

Democratic People's Republic of Korea

Drug Policy and Pharmaceuticals in Health Care Delivery

Mission Report 4-15 June 2012

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Contents

Programme Agenda	3
Acronyms	5
Executive Summary	6
Terms of Reference	9
Background	9
Medicines Supply	10
Medicines Selection and consumption	13
Medicines use	15
Medicines Regulation	23
Medicine Policy and health system issues	26
Workshop	28
Conclusions and Recommendations	29
References	33
Annex 1: Persons met during the mission	34
Annex 2: Participants in the workshop	35
Annex 3: Consultant's slide presentation given in workshop	36

Programme Agenda

Monday, June 4th

Afternoon: Arrive DPR Korea

Tuesday, June 5th

Morning: WHO Country Representative and office

Afternoon: Medicines Management Department and National Drug Regulatory Authority, Ministry of Public Health

Wednesday, June 6th

Morning: Central Medicines Warehouse and Hakson-ri People's hospital, Hyongjesan district, Pyongyang City

Afternoon: Taedonggang district People's Hospital and Chengryu Polyclinic in Taedonggang district, Pyongyang City.

Thursday, June 7th

Morning: Health Co. LVP factory and Kwangbok Polyclinic, Pyongyang City

Afternoon: Pyongyang Medicines University and Hospital of Kim Il Sung University, Pharmacy and Medicines Faculty.

Friday, June 8th

Morning: Travel to Hyangsang County in North Pyongyang Province,

Afternoon: Hyangsan County People's Hospital and Taepyong-ri People's Hospital, North Pyongyang Province, return to Pyongyang City.

Saturday, June 9th

Morning: Report reading in the hotel

Afternoon: WHO Country office

Sunday, June 10th

Morning: Preparation for workshop

Afternoon: Preparation for workshop

Monday, June 11th

Morning: Travel to Kangwon province and Kangwon Provincial Maternity Hospital

Afternoon: Kangwon provincial drug regulatory authority, Kangwon provincial warehouse, Kangwon People's Drug Store and Kangwon Province People's Hospital.

Tuesday, June 12th

Morning: Return to Pyongyang City

Afternoon: National Drug Regulatory Authority, Pyongyang City and Ryongsan-ri People's Hospital, Junghua County, North Hwanghae Province.

Wednesday, June 13th

Morning: Workshop, presentation of findings
Afternoon: presentation of findings and group work .

Thursday, June 14th

Morning: Presentation of group work, plenary discussion and
development of recommendations
Afternoon: Report writing

Friday, June 15th

Morning: WHO Representative debriefing
Afternoon: Leave DPR Korea

Acronyms

ABC	ABC analysis – method for measuring drug consumption
ADR	Adverse Drug Reaction
CPD	Continuing professional development
CME	Continuing medical education
CMW	Central Medicines Warehouse
DIC	Drug Information Centre
DHO	District Health Officer (doctor)
DPHO	District Public Health Office
DRA	Drug Regulatory Authority
DTC	Drug and Therapeutic Committees
EDL	Essential Drug List
EDP	Essential Drug Programme
EML	Essential Medicines List
FDA	Food and Drug Authority
GLP	Food Laboratory Practice
GMP	Good Manufacturing Practice
HQ	Headquarters
HPIC	Health Post in Charge
IPD	Inpatient department
LMIS	Logistics Drug Management Inventory System
MIC	Medicine Information Centre
MMD	Medicines Management Department
MO	Medical Officer (doctor)
MOPH	Ministry of Public Health
MRA	Medicines Regulatory Authority
MTC	Medicines and Therapeutic Committee
NGO	Non-governmental organization
NDP	National Drug Policy
NDRA	National Drug Regulatory Authority
NMP	National Medicines Policy
OPD	Outpatient department
OTC	Over-the-counter
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 to DPR Korea during 5-15 June, 2011. The programme was arranged in agreement with the MOPH. The TOR were to undertake a rapid situational analysis of the pharmaceutical situation, focusing on health care delivery and to conduct a 1.5-day workshop with national stakeholders to discuss the findings and develop a roadmap for national action. Visits were made to public health facilities in Pyongyang and neighbouring provinces, the major MOPH departments (including the Medicines Management Department, the national drug regulatory authority and the Central Warehouse) and the medicines and pharmacy faculty in Pyongyang Medicines University of Kim Il Sung University and its hospital. It was found that DPR Korea has an extensive health care system with many trained health care personnel. The ratio of personnel to the population is of the same order as in many developed nations. However, there are a number of serious problems in the pharmaceutical sector concerning drug supply, selection, use, regulation, policy, information and coordination, as highlighted below. With the large number of trained staff available, there are sufficient resources and capacity to address many of the problems.

Drug Supply and selection

Medicines are supplied by the Central Medicines Warehouse under the Medicines Management Department, MOPH, to all public district facilities. A 'push' system is used from the central level down to the district/county. Drugs are supplied according to the previous year's consumption with some adjustment according to local input and morbidity. All drugs are dispensed free to patients. Though no exact figures were available to the consultant, it would appear from general documentation that government expenditure on general drugs is less than 1 USD/capita/year. Thus there is a chronic shortage of drugs and many drugs belonging to the Essential Medicines List (EML) are not supplied. Some drugs used for chronic diseases are only used for emergency cases. Thus, it would seem that many patients cannot get adequate treatment for many diseases, particularly outside of Pyongyang City. Apart from a few private pharmacy outlets selling a larger selection of allopathic medicines in Pyongyang City, there are no private pharmacies selling allopathic medicines and the People's Drug Stores only sell limited simple drugs. Although there is an electronic logistic management inventory system for drugs at central and provincial levels, data on annual procurement and distribution could not be produced by MOPH and drug stock management is manually done in most facilities. Expired drugs and tablets disintegrating into powder were observed in all pharmacies. There is a national Essential Medicines List (NEML) currently being revised. The draft version of January 2012 had many errors and other versions were not seen.

It was recommended that an electronic logistic management inventory system be extended to county level to improve stock control and quantification and that the Medicines Management Department publishes an ABC analysis of procurement and distribution data annually. Monitoring of the drug dispensaries and pharmacies should be strengthened to ensure that all drugs dispensed to patients are of reasonable quality and not expired and the roles of the branch offices of the Central Warehouse and National Drug Regulatory in this activity should be clarified. It was

also recommended that the NEML be revised to: use only INN names; ensure all dosages are correct; separate Koryo and allopathic drugs; and involve clinicians in the core team to revise the list.

Drug use

No previous drug use surveys were identified. The consultant conducted a prescription audit in the 10 public health facilities visited. It was observed that the average number of drugs per patient was quite low in comparison with other countries, probably reflecting low drug availability. However, there was quite high use of antibiotics for upper respiratory tract infection cases, high injection use and other examples of inappropriate drug use. Some of the inappropriate use may be due to chronic drug shortages and also due to some recommendations in the Standard Treatment Guidelines (STGs) which are not in line with current international recommendations. While, prescriptions are reviewed on an adhoc basis by facility directors there is no systematic monitoring or benchmarking of prescriptions. Refresher training schools conduct continuing medical education (CME) 3 yearly for all staff but the curricula may not include sufficient focus on rational use of medicines. There is no national drug information centre (DIC). While hospitals do have sections on Treatment and Prevention, they do not have Drug and Therapeutic Committees (DTCs) which fully oversee all aspects of drug management and use.

It was recommended that prescription audit be undertaken both locally and through regular surveys conducted by the Institution of Public Health Administration. Other interventions recommended include: establishing DTCs in all hospitals and requiring them to monitor drug consumption and report annually to MOPH; establishing a National DIC; updating the STGs to be consistent with the national EML and more prescriptive and incorporating them into the curricula used for undergraduate education and by refresher training schools; strengthening post graduate training on clinical pharmacy and clinical pharmacology; and developing public education programs on medicines use to be delivered through the existing household and outreach programs operated at primary care level.

Drug Regulation

The national Drug Regulatory Authority (DRA) has 713 staff (113 staff centrally, 40 per province and 1 per county) to manage a pharmaceutical sector of 3000-4000 registered products, about 20 importers, about 60 private pharmacies in Pyongyang city, 200 government-owned People's Drug Stores (1 per county), 210 government factories (1 per county mostly manufacturing traditional medicines and 10 centrally mostly manufacturing allopathic and medicines) and 1 factory that is the Pyong-Su joint venture between the DPR Korea and Swiss governments, manufacturing allopathic medicines. There are national legislation and regulation and some SOPs but not translated into English. Therefore, very little comment on any function could be given or technical support offered. However, it appeared that many technical functions were weak and technical support was requested by the DRA.

The DRA does have its own central drug testing laboratory and one laboratory per province and thousands of samples are tested annually. The quality of all products used is not certain as disintegrating tablets were observed in every pharmacy. The DRA felt that the processes of GMP inspection, quality testing and drug registration all need improvement. There was no systematic national monitoring of adverse drug reactions (pharmacovigilance), although medical accidents, including adverse drug events in health facilities, are reported to the Bureau of Health and Prevention in MOPH). There was no separate drug schedule for narcotic and controlled drugs.

It was recommended that the SOPs for all functions be revised and also that all legislation, regulation and SOPs be translated into English so that technical support may be provided. It was further recommended to strengthen: monitoring of drug quality and expiry in all facilities; drug testing laboratories; drug registration; GMP inspections; and monitoring of adverse drug reactions. In addition, separate drug schedules for narcotic and controlled drugs, as well as separate schedules for drugs that should only be sold with a doctor's prescription (prescription-only) and drugs that may be sold without a doctor's prescription (over-the-counter drugs), should be initiated.

Coordination

Some functions such as monitoring of medicines use and establishing hospital DTCs are not undertaken by any MOPH department. Other functions such as - ensuring that undergraduate education meets the needs of the MOPH; ensuring that STGs are consistent with the national EML; distributing STGs to all facilities and ensuring that they are used in undergraduate and refresher training; and public education on medicines use - are undertaken by a variety of MOPH departments and also Ministry of Education. The Medicines Management Department has some difficulty to coordinate between departments and ministries.

It was recommended that (1) a multidisciplinary mandated independent statutory committee reporting directly to the Secretary of State or Minister of Health be established and (2) an executive unit (possibly Medicines Management Department in the MOPH) be established to carry out the recommendations of the statutory committee and to monitor drug supply and medicines use and coordinate the implementation of strategies to improve use.

Terms of Reference

The objectives were to:

- (1) meet senior officials of the DPR Korea Ministry of Public Health (MOPH).
- (2) undertake a rapid situational analysis of the pharmaceutical situation - with a focus on health care delivery and the use of medicines.
- (3) conduct a 1.5-day workshop with national stakeholders to:
 - a) review the findings of the WHO situational analysis;
 - b) identify the main priority problems to be addressed;
 - c) formulate recommendations for medicines policy to address the problems.

