Pharmaceutical Management of Antiretroviral Medicines in Guangxi Province, China: Site-Specific Reports of SPS/WHO Visits to Treatment and Distribution Sites, December 1–10, 2008

Helena Walkowiak
Sharri Hollist
Connie Osborne
Lan Zhang

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Strengthening Pharmaceutical Systems
Center for Pharmaceutical Management
Management Sciences for Health
4301 N. Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Phone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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Key Words

antiretroviral therapy, China, Guangxi Province, HIV/AIDS, pharmaceutical management

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Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: sps@msh.org
Web: www.msh.org/sps.org

CONTENTS

ACRONYMS

3TC	lamivudine
AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
AZT	zidovudine
BOH	Bureau of Health [China]
CDC	Center for Disease Control and Prevention [China]
d4T	stavudine
ddI	didanosine
EFV	efavirenz
FEFO	first expiry first out
HIV	human immunodeficiency virus
IDV	indinavir
LPV/r	lopinavir/ritonavir
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NCAIDS	National Center for AIDS/STD Control and Prevention [China]
NVP	nevirapine
PEP	postexposure prophylaxis [of HIV]
PMTCT	prevention of mother-to-child-transmission [of HIV]
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems Program [MSH]
TDF	tenofovir
WHO	World Health Organization

INTRODUCTION

Management Sciences for Health's Strengthening Pharmaceutical Systems (MSH/SPS) Program has received funding from the U.S. Agency for International Development's Regional Development Mission/Asia to provide technical assistance to strengthen pharmaceutical management operations for the HIV program in China. SPS traveled to China from December 1 to 10, 2008, to review pharmaceutical management operations at antiretroviral therapy (ART) treatment and distribution sites in Guangxi Province and to work with stakeholders, including the World Health Organization (WHO), the National Center for AIDS/STD Control and Prevention (NCAIDS) at the national level, and Guangxi Bureau of Health (BOH) and Guangxi Center for Disease Control and Prevention (CDC) managers, to develop an action plan for strengthening the antiretroviral (ARV) pharmaceutical management system in Guangxi Province. The visits were undertaken in collaboration with Guangxi BOH and CDC.

The key findings of the SPS/WHO visits, recommendations, and next steps agreed with stakeholders are presented in a separate technical report.[1] The summaries of the site-specific findings and recommendations are set out in this companion document.

Objectives of Site Visits

The objectives of the visits to ART treatment and distribution sites in Guangxi Province were to—

- Map the flow of ARV medicines through the supply system, including the processes of procurement, quantification, distribution, and dispensing
- Understand the roles and responsibilities of staff at each level in managing medicines for the ART program
- Identify forms, tools, and procedures used for procuring ARV medicines, managing inventories, recording medicine transfers, dispensing, and reporting data
- Solicit feedback on which procedures and tools currently being used are effective in managing ARV medicines and which may need to be strengthened to support program scale-up

[1] Walkowiak, H., S. Hollist, C.Osborne, and L. Zhang. 2009. *Pharmaceutical Management of Antiretroviral Medicines in Guangxi Province, China: Report of SPS/WHO Visits to Treatment and Distribution Sites, December 1–10, 2008.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

Methodology

The SPS/WHO team conducted semi-structured interviews with key informants, observed operations, and reviewed some records to prepare the site-specific reports. In addition, information was drawn from reports given by the CDC and ART site staff at most of the sites visited. The reports typically summarized the status of the ART program and outlined the key challenges related to pharmaceutical management encountered at their sites and suggestions to address these constraints.

The team members for the visits were—

Ms Helena Walkowiak, SPS
Ms Sharri Hollist, SPS
Dr. Zhang Lan, WHO
Dr. Connie Osborne, WHO
Liu Shuaifeng, Division of AIDS Prevention and Control of Guangxi CDC

The schedule for the SPS/WHO team visits follows.

Site	Date of Visit
Heng County CDC	December 3, 2008
Heng County People's Hospital	December 3, 2008
Liuzhou City CDC	December 4, 2008
Liuzhou City CDC ART Treatment Centre	December 4, 2008
Guangxi Zhuang Autonomous Region Longtan Hospital	December 4, 2008
Luzai County CDC	December 5, 2008
Luzai County People's Hospital	December 5, 2008
Guilin City CDC	December 6, 2008
Guilin The Third People's Hospital	December 6, 2008
Guangxi Provincial CDC ART Treatment Centre, Nanning	December 7, 2008
Guangxi Provincial CDC ARV Store	December 7, 2008
Nanning, The Fourth People's Hospital	December 7, 2008

The site-specific reports are organized by geographical regions into five sections—

- Nanning City
  - Guangxi Provincial CDC ARV Store (provincial-level distribution site)
  - Guangxi Provincial CDC ART Treatment Centre (provincial-level ART treatment center)
  - Nanning, The Fourth People's Hospital (city-level ART treatment center)

- Guilin City
  - Guilin City CDC (city-level distribution site)
  - Guilin The Third People's Hospital (city-level ART treatment center)

- Liuzhou City
  - Liuzhou City CDC (city-level distribution site)
  - Liuzhou City CDC ART Treatment Centre (city-level ART treatment center)
  - Guangxi Zhuang Autonomous Region Longtan Hospital (provincial-level ART treatment center)

- Heng County
  - Heng County CDC (county-level distribution site)
  - Heng County People's Hospital (county-level ART treatment center)

- Luzai County
  - Luzai County CDC (county-level distribution site)
  - Luzai County People's Hospital (county-level ART treatment center)

Caveats and Limitations

The information on which this report is based very often came from one source. Because of the limited time available for the visit and for interviews, SPS and WHO staff did not have the opportunity to cross-check information. The purpose of the SPS/WHO team visits was to understand and not to assess the existing forms and systems although the team did solicit input from staff on problems and issues that need to be addressed. As a result, the team observed and inventoried processes used and records kept but did not assess the quality of operations and record keeping.

NANNING CITY

ART Distribution and Treatment Sites Visited

- Guangxi Provincial CDC ARV Store in Nanning: provincial-level distribution site
- Guangxi Provincial CDC ART Treatment Centre: provincial-level ART treatment center
- Nanning, The Fourth People's Hospital: city-level ART treatment center

All three sites were visited on December 7, 2008.

Persons Met

MSH/SPS and WHO would like to thank Guangxi BOH and CDC, especially the staff from the provincial store and the treatment center, and staff from the ART treatment center at Nanning, The Fourth People's Hospital, for their tireless and exceptional cooperation during the visit.

