable drugs**
 - Prescription audit difficult
- **Serious overcrowding of patients in most OPDs**
 - Overload of doctors and dispensers
- **Serious overuse of injections**
- **Ranitidine to counter diclofenac or ibuprofen or paracetamol!**
- **Diclofenac as well as ranitidine for epigastritis**
- **New generation antibiotics (e.g. Cefadroxil) instead of older generation antibiotic for simple infections**
- **High use of antibiotics for upper respiratory infection**
- **Metronidazole and a fluoroquinolone for acute diarrhoea**

Health worker views

- **PHC medical officer**
 - We have to give injections because the patients demand it for quick relief.
- **CHC anaesthetist, gynaecologist, surgeon & dentist**
 - We are wasted here because there is no operating theatre or equipment so we cannot do what we are trained for.
- **Warehouse chief pharmacist**
 - We do not have enough staff to manage everything well. The staff are temporary contract staff and I am deputed here for several years from a PHC.
- **Medical Superintendent**
 - We will not be able to improve prescribing until we can solve the overcrowding in the outpatients.

Drug regulation

- **Karnataka State Drug Regulatory Authority implements:**
 - Drug and Cosmetics Act 1940 & rules that apply throughout India
 - Drug Prices Control Order of 1995
 - Drug & Magic Remedies (Objectionable advertisements) Act 1954
- **Drug Controller under-resourced**
 - Has 453 staff in post (out of 709 sanctioned posts)
 - Manages a sector consisting of >75,000 products, 247 drug manufacturing units, >6,000 wholesalers, >22,000 retail shops
 - asked for vacant posts to be filled & more sanctioned posts
- **Drug testing laboratories**
 - 3 labs with 187 staff, currently in process of NABL accreditation
 - 6,335 samples tested last year: 287 failed, 77 cases face prosecution
- **Outlet inspections**
 - Carried out 23,690 inspections last year & took 2,476 punitive actions
- **Prescription-only drugs often available over-the-counter (OTC)**
- **Only monitoring OTC adverts, not other drug promotional activities**
- **E-governance & guaranteed services**

Possible solutions for improving use (1)

- **Monitor drug use**
 - Prescription audit using diagnosis
 - Review outpatient (OPD) patient registers (to include drugs prescribed) & prescription writing practices (to write injections & oral drugs on the same prescription)
 - Identify specific inappropriate practices that you want to change e.g. overuse of injections; overuse of antibiotics in upper respiratory tract infection, use of ranitidine to 'counter diclofenac'
 - Should be done by all teaching hospitals & district health offices
- **Analyse prescriber workload**
 - To decrease OPD crowding & work overload
 - More prudent prescribing, better dispensing, less return of old patients, could reduce OPD crowding
 - Lobby central level for redistribution of staff according to workload & to match expertise with equipment

Possible solutions for improving regulation

- **Strengthen the Drug Controller**
 - More inspectors & pharmacists – adequate number of pharmacists to inspect all outlets regularly
 - SOPs and guidelines for all procedures
- **Continue computerization of all processes**
 - E-governance & Guaranteed services
- **Drug Testing Laboratories**
 - Increase services to 12,000 samples/year
- **Start monitoring all drug promotional activities**
- **Involve Drug Controller in ADR monitoring & investigation**
 - May allow better regulatory responsive action
- **Implement drug schedules more strictly**
 - Focus on certain prescription-only drugs e.g. new antibiotics, second-line TB drugs

Possible solutions for improving use (2)

- **Standard Treatment Guidelines (STG)**
 - Revise the STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines
 - Disseminate to every doctor & student & incorporate into CME
- **Drug and Therapeutic Committees (DTC)**
 - Establish DTCs in every hospital and require them to monitor drug use, encourage CME, and report annually on activities to MOHFW
- **Continuing medical education (CME)**
 - Incorporate prescription audit and feedback and ethics into CME
 - Involve State Institute of Health & Family Welfare, Karnataka medical association & Karnataka pharmacy council
- **Public Education**
 - Core pharmaceutical messages e.g. injections can be dangerous and should only be used for immunization or serious illness in hospital through Ashas and the media

Coordination and management

- **Principal Secretary Health & Family Welfare**
 - NRHM; Drug Controller; Commissioner Health & FW; Commissioner for food safety
- **Commissioner Health & FW**
 - Additional Director KDLWS
 - Director Health & FW Services
 - Director State Institute of Health & FW
- **Director Health & FW Services**
 - 16 joint directorates including planning, medical (hospitals), TB, leprosy, communicable diseases, reproductive child health, vector-borne diseases, public health, health education, ophthalmology...
- **Which MOH unit coordinates pharmaceutical services across MOH departments & between ministries?**
 - e.g. development of STGs & training in their use, monitoring DTCs in hospitals, monitoring drug use, CME & public education?
 - Ministry of Health Education, responsible for medical education, is separate from Ministry of Health & FW

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 –**
 - A new Joint Directorate?
 - To coordinate action between MOHFW departments (e.g. KDLWS, Drug Controller, Directorate Health & FW, State Institute of Health & FW) & with Ministry of Health Education, Ministry of Education & other Ministries
 - To be responsible for rational use of drugs: implementation of EML, STGs, DTCs, monitoring drug use, pre-service training, CME, public education, school health programs, etc.

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