Background

This mission was undertaken to conduct a national situational analysis with regard to the pharmaceutical sector, particularly supply and use of medicines, in order to aid MOPH 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 Committee Resolution, SE/RC64/R5, *National essential drug policy including the rational use of medicines*, also recommends undertaking a situational analysis to aid planning. This mission was undertaken during 5-15 June, 2011, for this purpose. During the situational analysis, a checklist/tool developed in HQ/WHO and now being revised in the region was used. This tool allows the systematic collection of information. The persons met during the fact finding mission can be seen in annex 1. An integral part of this mission was a 1.5-day workshop with about 20 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 (although not all stakeholders are recorded in annex 2).

DPR Korea has an extensive health care delivery system. Part of this health delivery system includes delivery of medicines, free to the patient, in the public sector. However, government is unable to supply the required quantity essential medicines to meet demand and so many health facilities have been reporting shortages of drugs. In addition, there have been concerns about irrational use of medicines. For these reasons, the government invited WHO to undertake a situational analysis of the pharmaceutical sector in order to advise on future policy and facilitate the formation of a plan of action. It is hoped that the recommendations made as a result of the situational analysis will be incorporated into future plans of action.

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

Medicines Supply

Drugs are procured by the Medicines Management Department (MMD) in the Ministry of Public Health and distributed to provinces by the Central Medicines Warehouse (CMW), which is under the MMD. Only drugs belonging to the National Essential Medicines List (NEML) are procured. Of about 260 essential drugs, 230 are procured locally through the Department of Manufacturing, which has 210 government factories under its control, and another 30 items are imported. In addition, international donors (mostly UNICEF and the International Federation of Red Cross Societies) supply a substantial amount of essential drugs. It has been estimated that donors supply 70% of the essential drugs outside Pyongyang City and that this may only cover less than 50% of the need (WHO CCS 2009-13). It was stated by some officials that DPR Korea manages on much less allopathic medicines because Koryo traditional medicines can be used for many conditions and that up to half of all patients may be treated with Koryo medicines. However, in the prescription survey done by the consultant (see prescribing, table 1) only in Pyongyang City did half the patients receive Koryo medicines. Outside Pyongyang City only 10-20% of patients received Koryo herbal medicines, although many more patients may have received non-drug therapies, for example, acupuncture, *cupping*¹, *moxa*² and *manual technique therapy*³.

It is the policy that medicines are dispensed free of charge to patients in the public sector at all facilities, including referral hospitals, provincial, district and county hospitals, ri-hospitals/Ri clinics (Rural PHC units) and polyclinics (urban PHC facilities). Government also operates “People’s Drug Stores”, at least one per county, where people may purchase a limited number of essential drugs (about 18-25 essential allopathic medicines and 60 Koryo medicines) over-the-counter. There is no private sector outside the capital, Pyongyang City, but within Pyongyang City there are about 60 private pharmacies, 9 of which are operated by Pyongsu Pharma (a joint government – Swiss venture) and which are well-stocked with allopathic medicines. Thus, patients in Pyongyang City can buy drugs privately when drugs are out-of-stock in government facilities but this option is much more limited outside Pyongyang City.

¹ **Cupping Therapy** is an ancient form of traditional Chinese/Korean medicine in which a local suction is created on the skin. Practitioners believe this mobilizes blood flow in order to promote healing. Suction is created using heat (fire) or mechanical devices (hand or electrical pumps).

² **Moxa** is made from dried mugwort, a kind of aromatic herb. The therapy using moxa is called moxibustion, which is a traditional Chinese/Korean medicine therapy using moxa. Suppliers usually age the mugwort and grind it up to a fluff; practitioners burn the fluff or process it further into a cigar-shaped stick. Practitioners use it to warm regions and acupuncture points with the intention of stimulating circulation through the points and inducing a smoother flow of blood and qi (Vital energy).

³ **Manual Technique Therapy** is a physical treatment primarily by using hands of the practitioners to treat musculoskeletal pain and disability. It is similar to massage but the therapy is performed according to the meridian theory, part of Traditional Chinese medicine.

Medicines Expenditure

Unfortunately, government did not share information on what government expenditure was annually. It was estimated that that government expenditure on general drugs (excluding the various vertical programs e.g. HIV/AIDS, TB, malaria) in 2008 was less than USD 1/capita/year – well below what is recommended by WHO. This estimate was based on data from MOPH and WHO documentation which states that total drug donation in 2008 was about USD 44 million (MOH 2011) and that donors supplied 70% of all essential drugs used outside Pyongyang City (WHO 2009). Estimation was made assuming that donors paid the same prices for drugs as government (unlikely since locally produced drugs are cheaper), and that government supplied the other 30% of drugs used outside Pyongyang City and most of the drugs used inside Pyongyang (not certain). If these assumptions are wrong then the per capital annual expenditure by government would have been much less than USD 1.

Quantification

Public purchase is based on the average past 3 year's consumption with some adjustment for morbidity and some input by provincial and county hospital directors. However, if there is a chronic shortage of drugs, then all quantification based on past consumption will result in a huge underestimation of need. All allocations are determined centrally for each health facility and then the drugs pushed from centre to province, province to county and county to individual facility.

There is an electronic logistic management inventory control system (LMIS) at central and provincial levels but no analyses of consumption e.g. ABC analysis appears to have been done.

Distribution

Medicines are distributed 3-monthly from the CMW in Pyongyang City to province warehouses and from there to county warehouses. For a few drugs, where the factory is nearby, such as in the case of streptomycin and Kangyon province, supply is directly from the factory to the provincial warehouse, but the transaction is controlled centrally. Drugs are supplied monthly from county warehouses to hospitals and polyclinics. All quantities are sent according to the centrally pre-calculated allocation. The central level has a 3-month buffer stock and the provincial level only 1-month buffer stock. Some of the hospitals visited mentioned that they make an emergency order 1-2 times per quarter.

The MMD stated that they were unable to procure sufficient drugs to meet demand, in particular 3rd generation antibiotics, haemostatic drugs, “blood thinners” and “brain activators”. The province visited had one truck, but apparently many provinces have no truck for transport and this severely hampers the distribution system which has to rely on borrowing truck space from other government departments. All donor drugs are distributed through the government distribution system and are included in the centrally calculated allocation. A provincial warehouse visited stated that some donor drugs arrived with a rather short shelf-life – sometimes only 6 months.

It was generally observed that many drugs were in very short supply and often not present in the dispensary. Most staff stated that drugs were in short supply but not actually out of stock. However on deeper probing it seemed that a substantial number of the essential medicines are not routinely distributed (e.g. ranitidine, antacid) and that other drugs for chronic diseases were used only for emergencies (e.g. glibenclamide for diabetes). Other drugs also were rarely used contrary to what one might expect for a primary care case-mix e.g. antibiotic eye ointment for conjunctivitis and benzoyl benzoate for scabies. Despite drugs being in short supply, expired drugs were seen in every facility including furosemide, captopril, propranolol, atenolol, quinine, adrenaline, ferrous fumarate, folic acid, chlorhexidine, acyclovir, multivitamin, salbutamol, vitamin A, paracetamol, metronidazole. In addition it was observed that many tablets were disintegrating into powder particularly if they had been transferred from their original containers.

Procurement

The MMD procures 230 allopathic essential drug products that are locally manufactured drugs by ordering directly from the allopathic Medicine Manufacturing Bureau in the MOPH every 3 months. Likewise they order about 60 traditional “Koryo” locally manufactured medicines from the Koyo Manufacturing Bureau in the MOPH every 3 months. About 30 allopathic drug items are procured from overseas manufacturers through international tender conducted annually.

There are 10 government factories centrally mostly producing allopathic medicines and a further 200 factories, one per county, in the provinces, mostly producing traditional Koryo medicine. It is unclear whether local manufacturing capacity is insufficient to meet local need or whether, with sufficient budget, sufficient drugs could be manufactured. The Health Co. LVP Factory which manufactures IV fluids is one of the best of all government allopathic factories and is aiming to get itself prequalified to sell to the UN system. They estimated that they only produced about 40% of the national need. Currently, many hospitals are producing their own IV fluids and government is concerned about the quality and would like production to be in controlled manufacturing plants. The Manyan Health Company is in charge of importing drugs and there is a procurement committee with representation from the Department of finance and the MMD in the MOPH.

Human resources

There were pharmacists in every facility and warehouse but they were not generally engaged in monitoring prescriptions or analyzing drug consumption. Mostly, they appeared to be engaged in manual stock counting for data which is submitted centrally. There is a need for greater monitoring of consumption and prescription patterns and this could be used to contribute to a more realistic quantification process. It would seem that there is the staff to do this. It was unclear whether the responsibility for ensuring the quality of drugs in the store and disposal of expired drugs lay with the Provincial and County warehouses or with the Provincial and County Drug Regulatory Authorities.

Possible Solutions

1. Strengthen the Medicines Management Department (MMD):
 - to produce an annual report on drug procurement and distribution with analysis;
 - to better use the existing electronic logistic management inventory system (LMIS) to allow (1) better estimation / forecasting of drug need and stock control, and (2) ABC analysis of drug procurement and distribution (as a proxy for consumption) for feedback to prescribers;
 - to expand the LMIS from central and provincial levels to county level for better stock management and quantification - providing the existing system is properly used and data shared with the donors.
2. Increase the budget for general drugs from less than 1 USD/capita/year to at least 2.0 USD/capita/year.
3. Ensure that every province has one truck to deliver medicines to county level.
4. Strengthen the monitoring of the quality of medicines in all facilities to ensure that no drugs that are expired, disintegrated into powder, discoloured or in poor packaging are dispensed to patients.
 - Need to clarify the roles of the branch offices of the central warehouse and national drug regulatory authority in monitoring drug quality and supplies.

Medicines Selection and Consumption

DPR Korea is in the process of updating its national Essential Medicines List (NEML). There are 260 allopathic items and about 60 Koryo medicines in the list. The drugs are categorised by level of facility in which they may be used – provincial hospital (P), county hospital (C), and ri-hospital and polyclinic (R). All traditional Koryo medicines are marked (K). The NEML was only shared in draft form. Therefore no booklet was seen. In the draft form, there were no page numbers, contents page, index or any description of the development process. Thus, the NEML was not in a form to make for easy use by end-users (pharmacists and doctors).

In a draft 2011 version shared with WHO for external review, many drugs were found to be written by brand name and there were many mistakes with regard to spelling and dosage forms. Some dosage forms were incorrect and some drugs were obsolete. The detailed review was shared with the MOPH. Examples of incorrect spelling include phenobarbithale (phenobarbital), tetradocaine (tetracaine), hydrocortisons hemisnccinas (hydrocortisone hemisuccinate) and colenbuterol (clenbuterol). Examples of brand names used instead of INN (generic names) include analgin (metamizole or dipyrone), omnopon (papaveretum), dimedrole (diphenhydramine). Sometimes there is a spelling mistake of a brand name. For example, diprovan, listed under the section on anaesthetics, is presumably diprivan, a brand name for propofol.

manufactured by Astra Zeneca. Some drug names were not recognized by the reviewer or authors e.g. β -strophanthine, isolanide, lobeline, plygeline, premaguine and some were given descriptive titles rather than names e.g. “powder for skin inflammation” and “water-eczema solution”. Some drugs have been incorrectly classified. For example, ephedrine and clenbuterol are listed as anti-cough medicines but in fact they have bronchodilator effects and ephedrine is used as a decongestant in cough and cold remedies but not as an antitussive. Amikacin is listed as a tablet but only exists in a parenteral form. The dose of naloxone is listed as 400mg/ml whereas the normal dose is 400 micrograms/ml. Adrenaline is listed as 100 mg powder for injection whereas it is usually available as 1mg/ml in a 1 ml ampoule. Mebendazole is listed as a 400mg tablet but the usual strength is 100mg. Some drugs on the DPR Korea list are now considered obsolete by the international community, having been deleted from the WHO model list many years ago e.g. emetine hydrochloride, propriamide and ether.