Guangxi Bureau of Health

- Dr. Chen Jie, Director, Division of AIDS Control, Bureau of Health

Guangxi Center for Disease Prevention and Control

- Dr. Liu Wei, Deputy Director of Guangxi CDC
- Dr. Liang Fuxiong, Deputy Director of Division of AIDS Prevention and Control of Guangxi CDC
- Liu Shuaifeng, Pharmacist, Division of AIDS Prevention and Control of Guangxi CDC
- Dr. Tang Zhirong, ARV Treatment Clinic of Division of Guangxi CDC
- Ms Hu Yueying, nurse, ARV Treatment Clinic of Division of Guangxi CDC
- Ms Liang Huanzhu, Pharmacist, Division of AIDS Prevention and Control of Guangxi CDC

Nanning, The Fourth People's Hospital

- Dr. Huang Shaolin, Director of Infectious Disease Department, including HIV/AIDS, The Fourth People's Hospital
- Dr. Lan Jiang, Leader of Party Community, The Fourth People's Hospital
- Dr. Liang Dexiong, Deputy Director, The Fourth People's Hospital

- Dr. Wang Guangcai, Deputy Director of Medical Administrative Department, The Fourth People's Hospital
- Ms Du Liqun, Nurse of Infectious Department, The Fourth People's Hospital
- Ms Zhou Jieliang, Technician, Director of General Office, The Fourth People's Hospital
- Ms Cen Haotao, Pharmacist, Medicine Manager, The Fourth People's Hospital
- Dr. Ban Xionghuan, Manager of Project Office

Key Observations and Findings

Guangxi Provincial CDC ARV Store

Please see the separate technical report[2] for the key findings at Guangxi Provincial CDC ARV Store, including procurement and distribution.

Guangxi Provincial CDC ART Treatment Centre

Topics	Observations/Findings
Status of the ART program	Provincial-level outpatient clinic located at and managed by Guangxi CDC ART program started in July 2003. Number of patients receiving ART— • 500 (approximately) as of December 7, 2008 (information not collected on number on ART at end of December 2007) • Children on ART: 71 • Second-line ART: 30 patients (supplied by Médecins Sans Frontières [MSF]-France)
ARV flow at the ART treatment center	ARVs are requisitioned from the Provincial CDC Store monthly. ARVs are collected, stored, and dispensed by the ART clinic. Stocks are held in one area at the ART clinic.
Availability of ARVs	Stock-outs— • Staff report that no stock-outs or treatment interruptions have occurred. Expired stock— • Some quantities of indinavir (IDV) are reported to have expired.
Policies and guidelines	Written standard operating procedures (SOPs) for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.

[2] Walkowiak, H., S. Hollist, L. Zhang, and C. Osborne. 2008. *Pharmaceutical Management of Antiretroviral Medicines in Guangxi Province, China: Report of SPS/WHO Visits to Treatment and Distribution Sites, December 1–10, 2008.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

Topics	Observations/Findings
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used for adults (10)— zidovudine (AZT) 300 mg tablet; stavudine (d4T) 15 mg capsule d4T 20 mg capsule; lamivudine (3TC) 300 mg tablet nevirapine (NVP) 200 mg tablet; efavirenz (EFV) 600 mg tablet didanosine (ddI) 25 mg tablet; ddI 100 mg tablet lopinavir/ritonavir (LPV/r) 200/50 mg tablet; tenofovir (TDF) 300 mg tablet Products used for children (7)— AZT 10 mg/ml liquid; AZT 100 mg capsule; d4T 1 mg/ml liquid 3TC 10 mg/ml liquid; 3TC 150 mg tablet; NVP 10 mg/ml liquid EFV 50 mg capsule
Storekeeping	Dispensing area— • ARVs are stored in a locked cupboard in an ART clinic room. Space for storage is adequate. • The clinic room is air-conditioned. Temperatures are not routinely monitored and recorded. • The cupboard is tidy and the room appears to be secure. • Products are stored according to expiry date, and staff report that ARVs are issued on a first-expiry, first-out (FEFO) basis.
Forecasting annual needs and order quantities	The doctor at the ART clinic prepares the annual forecast, and the nurse calculates the needs for the monthly order. • The clinic uses a morbidity-based method for annual forecasting. For monthly ordering, the nurse uses a consumption calculation to calculate needs for existing patients and a morbidity-based calculation to estimate needs for new patients. • For the annual forecast, the doctor considers the number of patients currently on ART, regimens used, switches caused by side effects and treatment failure, estimated number of new patients, transfers in and out, and stock on hand. • For the monthly order, the nurse adds up the quantity dispensed of each product in the last month and adds on the requirements for new patients (15 new adult patients per month at time of visit). The assumptions for new adult patients are that 100 percent will start on AZT and 3TC, 20 to 30 percent on EFV, and 70 to 80 percent on NVP. A small number of children start ART each month. • Add a buffer of five patients for both annual forecasts and monthly order quantities. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children Prevention of Mother-To-Child-Transmission of HIV (PMTCT) Free HIV Antiviral Therapy Medicine Use Plan* Constraints and comments reported— • A simple tool would be nice, but the nurse says she can manage the monthly forecast for now. • Experienced some unexpected stock shortages because of switches to

Topics	Observations/Findings
	AZT-based first-line regimens. • Inventory management and dispensing are all managed manually. Software would be very helpful to capture data and transfer information to a quantification tool.
Requisitioning ARVs	Requisition monthly using pull system. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 1 day. Orders are filled in full. No emergency orders placed last year. Nurse collects orders; clinic is next to Provincial Store.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • All boxes are opened for inspection. • Delivery list is endorsed, and one copy is sent back to the Provincial Store.
Record keeping at storage area	ARVs are held only at the dispensing area of the ART clinic.
Inventory control	Buffer stock held: five patients. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed monthly. No discrepancies were reported in the last stock-take performed in November 2008.
Monitoring expiry dates	Staff report that expiry dates are monitored regularly. Can return short-dated stock to the Provincial Store for exchange using *Medicine Withdraw Request Form* if needed.
Internal distribution	ARVs are held only at the dispensing area of the ART clinic.
Prescribing	Most common first-line regimen used is AZT/3TC/NVP. Many patients previously on d4T have switched to AZT. For children, AZT/3TC/NVP is the most commonly used first-line regimen. Very few patients are now taking ddI as part of a first-line regimen. Second-line: 30 patients on second-line. ARVs are supplied by MSF-France. EFV is in short supply so have to switch patients to NVP after complete treatment for tuberculosis. Official prescription form is used.
Dispensing	ARVs are dispensed at the ART clinic by the nurse. Tablet counters are not available. A plate and spoon are used to count ARVs. Packing and labeling: Use plastic resealable bags printed with instructions. Also have new preprinted ARV labels available (the printing error has now been corrected). All ARVs are reportedly labeled before issue. Record keeping— • Make entries into four forms for each dispensing encounter. • Use a “homemade” monthly tally sheet to record issues to patients and to