These kinds of error make it difficult to use the list for procurement and can also be dangerous as incorrect medicines may be distributed and administered. Some allopathic drug names were not recognized due to these errors and also because Koryo drugs are also included in the list. Koryo names would not normally be understood by any external reviewer. In view of the different standards and procedures followed and expertise needed for evaluating the efficacy and safety of allopathic and traditional medicines, it is not normally appropriate to have the two types of medicines in one essential list, rather one would normally have two lists.

The National Drug Regulatory Authority (NDRA) under the MMD coordinates development of the NEML. The Technical Advisory Committee for registration of drugs also deals with the NEML. During development, clinicians are invited to advise on various aspects and also the Chair of the Clinical Pharmacology Committee (that deals with drug trials) provides data for consideration by the committee members. The Pharmacopoeia Committee is also represented during the formation of the NEML. Once the NEML is finalized, it is submitted to the MMD and circulated within the MOPH for consultation. It is finally approved by the Minister and Vice-Minister in consultation with all the Directors of the MOPH. It would seem in this process that clinicians, particularly generalists, have a very small role to play in the process, yet the NEML is largely designed for their use. Normally the development process would involve representation from all the major clinical specialties including primary care practice.

Unfortunately, MOPH was not able to share any drug procurement or distribution (proxy for consumption) data despite having an electronic LMIS system. Therefore it was not possible to do any analysis of annual consumption such as identifying the top 20 drugs and what proportion of the budget they consumed or estimating the proportion of the budget spent on antibiotics or vitamins or calculating per capita expenditure by province. Furthermore, no facility could share any information about stock levels or stock-outs.

A prescription audit (see section on rational use) found that quite a number of drugs on the NEML were never used despite the diagnoses in prescriptions indicating that they could be used (e.g. antacids and ranitidine for gastritis and gastric ulcer). On

direct enquiry it appeared that these drugs are never distributed. Some drugs were regularly used that did not appear to be on the latest draft NEML, e.g. clonidine for hypertension and injectable camphor for myocarditis (and various other diagnoses such as cough and cold (grippe) and gastroenteritis).

Possible solutions

1. Revise and improve the NEML:
 - Use only INN generic drug names;
 - Correct all mistakes concerning spelling and dosage forms;
 - Print a booklet with an introductory section explaining the process of selection, a contents section, an index and page numbers.
2. Improve the updating process of the NEML:
 - Establish a selection committee that is separate from the other committees that are concerned with drug registration, clinical drug trials and drug registration, and include clinicians as core members.
3. Separate the lists for allopathic and Koryo traditional medicines:
 - The experts involved and criteria for selection would be different.
4. Use the LMIS to analyse drug procurement and distribution (consumption):
 - Annual expenditure, per capita expenditure;
 - Proportion of the budget spent on the top 20 items and by therapeutic class;
 - Audit of whether all procurement is of NEML drugs.

Medicines Use

The household doctor system in DPR Korea is a unique system whereby one household doctor is in charge of 134 families, on average, in his/her catchment area and attached to a primary care facility. In the primary care facilities, the patients are seen by household doctors who generally work in the facility in the mornings and visit families in their homes in the afternoons. Sometimes, household doctors only spend 1-2 days in the facility and spend the other days visiting families (since only one colleague need see patients coming to the facility). When the household doctors visit families in their homes, they tend to treat chronic cases, give immunizations and undertake health education.

In most of the public facilities visited, doctors were seeing about 5-30 patients per day (including inpatients, outpatients and home visits). The number of patients seen per day tended to be higher in hospitals as compared to primary care units but in the latter, the generalist (household) doctors have to visit approximately 5-6 households every day. Thus, doctors are generally not overburdened and can give adequate consultation time to patients. Dispensing was generally done by pharmacy staff who also seemed to have adequate time to dispense medicines to patients.

Prescribing

No studies of prescribing in DPR Korea were found in the published literature or in WHO archives. The consultant undertook a rapid prescribing survey in the outpatient departments in 10 public facilities (serving mostly acute patients). In each facility the prescribing in 30 patient encounters was examined by reviewing prescriptions in the outpatient dispensary. The results are shown in table 1. Since there was only a draft 2012 NEML that was not finalized and the previous one was not shared, the % of prescribed drugs belonging to NEML could not be calculated. Nevertheless it was noted that several drugs such as camphor injection, clonidine and cinnarizine were regularly prescribed but they are not on the current draft NEML.

Table 1 shows that, in general, more drugs were prescribed in hospitals as compared to primary care facilities, in urban areas as compared to rural ones, and in Pyongyang City as compared to outside Pyongyang City. This is particularly reflected by the average number of drugs per patient and the use of antibiotics in general and for upper respiratory tract infection. The finding that more drugs are prescribed in hospitals compared to primary care facilities is expected since patients will tend to be more serious and complex in hospitals as compared to primary care. However, the finding that use of medicines was significantly lower outside Pyongyang City reflects less drug availability. This may also be the reason for lower use in rural as compared to urban areas or it may be that rural populations have a lower expectation for drugs than urban ones.

Table 1: Prescribing survey undertaken by the consultant

Drug Use Indicator	Hospital		Primary care	
	Pyongyang city n=2	Outside Pyongyang city n=3	R-hospital (rural) n=3	Polyclinic (urban) n=2
Average number drugs per patient	2.6	1.8	1.3	1.8
% patients receiving antibiotics	51%	18%	31%	48%
% patients receiving injections	27%	20%	18%	14%
% patients receiving vitamins	16%	15%	12%	9%
% drugs prescribed by INN name	89%	91%	92%	88%
% URTI cases receiving antibiotic	81%	61%	58%	66%
% patients receiving Koryo drugs	-	20%	11%	51%

URTI = Upper respiratory tract infection.

The results were compared to the average results for neighbouring countries (WHO 2009). The average number of drugs per patient and % of patients receiving injections was similar to other Asian countries in Pyongyang City hospitals but was lower in all other types of facility in DPR Korea. The % of patients receiving antibiotics was similar in Pyongyang City (in both the hospital and primary care centres) to other Asian countries but was lower in all other types of facility. These results are likely to

reflect the poorer drug availability in rural facilities and those outside Pyongyang City as compared to other Asian countries. However, the % of patients with upper respiratory tract infection at 58-81% is higher than the average of 40-50% in Asia (WHO 2009) – thus indicating that there is some inappropriate use of antibiotics despite the shortage of drugs. Respiratory infections in DPR Korea are very prevalent due to the cold climate but still most upper respiratory tract infections will be viral and not require antibiotics. Prescription by generic name was generally higher than other Asian countries. A more detailed review was made and a number of inappropriate prescriptions were observed as shown in table 2 below.

Table 2: Examples of inappropriate prescribing

Diagnosis	Treatment	Comment
Hypertension	Captopril and diazepam	Diazepam not indicated
Lumbago	Paracetamol, multivitamin and zinc	Multivitamin and zinc not needed
Gastritis	Amoxycillin, metronidazole and paracetamol	Antacid &/or ranitidine, not amoxicillin or metronidazole, are indicated.
Schizophrenia	Chlorpheniramine	Chlorpromazine, not chlorpheniramine, is indicated.
Pyelonephritis	Penicillin and streptomycin (suitable for gram positive bacteria which do not generally cause urinary tract infections) and chlorpheniramine	An antibiotic active against gram negative bacteria is indicated e.g. cotrimoxazole, amoxicillin, ciprofloxacin but not penicillin & streptomycin. Chlorpheniramine is not indicated.
Enterocolitis	Sometimes Furazolidin, sometimes metronidazole, sometimes tetracycline, sometimes oral rehydration solution with Zinc and once camphor injection	Are all these different treatments correct? Is camphor injection indicated?
Cough and cold	Sometimes paracetamol or aspirin alone, but sometimes amoxicillin or cotrimoxazole or multivitamin and once camphor injection	Often common cold needs no medicine at all and certainly not antibiotics, vitamins or camphor injection
Pregnancy	Honey and multivitamin (yet there was expired Ferrous fumarate in the dispensary)	Iron is indicated yet was not given and allowed to expire

Inappropriate prescribing is common place in all countries and should always be looked for. Such prescribing has many causes and generally indicates problems in the health care system. In the cases of DPR Korea, the chronic shortage of drugs is probably leading to some of these inappropriate prescribing practices. Non availability of the correct antibiotic may have led to the prescription of an

inappropriate one. Similarly lack of a suitable drug for gastritis may lead to substitution with an inappropriate drug. However, unnecessary prescribing of antibiotics for common cold, diazepam in hypertension, and chlorpheniramine and camphor injection for multiple diagnoses is wasteful and potentially harmful. In general there was very little awareness of this kind of inappropriate prescribing. Facility directors who reviewed prescriptions tended to focus on spelling and dosage mistakes but did not tend to review or question whether the correct drugs had been prescribed.

Dispensing

Almost all the dispensaries visited appeared to have a very small drug supply. While few dispensaries admitted to an actual total stock-out, it appeared that many drugs, particularly those for chronic diseases, such as diabetes mellitus, were used only for “emergency” cases. On direct questioning it appeared that some drugs were never in stock, not being generally distributed, such as antacids and ranitidine. Some people mentioned items being out of stock that are not on the NEML e.g. omeprazole, ceftriaxone and cloxacillin. No other drug stores apart from the dispensary were shown to the consultant – so it was not clear whether there were any other such drug stores in the hospitals.

It was very common for drugs to be removed from their original containers and stored in other containers where the drug label was inadequate, the drug name being written in Korean but without expiry dates or any indication of how long the tablets had been in the other containers. Sometimes these other containers were just plastic bags. Drugs in busier dispensaries were often pre-packaged into small paper containers for individual patients and it was unclear how long drugs remained packaged in this way. Many tablets were disintegrating into powder particularly if they had been transferred from their original containers.

Although pharmacy staff seemed to have adequate time to dispense medicines to patients, it was observed in a few facilities that the patient-dispenser contact time was sometimes less than one minute and that there was little interaction between patient and pharmacist with little counseling of patients on how to take their medicines. Furthermore, labeling of medicines was sometimes inadequate and lacked written dosing instructions.

Some expired drugs were noticed in every dispensary and included the following drugs (not all in the same dispensary): furosemide, captopril, propranolol, atenolol, quinine, adrenaline, ferrous fumarate, folic acid, chlorhexidine, acyclovir, multivitamin, salbutamol, vitamin A, paracetamol, metronidazole, cefradine, oseltamivir, micronutrient, chlorhexidine, lidocaine, amoxicillin, aspirin, gentamicin eye drops.

Standard Treatment Guidelines (STG) and Formulary

There are national Standard Treatment Guidelines (STGs), aimed at primary care and specialist care and almost all the facilities had these STGs available. Since all the STGs were in Korean, no prescription audit of compliance with STGs could be undertaken. On discussion with staff, it seems that no survey has ever been done to examine compliance with STGs across and between facilities.

The refresher manual for household doctors has been translated into English. However, this is really a training manual, with elements of public health and how to do surveillance etc. There are modules on communicable disease and non-communicable diseases but generally (with a few exceptions such as in the case of TB) the treatment instructions are much less precise than in formal STGs. For example, drug names for treatment are mentioned but not dosages. Choices of treatment are too wide e.g. 4 antibiotic choices are given for typhoid and 5 choices for lower respiratory tract infection. Some statements would be better in a textbook than a treatment guideline, e.g. “selection of antibiotics depends on national protocols and available drugs.” The module on rational use of medicines covers some basic pharmacological concepts, the essential drug concept, hygienic use of injections and drug management. It does also include a formulary with a description of drugs, but problem-based pharmacotherapy or practical exercises on prescribing are absent so it is not clear that this module would actually improve prescribing.

In one ri-hospital, there was a copy of the 2007 STGs for primary health care in Korean. On-the-spot translation indicated that the treatment recommendations in this book may be quite wide and not always in agreement with international thinking. For example, for cough cold, the following drugs were recommended – aspirin, codeine, paracetamol, ephedrine, chlorpheniramine, cotrimoxazole - but most cases do not need any medicine and the recommendations for cotrimoxazole or codeine are questionable. For acute gastro-enteritis, ORS, tetracycline, atropine, camphor injection and IV fluids are recommended, but tetracycline, atropine and camphor injection are all questionable. For chronic gastritis and gastric/duodenal ulcer, magnesium/aluminium hydroxide, atropine, papaverine, famotidine, omeprazole, metronidazole, ampicillin and pancreatin are all recommended. However, the use of pancreatin, papaverine and atropine are questionable, either metronidazole or ampicillin should be used only to eradicate proven helicobacter pylori infection, and famotidine and omeprazole are not in the current draft NEML, nor are they being distributed.

Thus, the choices of drug can be seen to be quite wide. In the case of acute bronchitis, one is recommended to start with amoxycillin and cotrimoxazole, and change to ampicillin injection, penicillin injection, norfloxacin or ceftriaxone (not in the NEML) if not improved. In addition, there is recommendation for aspirin, paracetamol or codeine and prednisolone if necessary. For pneumonia, one is offered the choice of penicillin and streptomycin, then ampicillin, erythromycin, oxacillin (not in the NEML), chloramphenicol and ceftriaxone (not in the NEML). Of course, on-the-spot translation is not ideal and subject to misinterpretation. However, quick review of some treatments recommended in the STGs, suggests that the treatment choices recommended are too wide, are not always consistent with the NEML and may not be in accordance with international thinking. It is likely that some of the inappropriate

prescribing practices observed in the prescription audit are actually recommended in the STGs.

Since the household doctor is such a unique and effective service in DPR Korea, many international organizations have made efforts to update the STG for household doctors. This is the reason that the manual is in English as well as Korean. It would be beneficial if the STGs were updated to be more user friendly, less like a text book, more specific in recommending 1st line and 2nd line drugs and to be consistent with the NEML.

Education and Information

Undergraduate education

Every province has its own medical and pharmacy school. Basic pharmacology is taught in the first two years of medical school, with an option for another course in pharmacology in the 5th year. Each student receives 100 hours of teaching in this subject over 5.5 years but it is unclear how much focus is given to practical prescribing skills. Pharmacy students receive 100 hours of training in drug management over 5 years. Each university has its own curricula and runs its own examination system for doctors and pharmacists with some oversight by the MOPH which sits on the examination committee. It is not clear how well the standards in various provinces are maintained and whether there may be variation between provinces. It did appear that health staff were generally working in the same province in which they were trained and were born with very little movement between provinces.

Continuing Professional Development

Continuing Professional Development (CDP) or continuing medical education (CME) is organized by a system of refresher schools, one per province, which run courses for all cadres of health worker. All doctors are expected to go for refresher training once every 3 years - 4-6 weeks for household doctors, 2-3 months for specialists and one week annually for facility directors. These courses are obligatory.

Independent Drug Information

Sources of independent drug information are few. There is no Drug Information Centre (DIC) run by MOPH.

Public Education

The Department of National Hygiene and anti-Epidemic Bureau is responsible for Information, Education and Communication and all public education on health. There is an extensive community outreach program involving household doctors and other health workers and many public education programs have been run through this network. It is not clear, however, whether targeted messages on drug use have been propagated through this network with the aim of improving use of medicines. Relevant messages could include “don’t take antibiotics without seeing a health worker first” or “medicines are not needed for simple coughs and colds” or “ask your doctor whether your child really needs more than 2 medicines”.

Supervision and training for district level staff

There is extensive supervision of staff within the system. Facility Directors run weekly meetings with all their staff to discuss specific cases, general quality of care issues and sometimes drug issues. Most discussion of drug issues focuses on how to use new formulations. Most directors did look at some prescriptions on an adhoc basis looking for spelling mistakes and dosing errors. There did not seem to be much awareness on the need to discuss general prescribing issues and to look for whether the correct indications for drugs were being followed. Most facilities are visited monthly by a supervisor from the next level of facility above them. However, detailed supervision of prescribing, covering indications, contraindications, drug interactions, etc. does not appear to be undertaken. Most prescribers did not feel that their prescribing may be sub-optimal. Supervision of the pharmacies by the provincial and county drug warehouse staff does not seem to have focused much on good pharmacy practices, which were sometimes poor (see dispensing).

Drug and Therapeutic Committees (DTC)

All the hospitals have a department/section of treatment and prevention, that is led by the hospital director, and which has to report to the local county/district health department regularly (weekly, monthly or quarterly depending on the information to be given). The local health departments report to the provinces who, in turn, report to the central level. With regard to drugs, the information provided may concern adverse events, stock-outs and consumption. However, drug prescribing practices (covering indications, contraindications, dosing, etc.) are not routinely monitored or reported. Thus, the hospital department/section on treatment and prevention does not perform all the functions one would expect of a DTC, which should oversee all aspects of drug management and use within the facility under its jurisdiction. Similarly, there is a Bureau of Treatment and Prevention in MOPH which oversees the functions of all the hospital units but does not oversee all aspects of drug management, including the NEML and prescribing. Therefore, the Bureau of Treatment and Prevention is not performing the function of a national DTC. Most hospitals did not carry out many of the functions that a DTC may be expected to undertake such as managing a formulary system (which is done centrally), prescription audit, monitoring of adverse drug reactions or coordinating CPD/CME on prescribing.

Private Pharmacies and People's Drug Store

There are no private pharmacies outside Pyongyang City and none were visited by the consultant. There are some drugs sold in hotels for consumption by foreigners. In one hotel a small selection of injectable and oral antibiotics, plus paracetamol and aspirin, were sold.

People's Drug Stores are run by the government and supplied by the Central or Provincial Medicines Warehouse. They stock about 18-25 allopathic medicines and about 60 traditional medicines. Mostly they serve people who wish to self-medicate for a mild illness and the drugs are very cheap. For example, one paracetamol tablet cost only 0.1 Yuan and one packet of traditional medicine only 2 Yuan (140 Yuan =

1Euro). Only one People's Drug Shop was visited. No patient records were kept in the shop. It was observed that gentamicin eye drops were available in the shop but not in the nearby hospital so there may be instances when patients come to the shop to buy medicines that are out of stock in the local hospital.

Possible Solutions

1. Monitor drug use including:
 - Prescription audit and feedback to prescribers focusing on whether all the drugs are really needed and indicated and are appropriate for the diagnoses;
 - Use of the Institute of Public Health Administration, in-service pharmacists, clinical pharmacology and clinical pharmacy students to undertake drug use studies (see recommendation 9).
2. Annual reporting (ideally as a statutory requirement) by all major hospitals and districts/counties of prescription audit, with analysis of all reports in the MOPH.
3. Establish functional DTCs in all major hospitals with an obligation to:
 - monitor drug use;
 - include feedback on prescription monitoring in the weekly meetings run by directors and specialist chiefs;
 - report annually to MOPH on their activities so enabling MOPH to know what is and is not going on and what needs to be done (requires MOPH capacity to review these reports).
4. Develop an accreditation system for hospitals which includes a functional DTC as one of the criteria.
5. Revise and regularly update national STGs, for both primary care and hospitals, and ensure that:
 - recommendations are more prescriptive (less choices and more details on dosing and use),
 - all drugs recommended are in the NEML
 - the STGs are disseminated to all doctors, and
 - the STGs are incorporated into both undergraduate and postgraduate CPD/CME curricula.
6. Disseminate to the public core pharmaceutical messages through the existing primary care (household) network (run by the Department of National Hygiene and anti-Epidemic Bureau) and the media, e.g. does my child need more than one drug?
7. Strengthen pharmaceutical disciplines in the university system:
 - clinical pharmacology (to teach general prescribing at undergraduate and postgraduate levels) in all university hospitals teaching medical students;
 - clinical pharmacy (which includes the skills of drug monitoring, prescription audit, DTC management, drug evaluation) into all pharmacy courses.

8. Standardize training and examination of medical and pharmacy students across provinces with documented curricula and regular review by MOPH of the examination system.
9. Incorporate into the CPD/CME:
 - prescribing skills and how to do prescription audit and feedback into the curricula of all Medical Re-education schools and
 - good pharmacy practice and dispensing skills into the curricula of Pharmacy Re-education schools
10. Establish a National Drug Information Centre.
11. Revise the Household Doctor manual to have a section on standard treatment guidelines that is more user friendly, less like a text book, more specific in recommending 1st line and 2nd line drugs and to be consistent with the NEML.

Medicines Regulation

There is national legislation and regulation on drugs but none of it is in English so it was not possible to review the drug regulatory system in much detail. The aim of the national drug regulatory authority (NDRA) is to ensure the quality and safety of all medicines manufactured locally and imported. Currently the NDRA has no website. The NDRA has no role in issuing licenses to pharmacists or the People's Drug Stores. All health worker licenses are controlled by the Medical Education Department in the MOPH. The Medicines Management Department under the MOPH issues licenses to importers and the joint Swiss-DPR Korea joint venture private pharmacies in Pyongyang City. The Bureau of Allopathic Medicines Manufacturing in MOPH issues licenses for manufacturing plants. The NDRA should be involved in checking all documentation, analyzing drug samples, inspection for GMP, inspection of drug outlet premises, etc. prior to the issuance of licenses for manufacture, importation, pharmacy shops, etc. However, it is unclear what the role of the NDRA is in the issuing of such licenses.