Topics	Observations/Findings
	calculate monthly consumption. • No inventory records are kept at the ART clinic. • Maintain a longitudinal record for each patient, including ARVs and quantities dispensed. • Use a form to record pill counts and adherence. • Use a form to track appointments. • Computer seen but not used for ARV record keeping. Constraints reported— • Nurse would like software to assist in data collection.
Medication counseling and monitoring adherence	Nurse provides counseling to the patient in the dispensing room in the clinic. Adherence monitoring: pill counts are performed and recorded.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. The clinic submits a report of receipts, issues, balance, and losses using *Medicine Inventory List*. • Monthly report. The clinic reports monthly on the number of patients on treatment, regimens used and losses to follow up using *Adults ARV Monthly Report Form* and *Children ARV Monthly Report Form*. • Requisition report. In addition to needs, the clinic submits information on the number of patients taking each product, current stock on hand and the estimated number of patients expected to be on treatment in the next quarter. • Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Constraints reported— • Inventory management and dispensing are all managed manually and it is easy to make mistakes. Need software to capture data on transactions and issues data at the dispensing point.
Monitoring and supervision	Both national and provincial CDC staff visit the ART treatment clinic quarterly for follow-up monitoring.
Human resources	Staff are currently managing ARVs on a part-time basis and have many other responsibilities. Need simple tools and standardized procedures because staff use their own time to do work. Both staff attended the MSH/WHO training. They would like more training and for it to be more interactive.

Nanning, The Fourth People's Hospital

Topics	Observations/Findings
Status of the ART program	City-level Infectious Diseases Hospital ART program started in February 2005.

Topics	Observations/Findings
	Number of patients receiving ART— • 422 as of December 7, 2008 (350 end of December 2007) • Percentage increase in patients from 2007 to 2008: 21 percent • Children on ART: 0 • Second-line ART: 3 (3–5 patients are waiting for test results)
ARV flow at the ART treatment center	ARVs are requisitioned quarterly from the Provincial CDC Store. Supplies are collected by the hospital. ARVs are delivered to and stored by the pharmacy and dispensed by the nurse at the ART clinic in the Tuberculosis Unit. Stocks are held in two areas at the hospital: the pharmacy and the ART clinic.
Availability of ARVs	Stock-outs— • No stock-outs reported. Expired stock— • Information not collected.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used: information not collected because of time constraints.
Storekeeping	Storage area— • ARVs are stored in two rooms in the pharmacy storeroom. Space for storage is adequate; shelves and pallets are available, and no products were stored on the floor. • The store is air-conditioned. Temperatures are routinely monitored and recorded. • The storage room was observed to be tidy. Dispensing area— • ARVs are stored in a locked cupboard in a room at the ART clinic in the Tuberculosis Unit. Space for storage is adequate. • The pharmacy is not air-conditioned. Information on temperature monitoring not collected. • The cupboard is secure and tidy. • Products are stored according to expiry date.
Forecasting annual needs and order quantities	Process— • Use morbidity-based methods for both annual forecasting and quarterly ordering. • Consider the number of patients currently on ART, regimens used, estimated number of new patients (15 ART patients per month at time of visit) and stock on hand. Estimate that 30 percent of new patients will have tuberculosis. • Add a buffer of 25 to 30 percent for both the annual forecasts and order quantities.

Topics	Observations/Findings
	• Use an Excel spreadsheet to prepare forecasts. • Consumption data are not used to crosscheck estimates. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Suggestions given— • Difficult to forecast accurately for the year. Suggest preparing forecasts twice a year instead.
Requisitioning ARVs	Requisition quarterly using pull system. Recently have had to collect monthly because of shortages at the Provincial Store. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time: information not collected. Orders are generally filled in full. Placed one or two emergency orders in 2008, mostly as a result of regimen changes. Hospital collects supplies.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • Delivery list is endorsed and returned to the Provincial Store. • A *Medicine Warehouse Entry List* is generated each time a delivery is received. Suggest that the receiving forms for adults and children be consolidated.
Record keeping at storage area	No separate inventory records kept. One set of records (kept in the dispensary) used for stock held in both areas (see Dispensing section below).
Inventory control	Buffer stock held: 25 to 30 percent. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed and recorded daily.
Monitoring expiry dates	Information not collected.
Internal distribution	ART clinic staff collect stock two or three times per week as needed. No system in place to track the movement of ARVs from the storage area to the dispensary.
Prescribing	Second-line: 3 patients on second-line and 3–5 patients waiting for viral load results. Official prescription form is used.
Dispensing	ARVs are dispensed at the ART clinic by a nurse. Tablet counters are not available. A spoon is used to count ARVs. Packing and labeling: ARVs are dispensed in resealable plastic bags. All ARVs are reportedly labeled before issue. Record keeping—

Topics	Observations/Findings
	• Use a "homemade" form to record receipts, issues, and stock on hand. Staff request a standard preprinted stock card/book. Form also used to record physical stock-takes. • Maintain a longitudinal record for each patient, including ARVs and quantities dispensed. • Computer available and used to calculate stock on hand.
Medication counseling and monitoring adherence	Nurse gives some basic information (name of ARV and dose) to the patient, who then returns to doctor or peer educator for in-depth counseling. Adherence monitoring: daily pill boxes are used (filled by patient). Pill counts are performed and appointment keeping checked at the pharmacy.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. The clinic submits a report of receipts, issues, balance, and losses using *Medicine Inventory List*. • Monthly report. The clinic reports monthly on the number of patients on treatment, regimens used, and losses to follow-up using *Adults ARV Monthly Report Form*. • Requisition report. In addition to needs, the clinic submits information on the number of patients taking each product, current stock on hand, and the estimated number of patients expected to be on treatment in the next quarter. • Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Constraints reported— • Inventory management and dispensing are all managed manually. Need software to capture data on transactions and issues data at the dispensing point and automatically generate statistics. • Would like the software to link dispensing to the appointment system.
Monitoring and supervision	CDC staff visit the hospital one or two times per year for follow-up monitoring. The BOH visits the pharmacy one or two times a year.
Human resources	Attended the MSH/WHO training in July 2008. Would like more training in ARV pharmaceutical management. Suggest including the clinic doctors and also the nurses who have responsibility for dispensing.

Recommendations

In general, many pharmaceutical management operations appear to be working well. Key recommendations include the following.

- **Policies and guidelines**: At the provincial level, develop and field-test written SOPs for key pharmacy operations, including ordering, forecasting needs, inventory management, dispensing, information management, and reporting. Provide training in pharmaceutical management to support the implementation of tools and SOPs. Identify a few key indicators that can be used to monitor availability and the performance of pharmaceutical

management operations, and based on results, adapt and roll out SOPs across the province.

- **Procurement**: Address the procurement delays at the national level as a priority and identify interim measures at the provincial level to resolve supply shortages. Establish a mechanism for communicating information on delays to the provinces early so that alternative procurement methods such as the provincial bidding process can be launched in good time. Improving and stabilizing the supply of ARVs is a major priority for managers at Guangxi BOH and CDC and staff working in stores and ART treatment sites at all levels. Establish a formal system for monitoring supplier performance.

- **Storekeeping:** Identify additional storage space and pallets or shelving at the Provincial Store. At the local level, introduce procedures and charts for monitoring the temperature in the ART clinic rooms at both ART treatment centers where the ARVs are stored, if not already in place. At Nanning Hospital, monitor the temperature in the clinic room at the hottest part of the day. If temperatures exceed the maximum recommended for ARV products, either air-condition the rooms or relocate the ARVs to an air-conditioned area.

- **Forecasting annual needs and order quantities:** At the provincial level, improve forecasting by strengthening and standardizing methods for analyzing data, developing assumptions, and estimating needs, and by providing tools appropriate to each level and for the number of patients served. Pilot the tools and procedures and support staff with on-the-job training. At the provincial level, establish a working group for forecasting or planning to support the pharmacist tasked with preparing the annual forecasts. The role of this small group could include reviewing the quality of estimates and data submitted by lower levels; assisting in developing assumptions on future prescribing trends, guidelines changes, and scale-up; developing justifications for increased budgets, for example for EFV for the national level; and identifying barriers to forecasting and providing recommendations.

- **Requisitioning ARVs at lower-level stores and treatment centers:** At the local level, work with the provincial CDC to develop a budget and identify funding to cover transportation costs.

- **Inventory management:** At the provincial level, introduce standardized tools for capturing transactions (receipts, issues, losses) and monitoring inventory. At The Fourth People's Hospital, separate record keeping for the ARV storage area in the pharmacy from the clinic stock. Use a double-copy requisition to track movement of ARVs from the ARV storage area to the dispensary. Record both the batch number and expiry date when receiving ARVs, if not currently documented.

- **Dispensing:** Provide tablet counters and appropriate bags (resealable, moisture-proof plastic bags or bottles). Replace labels with errors with correctly printed ARV labels at all ART treatment centers.

- **Medication counseling and monitoring adherence:** At the provincial level, strengthen and standardize medication counseling practices and procedures for monitoring adherence and addressing adherence problems.

- **Pharmaceutical management information system:** At the provincial level, streamline record-keeping and reporting tools to facilitate data collection, analysis, and reporting, and improve information flow between each level. For both ART treatment clinics and other sites with more than 200 patients on ART, software is needed that can process data from dispensing encounters and inventory transactions to generate information for forecasts, order quantities, and reports.

- **Monitoring and supervision:** At the provincial level, develop standardized procedures and a supervision tool for CDC monitoring visits to ART treatment and prevention of mother-to-child transmission (PMTCT) sites.

- **Program management:** At the local level, work with the provincial CDC to develop a budget and identify funding to support ARV pharmaceutical management operations. At the provincial level, provide training in pharmaceutical management and link activities with the implementation of tools and SOPs. At the local level, ensure that all staff dispensing and managing ARVs receive training in pharmaceutical management. Include prescribers involved in pharmaceutical management as appropriate.

GUILIN CITY

ART Distribution and Treatment Sites Visited

- Guilin City CDC: city-level distribution site
- Guilin The Third People's Hospital: city-level ART treatment center

Both sites were visited on December 6, 2008.

Persons Met

MSH/SPS and WHO would like to thank Guilin CDC staff and staff from the ART treatment center and the pharmacy at Guilin The Third People's Hospital for their tireless and exceptional cooperation during the visit.

- Dr. Zhang Zhenkai, Deputy Director of Guilin CDC
- Dr. Chen Wei, Director of HIV/AIDS Department, Guilin CDC
- Dr. Wen Xiaoqing, Deputy Director of HIV/AIDS Department of Guilin CDC
- Dr. Zhou Meirong, HIV/AIDS Department of Guilin CDC
- Dr. Yang Jingyi, Deputy Director, Guilin The Third People's Hospital
- Mr. Qin Jusheng, Pharmacist, Director of Pharmacy Department of Guilin The Third People's Hospital
- Mr. Lee Hui, Deputy Director of Medical Administrative Department of Guilin The Third People's Hospital
- Dr. Wang Haiquan, Director of Internal Medicine Department, Guilin The Third People's Hospital

Key Observations and Findings

Guilin City CDC

Topics	Observations/Findings
ARV flow at the distribution site	ARVs are requisitioned from the Provincial CDC Store. No storage area so ARVs are distributed immediately on receipt. Facilities served (2)— • Guilin, The Third People's Hospital • Guilin Mother and Children Hospital
Availability of ARVs	No stock held—no store.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products distributed (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	No storage area.
Forecasting annual needs and order quantities	Work closely with ART treatment/PMTCT site staff to forecast needs. • Use morbidity-based methods for both annual forecasting and quarterly ordering. • Consider the number of patients currently on ART, regimens used, estimated number of new patients (15–20 ART patients per month at time of visit), and stock on hand. • Add a buffer of 10 percent for both the annual forecasts and order quantities. • Consumption data are not used to cross-check estimates. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Constraints reported— • Developing assumptions about new patients and regimens is problematic. Difficult to estimate how many of the HIV-positive clients who do not yet meet the criteria for ART will need ART in next year. • Lack of training, simple tools (ideally computerized), and standardized procedures for analyzing data and quantifying needs.
Requisitioning ARVs	Requisition quarterly using pull system. For first half of 2008, ordered monthly because of shortages at Provincial Store. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 1–2 days.