The NDRA enforces all national legislation and regulation concerning drugs. Currently there are 713 staff, 113 staff centrally, 40 per province and 1 per county. The NDRA manages a pharmaceutical sector of 3000-4000 registered products, about 20 importers, about 60 private pharmacies in Pyongyang City, 200 government-owned People's Drug Stores (1 per county), 210 government factories (1 per county mostly manufacturing traditional medicines and 10 centrally mostly manufacturing allopathic and medicines) and 1 factory that is a joint venture between the DPR Korea and Swiss governments, manufacturing allopathic medicines. The NDRA has a central office in Pyongyang City (capital) and a branch office in every province. The local county officer generally works within the factory of that county on quality control. The provincial staff undertake inspections covering drugs from manufacture to use – including inspection of factories to check quality and GMP and inspections of the People's Drug Stores and government health facilities to check on quality of drugs in the dispensaries. It is not clear what are the different roles and responsibilities of

the provincial warehouse, regulatory office and local health bureaus with regard to drug management (e.g. disposal of expired or disintegrated medicines) in the health facilities.

Regulation of outlets

There are no private pharmacies outside Pyongyang City and the law concerning them is not known. It would seem that all dispensing is done by pharmacists, whether in private pharmacies in Pyongyang City, the People's Drug Stores or health facilities. The shop assistants selling drugs in hotel stores to foreigners should be also pharmacists according to the regulation, but it is unclear whether they are all pharmacists. The NDRA is supposed to visit provinces quarterly and the province branch visits each county once per year.

Drug Schedules

There are Over-the-Counter (OTC) and prescription-only drug schedules but no separate schedule for narcotics. While OTC drugs are sold in the People's Drug Store it is not clear if some prescription drugs are also sold there. A few antibiotics were observed in the one shop visited. In Pyongyang City it was reported that there are about 20 private pharmacies with a large range of drugs (including many which would normally be prescription-only) all of which are freely sold OTC. The only restriction has been on the sale of diazepam which was introduced last year.

Drug Promotion

There is virtually no drug promotion activities and no monitoring of such activities.

Pharmacovigilance

There is no functional system of surveillance of adverse drug reactions or events.

Drug Quality

The NDRA has its own Drug Testing Laboratory centrally and in each province. As previously mentioned (see dispensing) some drugs in health facility dispensaries were not in a good condition, tablets disintegrating into powder. At central level about 3000-4000 samples are tested annually. Kangwon province branch office of the NDRA mentioned that they tested 3400 samples last year of which 1900 traditional medicines were tested locally and 1500 allopathic medicines were tested centrally. Of these about 100 samples failed quality testing – 80 allopathic medicines and 20 traditional medicines. About half the failures were locally manufactured and half imported drugs. It was not clear if some of the samples tested had already expired.

Drug registration

All products must be registered with the NDRA before being distributed to health facilities, whether locally manufactured in government factories, procured overseas by government or imported by donors. A technical Advisory Committee (TAC) meets 2-3 times per week to decide on about 80 new products per year. The TAC has 13 members, the Chairperson being the Director of the NDRA. Each NDRA section chief sits in the TAC which also has one clinician, the secretary of the Clinical Pharmacology Committee (on clinical trials) and a member from the Pharmacopoeia Committee. It was stated that product registration for old molecules requires review by the NFDA of all drug specifications and the GMP process within a dossier and then quality testing of the product. The criteria for judging new molecules is unclear.

Drug Pricing

Government controls the price of drugs sold in the People's Drug Stores and also the joint-venture private pharmacies in Pyongyang city. The National Price Control Committee, an independent government body, agrees prices for all commodities including drugs. However, the method used to decide drug prices is unknown.

Possible Solutions

1. Strengthen the NDRA by:
 - Sharing the legislation and regulations in English so that technical support may be provided;
 - Establishing Standard Operating Procedures (SOPs) and guidelines for all procedures.
2. Improve the process of drug registration by:
 - publishing the number of products approved by the technical advisory committee and the number of products approved without review by the committee.
3. Strengthen the drug testing laboratory to test more samples per year and to include bio-equivalence testing.
4. Start a unit within the NDRA to start doing pharmacovigilance and post-market surveillance
5. Review the procedures for GMP and strengthen the inspection process in order to improve the quality of drugs manufactured locally.
6. Strengthen the drug schedules:
 - Establish a new drug schedule for narcotics;
 - Establish/enforce drug schedules to separate drugs that may be sold over-the-counter from those that should only be sold with a doctor's prescription;
 - Inspect drug sales regularly in hotels and other private outlets.

Medicine Policies and Health system issues

There is an extensive health care system where patients are supposed to receive free health care. The ratio of health staff to the population is the equivalent of many developed nations. However, a chronic shortage of drugs means that many patients are not receiving the medicines they need and also it is distorting prescribing patterns with substitution of some inappropriate drugs when the indicated ones are absent. There are good systems of supervision and continuing medical education but there is not much focus on rational prescribing. Indeed most health workers were unaware that there were any such problems at all. There is no known national medicines policy document and many aspects of the pharmaceutical sector are not known in detail. The various medicine policies that are in place, as found by the WHO consultant during the mission, and that may impact on drug use, are shown in table 3.

Table 3: Medicine Policies in place in DPR Korea

Drug Policy	State of implementation
National Medicines Policy	Some policies exist but there is no overall drug policy document.
Monitoring the use of medicines	Very little monitoring of consumption centrally or locally.
Essential Medicines List	Draft 2012 National Essential Medicines List.
Standard Treatment Guidelines	Many national STGs in Korean language extensively used by practicing doctors, but the quality of advice in them is unknown.
Formulary	National Formulary published
Generic Policies	No private sector.
Regulation of medicines promotion	No drug promotion.
Monitoring ADRs	No functional system
Payment for medicines	All medicines should be received free of cost in all public facilities but the stock-outs are so severe that many patients must go without, particularly those with non-communicable diseases
Health Insurance	No insurance but all health government health services free.
Revenue from medicines	No.
Medicine Pricing policies	Only relevant for Pyongyang City and unknown.
Undergraduate medical training	NEML and STGs are part of the curricula. No training on problem-based pharmacotherapy.
Continuing medical education	CPD/CME provided to all staff and includes the NEML and STGs.
Drug Info Centre	No national medicines information centre.
Public education on medicines use	Extensive public education system but not known to what extent it has been used to improve drug use.
DTCs	No Drug and Therapeutic Committees (DTCs) in any hospital
National Strategy to contain AMR	No national strategy to antimicrobial resistance (AMR).

Coordination and Management

The relative lack of information concerning government structure and policy precludes much discussion on coordination and management. Much information exists in Korean but has not been shared with foreigners.

The MOPH currently consists of 20 departments, of which three are directly concerned with drugs:

- Medicines Management Department (MMD)
- Allopathic Medicines Manufacturing Bureau
- Traditional Medicines Manufacturing Bureau

Other departments in the MOPH are responsible for other areas which may impact on drugs use. For example, the Department of National Hygiene and anti-Epidemic Bureau is responsible for Information, Education and Communication and all public education on health. The Department of Treatment and Prevention is responsible for the quality of care, which includes the rational use of medicines. Other Ministries involved in areas impacting on the pharmaceutical sector include: Education (school and university education), Finance (drug budget), Commerce (price of drugs imported) and Industry (manufacturers). It is not known the exact functions of these Ministries in DPR Korea, but there is likely to be need for coordination between various Ministries and also between Departments within the MOPH.

One way to overcome the problem of drug policy coordination would be to: (1) establish a Permanent Statutory Committee to advise the Minister of Health or Secretary of State on pharmaceuticals and (2) establish an Executive Body in the MOPH to carry out the statutory recommendations of the Permanent Statutory Committee. This has been recommended internationally and in resolutions WHA60.16 and SEA/RC64/R5.

Possible Solutions

1. Establish a permanent, independent, national statutory committee, with wide membership of all the major stakeholders, (including laypersons, professional bodies, academicians, consumers and all concerned departments/divisions in the MOPH), under the chairmanship of the Minister of Health, to advise the Secretary of State on Pharmaceuticals.
2. Establish an Executive Division in the MOPH to carry out the statutory committee recommendations – a strengthened Medicines Management Department?
 - To coordinate action between all MOPH divisions and different Ministries;
 - To develop a National Medicines Policy.
3. Develop a National Medicines Policy to set out a framework for comprehensive and coordinated government action in the pharmaceutical sector.

Workshop

At the end of the mission, a one and a half-day workshop was held on June 13th and 14th with about 20 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

Day 1

Morning

- Introduction to National Medicines Policy and regional experience;
- Presentation of the findings by the WHO consultant and discussion of the findings with identification of main problems and possible solutions.

Afternoon

- Group work to discuss solutions and develop recommendations for implementation.

Day 2

- Presentation of group work with plenary discussion and finalization of recommendations.

Group work instructions

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

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. Coordination was not discussed by group on drug regulation. The following conclusions and recommendations were agreed by all stakeholders and incorporate all comments from the workshop participants.

Conclusions and Recommendations

A. Drug Supply

The group agreed that drug availability was sub-optimal due to not being able to purchase some drugs to meet demand, lack of an electronic LMIS and lack of transport in the provinces. It was also agreed that an ABC/VEN analysis of drug distribution would be useful but had not materialised and that store management needed improvement. Based on these findings it is recommended to:

1. Expand the LMIS computer network system to county level and ensure better use of the system to analyse drug distribution and better estimate drug need - which will require:
 - Strengthening the capacity of human resources through trainings and workshops;
 - Provision of IT equipment for county level, eventually to all 213 counties/districts.
2. Provision of at least one vehicle to transport medicines at provincial level, eventually to all 9 provinces, (as there only 6 provinces with a vehicle and the other provinces have to borrow from other sectors).
3. Improve store management through:
 - Development of guidelines on good storage practices;
 - Training of staff at provincial, country and local levels;
 - Monitoring store management in accordance with this developed guideline;
 - Yearly reporting system on procurement and supplies of medicines.
4. MOPH to produce an annual report on drug procurement and distribution.

B. Drug Selection

The group agreed that draft NEML had too many errors and needed revisions. Based on these findings it is recommended to:

1. Update NEML:
 - Use only INN drug names and ensure correct spelling, dosage forms, routes of administration, classification of medicines;
 - Separate Koryo and allopathic lists (which may require development of a national guideline).
2. Improve the process of updating the NEML:
 - involve PHC providers and clinicians in the existing national selection committee.
3. Develop a formulary manual based on the revised NEML and use the same design as the WHO model formulary.

4. Disseminate the NEML and formulary manual to all health facilities.

C. Rational use of medicines

The group agreed that there was some inappropriate prescribing and that current monitoring of prescribing was not sufficient to detect and rectify all the problems. They also felt that many of the problems were due to lack of updated information. Based on these findings it is recommended to:

1. Monitor drug use:
 - Self monitoring and prescription audit with feedback in every health facility run by facility Directors and/or DTCs and using indicators developed by the central level;
 - Regular surveys on prescribing to detect trends and variation in use across provinces and counties – to be done by the research department in National Institute of Public Health Administration.
2. MOPH to regularly update and distribute STGs at both PHC and hospital levels:
 - To be consistent with the national EML and formulary;
 - To give details of drugs in order of preferred use and also their dosages;
 - To involve clinicians from all relevant specialties in the development;
 - To distribute to all facilities;
 - To include in all under-graduate and refresher medical training.
3. MOPH to establish a national medicine information centre:
 - To provide updated information on new drugs and their formulations regularly;
 - May be done in collaboration with Pyongyang Medical University, which already has information on 30,000 drugs (allopathic and Koryo);
 - Would need new IT equipment, informational materials and internet access;
 - Would require training of staff on drug information centre;
 - Could provide medicine information on a regular basis for use by the existing telemedicine program;
 - Could provide a regular newsletter for prescribers;
 - Could reserve space in newspapers to do public education on new drugs and formulations.
4. Strengthen continuing medical education on pharmaceutical and prescribing disciplines by:
 - developing post graduate courses on clinical pharmacy and clinical pharmacology (through coordination between MOPH & MOE);
 - including prescribing and prescription audit (for prescribers) and store management and prescription monitoring (for pharmacists) in the curricula of all refresher/reorientation schools;
 - including prescription audit in the regular weekly meetings of health facilities (run by Directors).

5. Establish functional DTCs in all major hospitals with an obligation to:
 - monitor drug use;
 - include feedback on prescription monitoring in the weekly meetings run by directors and specialist chiefs;
 - report annually to MOH on their activities so enabling MOH to know what is and is not going on and what needs to be done (requires MOH capacity to review these reports).

D. Regulation and Monitoring of quality of medicines

The group agreed that many of the functions of the national DRA were sub-optimal and that new SOPs were needed. They also appreciated that lack of translation into English meant that it is difficult for WHO to provide technical support in this area. In particular, it was felt that there is a need to improve the procedures for drug registration, GMP inspection, GLP certification of laboratories, monitoring of drug quality and providing Quality Control information. Based on these findings it is recommended to:

1. Undertake drug registration in accordance with WHO recommended processes and procedures:
 - Publish and distribute regularly a list of registered drugs;
 - Requires technical support, training and translation of current SOPs.
2. Strengthen quality control and existing drug testing laboratories:
 - aim to reach WHO GLP standards for testing of allopathic medicines at the national drug testing laboratory;
 - improve quality control of provincial drug testing laboratories;
 - Requires technical support, new equipment, training and translation of current SOPs.
3. Strengthen monitoring and evaluation of drug quality:
 - Observe product quality in all drug stores, dispensaries and pharmacies at all levels of the public health care system and also in private pharmacies (to include expiry date, quality of packaging, quality of drug products (disintegration into powder, discoloration));
 - Report drug quality and quantities at all levels of the health care system;
 - Dispose of all damaged and expired drugs;
 - Requires adequate transport of staff to undertake monitoring (one bus and motor-cycle per province);
 - Requires clear allocation of responsibility between the branch offices of the national DRA and the central warehouse for doing the monitoring and acting upon the results.
4. Strengthen the procedures for GMP and strengthen the inspection process for domestically produced drugs to ensure highest quality:
 - Requires development of SOPs, guidelines, training and technical support.

5. Strengthen the NDRA by:
 - Establishing Standard Operating Procedures (SOPs) and guidelines for all procedures;
 - Improving the availability of international evidence-based information:
 - a. requires internet access and communication with other national drug regulatory authorities (needs internet access)
 - b. requires sharing of information between the centre and branches (needs IT equipment);
 - Providing external technical support which will require sharing the legislation and regulations in English.
6. Consider starting a pharmacovigilance unit in the national DRA to monitor adverse drug reactions
7. Consider developing a new drug schedule to cover narcotic and controlled drugs in line with international standards.

E. Coordination and Management

No recommendations were made in the workshop.

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

	Name	Affiliation
1	Pak Song Chol	Deputy Director, Medicines Management Department, Ministry of Public Health (MOPH)
2	Ma Chang Nam	Director of National Drug Regulatory Authority
3	Han Chae Sun	Chief of the Institute of Public Health Administration
4	Hyon Pyong Chol	Deputy Director, Central Medicines Warehouse
5	Kim Song Yong	Chief of Importation Department, Central Medicines Warehouse
6	Han In Chol	Director, Hakson-ri People's Hospital
7	Ri Yong Il	Director, People's Hospital, Taedonggang district
8	Han Jong Suk	Director, Chengryu-dong Polyclinic
9	Jon Chun Kwon	Deputy Director, Health Co. LVP factory
10	Kim Hye Lan	Kwangbok Polyclinic, Pyongyang City
11	Han Ho	Deputy Director responsible for pharmaceutical sector, Pyongyang Medical University of the Kim Il Sung University
12	Kye Yong Byok	Chief, Pharmaceutical Faculty, Pyongyang Medical University
13	Kim Gil Su	Chief, Pharmaceutical Administrative Department, Pyongyang Medical University
14	Jon Chol	Director, Hyangsan People's Hospital, Hyangsan County, North Pyongyang province
15	Kim Si Ung	Director, Medical Department of the People's Committee, Hyangsan County, North Pyongyang province
16	Kim Gi Son	Director, Taepyong-ri People's Hospital, North Pyongyang Province
17	Jo Mu Song	Director, Kangwon Provincial Maternity hospital, Kangwon province
18	Ryu Jae Duk	Director, Kangwon provincial drug regulatory authority
19	Ri Pong Gwon	Chief, Distribution Department of Kangwon Medicines Warehouse
20	Pak In Nam	Chief, Planning Department of Kangwon Medicines Warehouse
21	Kim Yong Lan	Pharmacist, Kangwon People's Drug Store
22	Kwon Yong Jun	Director, Kangwon Province People's Hospital
23	Choe Sun Ok	Director, Ryongsan-ri People's Hospital, Junghua County, North Hwanghae Province
24	Remy Cardinois	Manager Pyonsu Pharma
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**Annex 2: Participants of Workshop on the Pharmaceutical Situation
– Potonggang Hotel, Pyongyang City, DPR Korea, 13-14 June 2012**

SN	Name	Organization
1	Pak Song Chol	Deputy Director, Medicines Management Department (MMD), Ministry of Public Health (MOPH)
2	Kim Myong Hwa	MMD, MOPH
3	Ri Hak Bom	MMD, MOPH
4	Kim Sun Nyo	Office of Health Bureau, Pyongyang City
5	Ma Chang Nam	Director of National Drug Regulatory Authority (NDRA)
6	Choe Hie Suk	Inspector, NDRA
7	Choe Kwang Nam	Clinical Pharmacology Committee, NDRA
8	Kim Song Ryong	Section Chief, Central Medicines Warehouse (CMW)
9	O Zong Hak	Section Chief, CMW
10	Zo Hwa Sun	Distribution Chief, CMW
11	Kim Kill Su	Chief Drug Management Department, Pyongyang Medical University
12	Hwang Kwang Yun	Drug Management Section, Pyongyang Medical University
13	Kim Hye Ran	Director of Kwangbok Polyclinic
14	Dr Chae Sun Han	Chief, Institution of Public Health Administration
15	Dr Kamrul Islam	Chief of Health, UNICEF
16	Annemari Raikkola	Health Delegate, International Federation of the Red Cross delegation in DPR Korea
17	Kim Hui Glyong	Procurement & Supply Management, Global Fund
18	Dr Jo Kwang Chol	National Professional Officer, WHO
19	Dr Kim Toiy Hyok	National Professional Officer, WHO
20	Dr Mandal	Medical Officer, WHO DPR Korea
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Annex 3: Slide presentation given by consultant to stakeholders in the 1-day workshop

Medicines supply and use in DPR Korea

WHO mission: 4-15 June 2012

Dr Kathleen Holloway
Regional Advisor in Medicines, WHO/SEARO

Agenda of the workshop

- Presentation by WHO
 - Global and regional situation
 - Findings of DPR Korea mission with discussion, 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
 - Road map for MOH, stakeholders and WHO to follow

Background

- **Irrational use of medicines in all countries of region**
 - Increasing demand for medicines but limited government budget
- **SEAR regional meeting, July 2010**
 - Attended by 9 Member States
 - Recognised the need for a comprehensive health system approach to promote rational use of medicines
 - Recommended doing national situational analyses to identify major problems, prioritize solutions and develop national action plan
- **RC Resolution, SEA/RC64/R5, Sept 2011**
 - National Essential drug policy including rational use of medicines
 - Recommends doing national situational analyses
- **DPR Korea MOPH invites WHO**
 - To do situational analysis to review drug policy, supply & use
- **Situational analysis**
 - WHO fact finding mission, 4-15 June, 2012
 - Workshop to develop recommendations for national drug policy

National medicines policy (NMP):

A commitment to a goal & a guide to action

Source: WHO 2001 & 2003

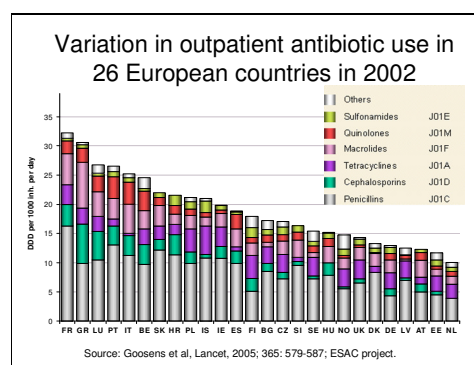
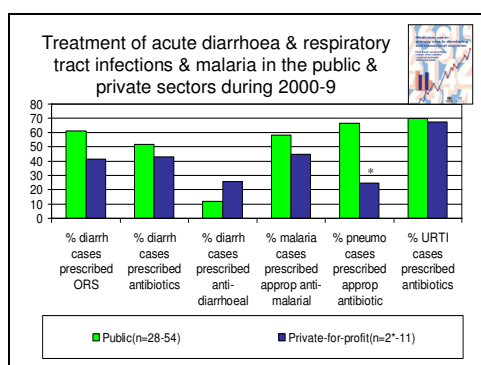
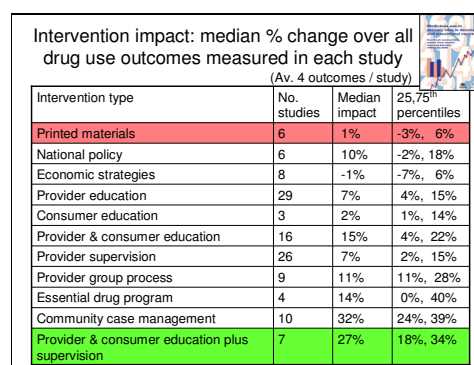
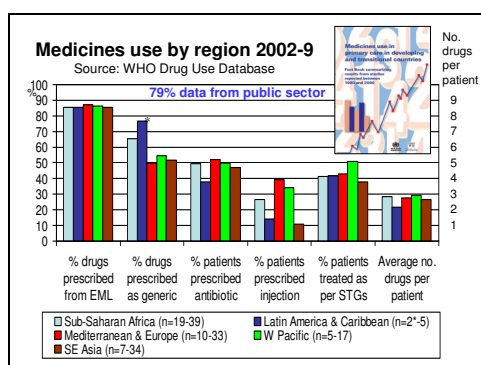
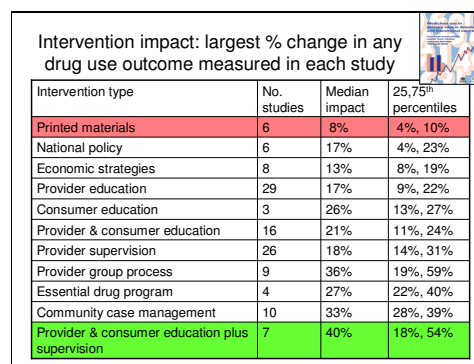
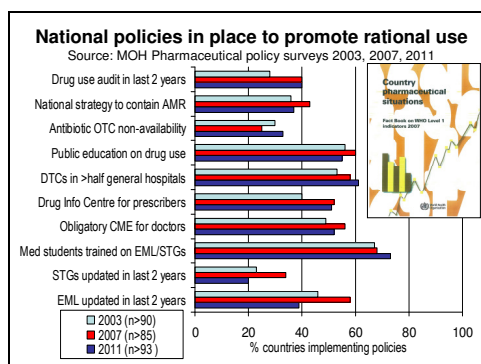
- **Objectives**
 - **Access:** equitable availability and affordability of essential medicines, including traditional medicine;
 - **Quality:** the quality, safety and efficacy of all medicines;
 - **Rational use of medicines (RUM):** the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers
- **Content**
 - Coordinated set of policies to achieve the objectives
 - NMP Document & action plan endorsed by government
 - Essential Drug Concept central to NMP