Topics	Observations/Findings
	Staff collecting ARVs must stay overnight in Nanning because of distance. Guilin CDC covers transport costs. Constraints reported— • Orders are often not filled in full because of shortages at provincial level. • Transportation costs are significant.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • One or two boxes of each batch are opened to inspect the contents. • Delivery list is endorsed and faxed back to the Provincial Store. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping	No inventory records kept because there is no storage area.
Inventory control	No inventory is held because there is no storage area.
Monitoring expiry dates	No stock held. Guilin CDC returns short-dated stock on behalf of the ART treatment/PMTCT sites to Provincial Store for exchange using *Medicine Withdraw Request Form*.
Distributing ARVs	No storage area. ARVs are distributed immediately on receipt. Both facilities served are in Guilin City and therefore transportation is not a significant cost. Guilin CDC also issues ARVs for postexposure prophylaxis (PEP) of HIV to clients and provides follow-up according to the national PEP guidelines.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. ART treatment/PMTCT sites prepare a report of receipts, issues, balance, and losses every quarter using *Medicine Inventory List*. Guilin CDC forwards the report to the level above. • Monthly report. ART treatment/PMTCT sites report monthly on the number of patients on treatment, regimens used, and losses to follow-up, using *Adults ARV Monthly Report Form* and/or *Children ARV Monthly Report Form*. Guilin CDC forwards the report to the level above. • Requisition report. In addition to needs, Guilin CDC submits information on the number of patients taking each product, current stock on hand, and estimated number of patients expected to be on treatment in the next quarter. Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked.
Monitoring and supervision	CDC and treatment/PMTCT sites cooperate well to avoid wastage of ARVs. No regular supervision, but staff suggest CDC staff visit ART treatment/PMTCT sites for follow-up monitoring.
Human resources	Guilin CDC reports that funding is needed to support pharmaceutical management operations (see Requisitioning ARVs). One person is dedicated for ordering, receiving, and distributing ARVs. Has received some training in pharmaceutical management.

Guilin, The Third People's Hospital

Topics	Observations/Findings
Status of the ART program	City-level Infectious Diseases Hospital ART program started in September 2006. Number of patients is growing rapidly with 15–20 new patients every month. Number of patients receiving ART— • 300 (approximately) as of December 2008 (approximately 110 end of December 2007) • Percentage increase in patients from 2007 to 2008: 173 percent (approximately) • Children on ART: 0 • Second-line ART: 0 • 20 percent of clients are estimated to be injecting drug users.
ARV flow at the ART treatment center	ARVs are requisitioned from the Guilin CDC Store. No storage area at Guilin CDC so ARVs are distributed to the treatment site immediately on receipt from the Provincial Store. ARVs are delivered to, stored by, and dispensed by the pharmacy. Stocks are held in two areas at the pharmacy.
Availability of ARVs	Stock-outs— • Many shortages in 2008 but no treatment interruptions for patients. • Have avoided treatment interruptions through good communication and careful monitoring of ARV stock levels. • Require patients to return monthly and sometimes every 2 weeks instead of quarterly to collect refills, increasing transportation and, in some cases, accommodation costs for the patient. Expired stock— • Information not collected.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition 2008). Products used (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	Storage area— • ARVs are stored in a room near the pharmacy. Space for storage is adequate; pallets are available, and no products were stored on the floor. • The store is air-conditioned. Temperatures are not routinely monitored and recorded. • The storage room was observed to be secure and tidy. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.

Topics	Observations/Findings
	Dispensing area— • ARVs are stored in a locked cupboard in the main dispensary. Space for storage is adequate. • The pharmacy is air-conditioned. Temperatures are not routinely monitored and recorded. • The cupboard is secure and tidy. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	Staff work closely with Guilin CDC staff to forecast needs. See report for Guilin CDC for forecasting process including methodology and constraints reported by staff.
Requisitioning ARVs	Requisition quarterly using pull system. For first half of 2008, ordered monthly because shortages at Provincial Store. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* Lead time is 1–2 days. Guilin CDC sends the entire stock of ARVs immediately on receipt. Constraints reported— • Orders are often not filled in full because of shortages at provincial level. • Shortages of EFV are a particular problem.
Receiving ARVs	Process— • Receiving procedures are completed by Guilin CDC. See report for Guilin CDC.
Record keeping at storage area	No separate inventory records kept. One set of records (kept in the dispensary) used for stock held in both areas (see Dispensing section below).
Inventory control	Buffer stock held: 10 percent. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed monthly.
Monitoring expiry dates	Monitor expiry dates every 6 months. Work with Guilin CDC to return stock to the Provincial Store for exchange using *Medicine Withdraw Request Form* when 4 months of shelf life is left.
Internal distribution	Staff transfer stock as needed. No system in place to track the movement of ARVs from the storage area to the dispensary.
Prescribing	Most common first-line regimen used is AZT/3TC/NVP. Second-line: no patients on second-line yet but have some patients waiting for viral load results. Official prescription form is used. Issue 3 months once patients are stabilized on therapy but because of ARV shortages have required patients to return monthly and sometimes every 2 weeks to collect refills, increasing transportation and sometimes accommodation costs for patients.
Dispensing	ARVs are dispensed at the hospital pharmacy by a pharmacist. Pharmacist checks the prescription with the patient record before dispensing.

Topics	Observations/Findings
	Tablet counters are not available. A spoon is used to count ARVs. Packing and labeling: ARVs are dispensed in a waxed envelope preprinted with a label. Additional labels are available for labeling original packs. All ARVs are reportedly labeled before issue. Record keeping— • Use a "homemade" inventory form to track receipts, issues to patients, and stock on hand; also used to calculate consumption. One set of records is used for both the storage area and dispensary. Pharmacy reports stock on hand to ART clinic weekly. • Maintain a longitudinal record for each patient, including ARVs and quantities dispensed and adherence monitoring (pill counts). • Use a "homemade" form to maintain a daily record of patients seen and ARVs dispensed. • Computer available but not used for ARV record keeping. ARVs are not entered in pharmacy inventory software.
Medication counseling and monitoring adherence	Pharmacists give some basic information (name of ARV and dose) to the patient, who then returns to ART clinic for in-depth counseling. Adherence monitoring: pill counts are performed and recorded at the pharmacy.
Pharmaceutical management information system	Pharmacy staff report consumption and stock on hand to the ART clinic. The ART clinic then reports to Guilin CDC as described in the Guilin CDC section on Pharmaceutical management information system.
Monitoring and supervision	CDC and treatment/PMTCT sites cooperate well to avoid wastage of ARVs. No regular supervision, but staff suggest CDC staff visit the ART treatment clinic and pharmacy for follow-up monitoring.
Human resources	Four pharmacists are available in the hospital pharmacy, and all dispense ARVs. None has had formal training in ARV pharmaceutical management, but they have received some general training in HIV/AIDS organized by the hospital.

Recommendations

In general, many pharmaceutical management operations appear to be working well. Key recommendations include the following.

- **Policies and guidelines**: At the provincial level, develop and field-test written SOPs for key pharmacy operations, including ordering, forecasting needs, inventory management, dispensing, information management, and reporting. Provide training in pharmaceutical management to support the implementation of tools and SOPs.

- **Storekeeping:** At the local level, introduce procedures and charts for monitoring temperatures and expiry dates in the storage area and pharmacy at Guilin The Third People's Hospital.

- **Forecasting annual needs and order quantities:** At the provincial level, improve forecasting by strengthening and standardizing methods for analyzing data, developing assumptions, and estimating needs, and by providing appropriate tools and training.

- **Requisitioning ARVs:** At the provincial and national levels, address the procurement delays to resolve supply shortages and ensure that orders from lower levels are filled in full. At the local level, work with the provincial CDC to develop a budget and identify funding to cover transportation costs.

- **Inventory Management:** At the provincial level, introduce standardized tools for capturing transactions (receipts, issues, losses) and monitoring inventory. At The Third People's Hospital, separate record keeping for the ARV storage area in the pharmacy from the dispensary stock. Use a double-copy requisition to track movement of ARVs from the ARV storage area to the dispensary. Record both the batch number and expiry date when receiving ARVs.

- **Dispensing:** Provide tablet counters and appropriate bags (resealable, moisture-proof plastic bags or bottles), and make printed ARV labels available at all ART treatment sites.

- **Medication counseling and monitoring adherence:** At the provincial level, strengthen and standardize medication counseling practices and procedures for monitoring adherence and addressing adherence problems.

- **Pharmaceutical management information system:** At the provincial level, streamline record-keeping and reporting tools to facilitate data collection, analysis, and reporting, and improve information flow between each level. For The Third People's Hospital and other hospitals with more than 200 patients on ART, software is needed that can process data from dispensing encounters and inventory transactions to generate information for forecasts, order quantities, and reports.

- **Monitoring and supervision:** At the provincial level, develop standardized procedures and a supervision tool for CDC monitoring visits to ART treatment and PMTCT sites.

- **Program management:** At the local level, work with the provincial CDC to develop a budget, and identify funding to support ARV pharmaceutical management operations. At the provincial level, provide training in pharmaceutical management, and link activities with the implementation of tools and SOPs. At the local level, ensure that all pharmacists dispensing and managing ARVs receive training in pharmaceutical management.

LIUZHOU CITY

ART Distribution and Treatment Sites Visited

- Liuzhou City CDC: city-level distribution site
- Liuzhou City CDC ART Treatment Centre: city-level ART treatment center
- Guangxi Zhuang Autonomous Region Longtan Hospital: provincial-level ART treatment center

All three sites were visited on December 4, 2008.

Persons Met

MSH/SPS and WHO would like to thank Liuzhou CDC staff and staff from the ART treatment center at Guangxi Zhuang Autonomous Region Longtan Hospital for their tireless and exceptional cooperation during the visit.

Liuzhou City CDC

- Dr. Gan Zhigao, Professor, Vice Director of Liuzhou CDC
- Dr. Liu Jinji, Director HIV/AIDS Control Department of Liuzhou CDC
- Dr. Feng Weidong, Deputy Director of HIV/AIDS Control Department of Liuzhou CDC
- Dr. Xiao Wenlian, Director of Tuberculosis Control Department of Liuzhou CDC
- Mr. Zheng Yuanjia, ARV drug manager, clinic physician of Liuzhou CDC
- Dr. Zhou Ping, Deputy Director of Tuberculosis Control Department of Liuzhou CDC

Guangxi Zhuang Autonomous Region Longtan Hospital

- Dr. Zhang Baoyu, , Leader of Community Party, responsible for administration
- Dr. Li Yong, Deputy Director and Assist Professor, responsible for HIV/AIDS
- Dr. Lu Ruichao, Director of HIV Care Department, outpatients
- Dr. Meng Zhihao, Director for Internal Department (HIV Department), in charge of inpatients
- Ms He Lichun, Director of Pharmacy Department

- Mr. Liao Jianning, Director of Pharmacy Department
- Mr. Qin Xiongzhi, Pharmacist, in charge of dispensing and management of ARVs
- Ms Huang, Chief Nurse of HIV Department

Key Observations and Findings

Liuzhou City CDC Store

Topics	Observations/Findings
ARV flow at the distribution site	ARVs are requisitioned from the Provincial CDC Store. ARVs are stored at Liuzhou CDC and distributed monthly. Facilities served (4)— • Luzai, Liucheng, and Liujiang county-level CDC stores (3) • Liuzhou City CDC ART Treatment Centre (1)
Availability of ARVs	Stock-outs— • No stock-outs reported. Expired stock— • No reports of expired stock in 2008.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition 2008). Products distributed (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	• ARVs are stored on pallets in a room in the CDC building together with anti-tuberculosis medicines. Storage space is adequate. • The room is not air-conditioned, but they plan to install air-conditioning in the next month. Supplies are protected from sunlight. Temperatures are not routinely monitored and recorded. • The storage room was observed to be secure and tidy. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	ARV drug manager/clinic physician at CDC ART Treatment Centre forecasts needs for both the Liuzhou CDC Store and the treatment center. • Use morbidity-based methods for both annual forecasting and quarterly ordering. • Consider the number of patients currently on ART, regimens used, estimated number of new patients, and stock on hand. • Do not add a buffer for annual forecasts. Add a buffer of 1 month for quarterly order quantities.