Objectives of the workshop

- Introduction to global and regional situation and the need for coordinated national drug policies
- Review the WHO fact finding results
- Identify the main priority problems to be addressed in pharmaceutical sector
- Formulate recommendations for policies to resolve / address the problems
 - for use by MOPH, WHO and partners

Key components of a National Medicines Policy (NMP)

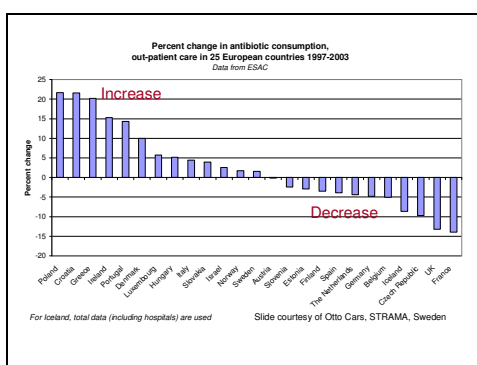
- Selection of essential medicines
- Affordability
- Financing options
- Supply systems
- Regulation and Quality Assurance
- Rational Use
- Research
- Human Resources Development
- Monitoring and Evaluation



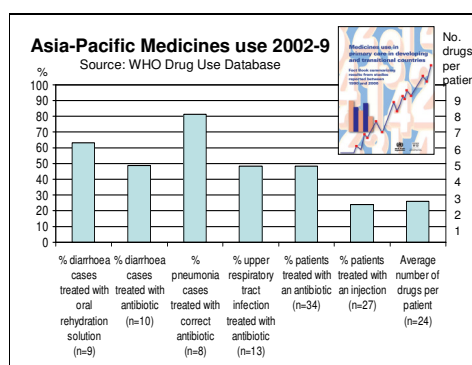
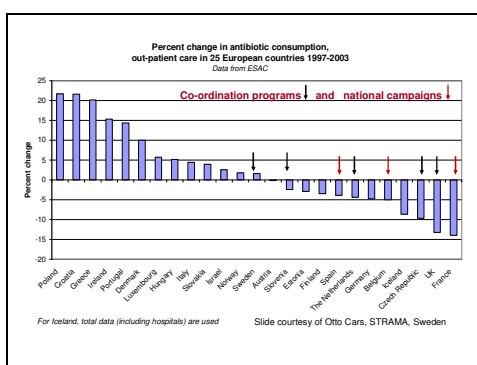
Public education campaigns in industrialised nations Huttner et al 2009, Lancet Infectious Diseases, 2009,10(1):17-31.			
Country	Period	Campaign Type	Antibiotic (AB) reduction
France	2002 -	Yearly mass media targeting Providers & Consumers	27% AB prescriptions
Belgium	2000 -		36% reimbursed packages
UK	Yearly		Stable use
Australia	2000-8		14% AB consumption (DDDs)
USA	1995 -		18-36% in ABs for ARI
Canada*	1996-2005	Limited Seasonal	9% AB Prescriptions
Spain	2006-8	mass media	High use / No change
Portugal	2004-7	campaign	Low use / No change
Germany	2000 -	targeting consumers	
Norway	2004		

* Providers also targeted

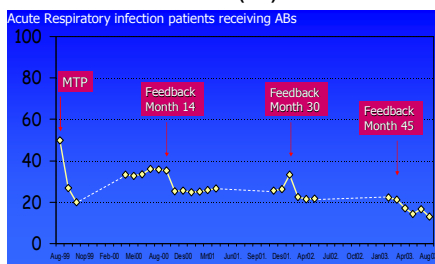
National Medicines Policies (NMP) in SEAR (1)	
• Sri Lanka	– NMP 2005 non-specific and not implemented leading to court action by patients and demand outstrips supply by 30%
• Bangladesh	– NMP 2005 is comprehensive but the focus has been mostly on building manufacturing capacity & half of patients attending public facilities have to buy their drugs from private pharmacies
• Indonesia	– NMP 2006 is comprehensive but central drug selection policies are not followed by the decentralised regions resulting in serious irrational use of medicines
• Bhutan	– NMP 2007 is comprehensive and many aspects are implemented leading to good drug availability & use due to sustained government support & monitoring



National Medicines Policies (NMP) in SEAR (2)	
• Nepal	– NMP 1995 is comprehensive but many aspects not implemented and of all the drugs on the national EML less than 20% are supplied to district hospitals and less than half to primary health care facilities
• Maldives	– NMP 2007 is comprehensive & recommends centralised public sector drug supply but is now undermined by the new constitution in 2008 which focuses on decentralised private sector drug supply
• Myanmar	– NMP 2001 is comprehensive but many aspects not implemented and government expenditure is so low that essential medicines are available in public facilities for only 10% of the time
• Timor-Leste	– NMP 2010 is comprehensive but does not match national capacity & many aspects are implemented by donors



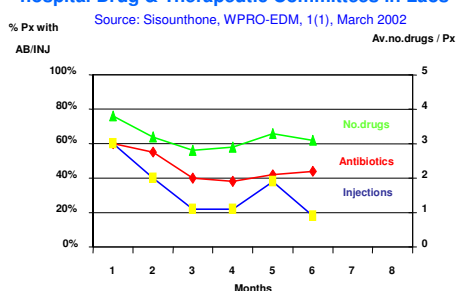
Monitoring training & planning (MTP) by health centre staff on antibiotic (AB) use in Indonesia



Mission findings

- **Extensive health care system with:**
 - substantial infrastructure, many trained health care personnel in more numbers than in many industrialized nations
 - 1 household doctor for every 100-130 households (about 500 people)
 - About 5 contacts with a doctor per person per year but...
- **Some serious problems in the pharmaceutical sector concerning:**
 - drug supply, selection, use, regulation, policy, information and coordination, but...
- **Sufficient resources and capacity to address some of the problems, but...**
 - only if data is shared and used for planning in a transparent manner at central & peripheral levels
 - external technical support can only be provided if the documents and data are shared in English

Effect of monitoring, training & planning through hospital Drug & Therapeutic Committees in Laos



Medicines Expenditure

- MDGs Progress & Annual Report on Health Status, DPR Korea 2011, Ministry of Public Health (MOPH) Juche 100
 - Value of essential medicines provided through international cooperation was USD 44,170,000 in 2008
- WHO Country Cooperation Strategy 2009-2013
 - Donors supplied 70% of essential drugs used outside Pyongyang
- Estimate of government drug expenditure outside Pyongyang, 2008
 - Assuming similar prices locally & internationally, and that donors only supplied drugs outside Pyongyang, and using 2008 census data where population outside Pyongyang was 20,094,571.....
 - Total value of medicines supplied outside Pyongyang = 44,170,000 x 100/70 = 63,100,000
 - Value of medicines supplied by government outside Pyongyang = 63,100,000 – 44,170,000 = 18,930,000
 - Per capita government expenditure outside Pyongyang in 2008 = 18,930,000 / 20,094,571 = 0.942 USD/capita/year
 - This is less than WHO recommended minimum of USD 2/capita/year

Mission 4-15 June, 2012

- **5 June:** visits to Ministry of Public Health (MOPH), Medicines Management Department, National Regulatory Authority and WHO.
- **6 June:** visits to Central Medicines Warehouse, Hakson-ri hospital, Taedonggang district hospital & Chengryu polyclinic in Pyongyang.
- **7 June:** visits to Health Co. LVP factory, Kwangbok polyclinic, Pyongyang Medicine University & hospital of Kim Il Sung University.
- **8 June:** visits to Hyangsan County Hospital & Taepyeong-ri hospital in North Pyongsan province.
- **9 June:** WHO Country Office
- **11 June:** visits to Maternity hospital, Kangwon Peoples' hospital, Regulatory authority & Medicines store in Kangwon Province
- **12 June:** visits to National Regulatory Authority, Ryongsan-ri hospital
- **13 June:** workshop on National Drug Policy, Pyongyang
- **14 June:** workshop on National Drug Policy, Pyongyang
- **15 June:** WHO Country Office debriefing

Medicines availability

- **Complaints of stock-outs outside Pyongyang**
 - Donors state that they supply about 10 million USD worth of medicines annually but that this is less than half total need
 - Medicines Management Department in MOPH stated that they could not procure all the quantities of medicines requested to meet demand, especially 3rd generation antibiotics, blood thinners & haemostatics
- **No stock-outs observed by consultant, but ...**
 - Few facilities outside Pyongyang visited
 - Limited availability was suggested by:
 - non-use of some medicine categories for commonly occurring illness e.g. gastro-intestinal medicines, ophthalmologic and skin preparations, and
 - very small quantities of all medicines plus some expired drugs seen in every store ...

Medicines supply system

- **Government Procurement**
 - 230 items are purchased quarterly from the State Manufacturer by ordering from the concerned MOPH department & 30-40 items are purchased & imported annually after international tendering
- **Medicines stock control and distribution**
 - Central Medical Warehouse has an electronic inventory system that extends to provincial but not county level or below
 - Local monitoring of consumption is manual & often not done
 - Quantification of drug need is done centrally based upon the average of the last 3 year's consumption plus some adjustment is done using morbidity data & input from province & county hospital directors but the process is unclear
 - Medicines are sent quarterly from central to provincial levels & monthly from county level to health facilities according to a pre-planned allocation done centrally i.e. a push system
 - Health facilities may place emergency orders 2-3 times per year
 - Buffer stock of 4 months at central level & 1 month at province level

Possible solutions for selection

- **Improve the current National EML**
 - Use International Non-Proprietary Names (INN) or generic names for all allopathic medicines
 - Correct all spelling mistakes & dosage forms
 - Print a booklet with an introductory section explaining the process of selection, a contents section, an index & page numbers
- **Improve the updating process of the national EML**
 - Establish a selection committee that is separate from the other committees that are concerned with drug registration, clinical drug trials & drug registration & include clinicians as core members
 - Ensure that the process involves representation from all the provinces & clinical specialties including generalists
 - Establish criteria for selection based on efficacy, safety, quality & staff capacity to use the medicines
- **Separate the lists for allopathic & Koryo medicines**
 - The experts involved & criteria for selection would be different

Possible solutions for supply

- **Government Expenditure on medicines**
 - Increase government expenditure on medicines to at least 2 USD per capita per year
- **Monitor procurement & distribution**
 - Medicines Management Department (with Central Warehouse and Procurement Units) should produce an annual report on procurement & distribution of medicines with an ABC analysis
 - e.g. top 20 drugs by value, % of expenditure on antibiotics, per capita expenditure by province
- **Expand the electronic inventory management system**
 - Expand to county level for better data collection
 - Build local capacity to monitor consumption in order to:
 - contribute to central level quantification of drug need & stock control, and
 - feedback to prescribers in order to improve use

Prescribing

- **Workload**
 - Doctors see about 5-30 patients per day
- **Monitoring**
 - Some review of individual patient treatment by facility directors
 - No standardised routine monitoring of drug consumption or prescription audit
- **Prescribing Information**
 - Standard Treatment Guidelines (STG) & National Formulary were available in all facilities but it is unclear how much doctors use them
 - No National Medicines (Drug) Information Centre or other sources of independent drug information exist
- **Drug and Therapeutic Committees**
 - Health facility directors (or specialist chiefs) run weekly meetings to discuss specific cases but there is no specific committee to monitor medicines use, monitor adverse drug events or undertake training on prescribing & other medicines issues

Medicines selection

- **National Essential Medicines List (EML) 2012**
 - No printed booklet with contents page, index or page numbers
 - All government purchase limited to the national EML
 - Includes 260 drug items & also 60 traditional medicines
- **Selection process**
 - National Drug Regulatory Authority coordinates the process, inviting consultation from the Technical Advisory Committee for drug registration, the Clinical Pharmacology Committee for clinical drug trials & the Pharmacopoeia Committee
 - Draft EML is submitted to the Medicines Management Department for consultation in MOPH & final ratification by the Minister
- **International review of national EML by SEARO**
 - 25 allopathic drug names not recognised
 - Multiple spelling mistakes & missing dosage forms
 - Recommendation to have separate allopathic & Koryo lists
- **Categorisation of use by level of facility**
 - Drugs for province hospital, county hospital, ri-hospital & polyclinic

Dispensing

- **Pharmacist-patient interaction time**
 - often less than 1 minute with no verbal communication & only the drug name (with no dosage) written on the packet
- **Medicines generally transferred from their original packaging to:**
 - small plastic or paper bags to dispense to the patient
 - other storage containers in the dispensary or store with:
 - the name hand-written in Korean but no new expiry dates
 - the old original labels (for different medicines) often remaining
- **Sub-optimal condition of some medicines**
 - tablets were often disintegrating into powder especially in the packets dispensed to patients
 - labelling on ampoules was often faint & unclear
 - Expired medicines were observed in every dispensary & drug store e.g. furosemide, captopril, propranolol, atenolol, quinine, adrenaline, ferrous fumarate, folic acid, chlorhexidine, acyclovir, multivitamin, salbutamol, vitamin A, paracetamol, metronidazole.

Education on Medicines Use

- **Undergraduate Education**
 - 100 hours on pharmacology for medical students over 5.5 years but the amount spent on prescribing is unclear and...
 - 100 hours on drug management for pharmacy student over 5 years, but...
 - Hours of study for part-time students unclear
 - Loose MOPH supervision so curricula & exams may vary slightly across provinces with consequent variation in standards
- **In-service training**
 - 1-2 months training for household doctors & specialists 3 yearly
 - 1 week training on health management yearly for facility directors
 - STGs & EML used but the time spent on prescribing is unclear
- **Public education**
 - No information on nationwide public education campaign on medicines use

Possible solutions for improving use (1): Quality improvement actions

- **Monitor prescribing**
 - Do ABC drug consumption analysis and prescription audit locally
- **Monitor the dispensary**
 - Monitor the expiry date & condition of all medicines & destroy all expired or disintegrated/deteriorated medicines
- **Standard Treatment Guidelines (STGs)**
 - Continue to develop & update STGs, disseminate them to every doctor & incorporate them into pre- & in-service education
- **Drug and Therapeutic Committees (DTC)**
 - Establish DTCs in all province & county hospitals to monitor use, discuss drugs with staff, & report annually on activities to MOPH
 - Could incorporate the current weekly meetings in this process
- **Public Education**
 - Spread core pharmaceutical messages e.g. *does my child need more than 1 drug?* through Household Doctors, schools & the media

Examples of sub-optimal prescribing

- **Hypertension**
 - Captopril and diazepam
- **Lumbago**
 - Paracetamol, multivitamin and zinc
- **Gastritis**
 - Amoxycillin, metronidazole and paracetamol but no antacid or ranitidine
- **Schizophrenia**
 - Chlorpheniramine and diphenhydramine but no major tranquilizer
- **Pyelonephritis**
 - Penicillin, streptomycin and chlorpheniramine but no antibiotic for gram negative bacteria
- **Enterocolitis**
 - Sometimes Furazolidin, sometimes metronidazole, sometimes tetracycline and sometimes oral rehydration solution with Zinc

Possible solutions for improving use (2): Education

- **Undergraduate Medical Education**
 - Standardize training & examination across universities & provinces, including content & time on:
 - clinical pharmacology & prescribing for medical students
 - drug management & monitoring for pharmacy students
 - MOPH should supervise the curricula & examination system for all medical & pharmacy schools in all provinces
 - Part-time students should have compulsory minimum attendance
 - Establish post-graduate studies on clinical pharmacology & clinical pharmacy & encourage these students to analyse drug consumption & do prescription surveys
- **Continuing Medical Education (CME)**
 - Incorporate prescribing & how to do prescription audit & feedback into the curricula of all Medical Re-education Schools
 - Incorporate good dispensing practices into the curricula of all Pharmacy Re-education Schools

Medicines use indicator survey

Drug use indicator	Hospital		Primary Care	
	Pyongyang City n=2	Outside Pyongyang n=3	Ri-hosp (Rural) n=3	Polyclinic (Urban) n=2
Av.no.drugs/patient	2.6	1.8	1.3	1.8
% patients with ABs	51%	18%	31%	48%
% patients with INJs	27%	20%	18%	14%
% patients with VITs	16%	15%	12%	9%
% URTI cases with AB	81%	61%	58%	66%
% Generic drugs	89%	91%	92%	88%
% TM drugs	-	20%	11%	51%

Drug regulation (1)

- **National Drug Regulatory Authority (NDRA)**
 - Has 713 staff to manage a sector consisting of 3000-4000 drug products, 211 factories (all government owned) & 200 People's Drug Stores (1 per county)
 - 113 staff in the centre, 40 staff per province & 1 staff per county
 - Drug Testing Laboratories: 1 at the centre & 1 per province
 - Provincial & local staff inspect government factories & people's drug stores (one each per county) & undertake drug quality testing
- **Drug schedules**
 - There are 2 schedules – over-the-counter & prescription-only
 - Doctors prescribe all medicines dispensed in government facilities
 - Some medicines (not all on the EML) are sold without prescription in the People's Drug Store (staffed by government employees)
 - Some medicines are sold without prescription in hotels for foreigner consumption, but it is not clear if the NDRA inspects these shops

Drug Regulation (2)

- **Drug Registration**
 - Technical Advisory Committee decides on whether products may be registered
 - 13 members, including the Director of the National DRA (Chair), the section chiefs of the DRA, 1 clinician, the Secretary of the Clinical Pharmacology Committee (for clinical trials) and a representative of the Pharmacopoeia Committee
 - Meets 2-3 times per week to decide on about 80 new products per year
 - Drugs from WHO, UNICEF, Global Fund, all registered
 - Registration based on documentation showing Good Manufacturing Practice and quality testing but criteria for judging new molecules is unclear
- **Pharmacovigilance**
 - No functional system yet set up

Possible solutions for policy coordination

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies ...**
- **Strengthen the Medicines Management Department to be the Executive Division in MOPH to carry out the statutory committee recommendations**
 - To coordinate action between all MOPH departments & different Ministries
 - To be responsible for rational use of drugs: EML, STGs, DTCs, monitoring drug use, CME, Drug Info Centre, public education
 - Could liaise with universities to provide students to collect information needed by the MOPH as part of their research studies
 - To develop or update the National Medicines Policy to include an implementation plan & time line & share it in English so that technical support could be provided

Possible solutions for improving regulation

- **Strengthen the National Drug Regulatory Authority**
 - Share the legislation & regulations in English so that technical support may be provided
 - Establish Standard Operating Procedures (SOPs) & guidelines for all procedures
- **Strengthen the drug registration process**
 - Publish the criteria for drug registration & what products have been registered each year
- **Strengthen the drug schedules**
 - Establish a new drug schedule for narcotics
 - Inspect drug sales in hotels & other private outlets
- **Start a unit to undertake pharmaco-vigilance**
 - To monitor Adverse Drug Reactions
- **Strengthen the Drug Testing Laboratories**
 - To test more samples to a higher standard

Group work

- **Each group to draft recommendations with practical steps including:**
 - Prioritize the problems and choose the most important (max 3)
 - For the most important problems
 - What will we do
 - Who will do it
 - Budget needed
 - Time-line
- **Groups**
 - Drug supply and selection
 - Promoting rational drug use
 - Drug regulation and national drug law
 - Drug policy and coordination

Coordination and management

- **Ministry of Public Health (MOPH) Structure:**
 - 20 departments, including the Medicines Management Department, a department for manufacturing allopathic medicines, a department for manufacturing traditional medicines & 17 other departments
 - Medicines Management Department has 12 technical staff who develop drug policy
 - National Drug Regulatory Authority & Central Medical Warehouse are under the Medicines Management Department
 - Drug Management Department in the Institute of Public Health liaises with the Medicines Management Department & is researching required & actual activities for all cadres of health staff
- **Policy Coordination needed to manage medicines well**
 - Can the Medicines Management Department coordinate between all the different departments in MOPH & the different Ministries?
 - Ministries of Education (school & university curricula), Finance (drug budget), Human Resources (posts), Commerce (prices of drug imports), Industry (manufacturers)