Topics	Observations/Findings
	• Consumption data are used to cross-check estimates. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Constraints reported— • Some lower-level stores and ART treatment sites lack the capacity to estimate needs, and Liuzhou CDC prepares estimates for them. Also, staff at ART treatment centers have other responsibilities and lack time for forecasting. • Developing assumptions about new patients is problematic. Liuzhou City CDC has not yet submitted annual forecasts because of difficulties in estimating the rate of scale-up accurately. • Lack of training and simple tools, ideally computerized, but need manual tools too for staff not familiar with computers.
Requisitioning ARVs	Requisition quarterly using pull system. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 1 day if stock is available. Staff need a whole day to collect ARVs because of distance. Liuzhou CDC covers transport costs. Constraints reported— • Orders are often not filled in full because of shortages at provincial level. Two or three emergency orders placed in the last quarter. • Transportation costs are significant, and Liuzhou CDC reports that the budget needs to be increased to cover costs.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • Open boxes to inspect contents only if the boxes are damaged. • Delivery list is endorsed and faxed back to the Provincial Store. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping	Use a “homemade” inventory book to record receipts, issues, and stock on hand. Also record batch number and expiry date. Entries are made at the time stock is received or issued. A computer is available. Data from the manual tool are entered into an Excel spreadsheet and used to generate data on monthly consumption for reporting and forecasting.
Inventory control	Buffer stock held: 1 month. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed monthly. No discrepancies were reported in the last stock-take performed in November 2008.
Monitoring expiry	Monitor expiry dates every 3 months, and maintain a list of short-dated stock in

Topics	Observations/Findings
dates	the computer. Short-dated stock is exchanged for longer-dated stock with Longtan Hospital or returned to the provincial store for exchange using *Medicine Withdraw Request Form.* Lower-level stores can return short-dated stock for exchange.
Distributing ARVs	Three county CDC stores requisition supplies monthly using a pull system. Liuzhou CDC ART Treatment Centre orders supplies as needed. Use forms *Adults HIV Antiretroviral Therapy Medicine Use Plan* and *Children/PMTCT Free HIV Antiviral Therapy Medicine Use Plan* to order ARVs. Orders are reviewed by Liuzhou CDC staff, who contact the facility to check any unusually large orders. ARVs are issued with *Medicine Warehouse Delivery List* form. ARVs are collected and transportation costs are covered by the treatment site or lower-level CDC.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. ART treatment sites and lower level stores prepare a report of receipts, issues, balance, and losses every quarter using *Medicine Inventory List*. Liuzhou CDC forwards the report to the level above. • Monthly report. ART treatment sites and lower-level stores report monthly on the number of patients on treatment, regimens used, and losses to follow-up using *Adults ARV Monthly Report Form* and/or *Children ARV Monthly Report Form*. Liuzhou CDC forwards the report to the level above. • Requisition report. In addition to needs, Liuzhou CDC submits information on the number of patients taking each product, current stock on hand, and estimated number of patients expected to be on treatment in the next quarter. Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Suggestions offered— • CDC staff ask if reports can be e-mailed to the provincial level.
Monitoring and supervision	CDC visits are scheduled annually. Check expiry dates and look at records and balances.
Human resources	One person (ARV drug manager/clinic physician at CDC ART Treatment Centre) is dedicated for ordering, receiving, and distributing/dispensing ARVs for both the CDC store and the treatment center. Has received some training in pharmaceutical management but requests more training.

Liuzhou City CDC ART Treatment Centre

Topics	Observations/Findings
Status of the ART program	City-level outpatient clinic located at and managed by CDC. ART Program started in December 2005. Number of patients receiving ART— • 138 as of December 4, 2008 (approximately 70 at end of December 2007) • Percentage increase in patients from 2007 to December 4, 2008: 97 percent (approximately) • Children on ART: 0 • Second-line ART: 0 (1 patient is waiting for approval to start)
ARV flow at the ART treatment center	ARVs are requisitioned from the Liuzhou CDC Store as needed. ARVs are collected, stored, and dispensed by the ART clinic.. Stocks are held in one area: at the ART clinic.
Availability of ARVs	Stock-outs— • No stock-outs reported. Expired stock— • No reports of expired stock in 2008.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	Dispensing area • ARVs are stored in a locked cupboard in an ART clinic room. Space for storage is adequate. • The clinic room is not air-conditioned. Temperatures are not routinely monitored and recorded. • The cupboard is tidy and the room appears to be secure. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	ARV drug manager/clinic physician at CDC ART Treatment Centre forecasts needs for both the Liuzhou CDC Store and the treatment center. See report for Liuzhou CDC for forecasting process including methodology and constraints reported by staff.
Requisitioning ARVs	ARV drug manager/clinic physician orders ARVs as needed as the CDC store is upstairs. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan*

Topics	Observations/Findings
Receiving ARVs	Process— • ARV drug manager/clinic physician endorses a *Medicine Warehouse Delivery List* form when he collects the ARVs from Liuzhou CDC Store.
Record keeping at storage area	ARVs are held only at the dispensing area of the ART clinic.
Inventory control	Buffer stock held: 1 month. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Information not collected on physical stock-takes.
Monitoring expiry dates	Monitor expiry dates every 3 months, and maintain a list of short-dated stock in the computer. Short-dated stock is exchanged for longer-dated stock with Longtan Hospital or alternatively returned to the provincial store for exchange using *Medicine Withdraw Request Form.*
Internal distribution	ARVs are held only at the dispensing area of the ART clinic.
Prescribing	Most common first-line regimen used is AZT/3TC/NVP. Second-line: no patients on second-line yet; 1 patient is waiting for approval to start. Official prescription form is used. Almost all patients collect ARVs monthly. A few collect refills every 3 months.
Dispensing	ARVs are dispensed at the ART clinic by ARV drug manager/clinic physician. Tablet counters are not available. The cap of the bottle is used to count ARVs. Packing and labeling: Writes instructions on the label of the original pack. All ARVs are reportedly labeled before issue. Record keeping— Makes entries into five forms for each dispensing encounter including a daily record of patients seen and ARVs dispensed and quantities issued. • No inventory records are kept at the ART clinic. Constraints reported— • Difficult to extract data for forecasting from existing dispensing records. Very tedious to count issues/consumption. • No linkage between the patient record keeping system and consumption for forecasting.
Medication counseling and monitoring adherence	ARV drug manager/clinic physician provides counseling to the patient in the counseling area in the clinic. Adherence monitoring: only monitor patients who are identified as having problems with adherence. Check if patient is late for appointment. Liuzhou CDC identified a need for a tool or software to assist in monitoring adherence.
Pharmaceutical management information system	The reports submitted by the ART clinic are described in the Liuzhou CDC section on Pharmaceutical Management Information System.
Monitoring and supervision	CDC visits are scheduled annually.

Topics	Observations/Findings
Human resources	One person (ARV drug manager/clinic physician at CDC ART Treatment Centre) is dedicated for ordering, receiving, and distributing/dispensing ARVs for both the CDC store and the treatment center. He also sees patients and prescribes ARVs. Has received some training in pharmaceutical management but requests more training. Total of four doctors at the clinic. Everyone is very busy.

Guangxi Zhuang Autonomous Region Longtan Hospital

Topics	Observations/Findings
Status of the ART program	Provincial-level Infectious Diseases Hospital ART program started in July 2005. Largest ART treatment center in Guangxi Province. Number of patients receiving ART— • 1,464 as of November 1, 2008 (973 end of December 2007) • Percentage increase in patients from 2007 to 2008: 51 percent by November 1, 2009. • Children on ART: information not collected • Second-line ART: 5 patients
ARV flow at the ART treatment center	ARVs are requisitioned from the Provincial CDC Store monthly because of the shortage of space at the pharmacy store. ARVs are delivered to, stored by, and dispensed by the pharmacy. Stocks are held in two areas at the pharmacy.
Availability of ARVs	Stock-outs— • Frequent shortages earlier in 2008 but less at time of visit. However, staff report that no stock-outs or treatment interruptions for patients have occurred. • Have avoided treatment interruptions through good communication and careful monitoring of ARV stock levels. Expired stock— • Some small amounts reported to have expired.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used for adults (11)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet ddI 25 mg tablet; ddI 100 mg tablet; IDV 200 mg capsule LPV/r 200/50 mg tablet; TDF 300 mg tablet Products used for children (8)— AZT 10 mg/ml liquid; AZT 100 mg capsule; d4T 1 mg/ml liquid

Topics	Observations/Findings
	3TC 10 mg/ml liquid 3TC 150 mg tablet NVP 10 mg/ml liquid EFV 50 mg capsule EFV 200 mg capsule
Storekeeping	Storage area— • ARVs are stored in a room in the "old" pharmacy store together with other medicines. A new store was under construction at the time of the visit, and the pharmacy plans to move to the new store in the next month. There will be a separate room for ARVs. • Space for storage is inadequate; pallets are available, and no products were stored on the floor. • The store is air-conditioned. Staff report that temperatures are regularly monitored and recorded. Not known if the new store will be air-conditioned. • The storage room was observed to be very secure and tidy. • Products were observed to not always be stored according to expiry date, perhaps because of the shortage of space. Staff report that ARVs are issued on a FEFO basis. Dispensing area— • ARVs are stored in a locked cupboard in the main dispensary. Space for storage is adequate. • The pharmacy is air-conditioned. Staff report that temperatures are regularly monitored and recorded, and an updated monitoring chart was seen in the pharmacy. • The cupboard is secure and tidy. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	The pharmacy is responsible for forecasting ARV needs at Longtan Hospital. • One pharmacist and one staff member from the ART clinic collect data at the clinic and prepare a report for the pharmacy. • The pharmacy use morbidity-based methods for both annual forecasting and monthly ordering. • Consider the number of patients currently on ART, regimens used, switches caused by side effects and treatment failure, estimated number of new patients, and stock on hand, including expiry dates. • Add a buffer of 2–3 months for annual forecasts and 1 month for monthly order quantities. • Consumption data are not used to cross-check estimates. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Constraints reported— • Lack of training and simple tools. Ideally, computerized, Excel tool preferred. • Missing or inaccurate data resulting in forecasting inaccuracies. Inventory management and dispensing are all managed manually. With over a thousand patients on ART, it is difficult to count the number of patients on each regimen. Need software to capture data.

Topics	Observations/Findings
	• Need to improve communication between the pharmacy and the clinic. Sometimes doctors change regimens without informing the pharmacy. • Have not submitted an annual forecast for 2009 because submission was "not strongly recommended."
Requisitioning ARVs	Requisition monthly using pull system. Used to order quarterly but now do not have sufficient storage room to hold 3 months' supply. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 1–2 days. Hospital collects ARVs by car. Constraints reported— • Orders are often not filled in full because of shortages at provincial level. Many emergency orders placed in 2008 to date. • Transportation costs are significant. Hospital car not always available.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • Some boxes are opened for inspection. If the box is damaged, then the stores staff inspect the contents. • Delivery list is endorsed, and one copy is sent back to the Provincial Store.
Record keeping at storage area	No manual inventory tools are used. Use the hospital inventory software to track issues, receipts, and stock on hand of ARVs. The software is also used to generate data on monthly consumption for reporting. Batch number and expiry date are also recorded.
Inventory control	Buffer stock held: 1 month. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed monthly.
Monitoring expiry dates	Expiry dates are monitored regularly, and the shelves are labeled to alert the pharmacy staff that the stock is close to expiry. Can return short-dated stock to the Provincial Store for exchange if needed.
Internal distribution	Dispensary staff use internal e-mail to order ARVs daily from the store. Quantities ordered are determined by experience. The Internet request is used to track the movement of stock from the ARV storage area to the dispensary.
Prescribing	Most common first-line regimen used for adults is d4T/3TC/NVP. Very few patients are now taking ddI as part of a first-line regimen. Second-line: 5 patients on second-line. Regimen used LPV/r, ddI, and TDF. Official prescription form is used. ARVs are dispensed at the hospital pharmacy by a pharmacist. Pharmacist checks the prescription with the patient record before dispensing.

Topics	Observations/Findings
	ARVs for inpatients are collected daily. Most outpatients collect ARVs monthly. Tablet counters are not available. The bottle cap is used to count ARVs. Packing and labeling: ARVs are dispensed in a waxed envelope preprinted with a label. Additional labels are available for labeling original packs. Do not use preprinted ARV labels because of a printing error. All ARVs are reportedly labeled before issue. Record keeping— • Keep a patient record book for each patient to maintain a daily record of dates seen and ARVs dispensed and quantities issued. Also track regimens prescribed and regimen changes. • Use a receipts book to track receipts and a record of stock on hand and quantities requisitioned from the store. • Use a consumption record to collect information on daily issues by drug. Prescriptions are used to total the daily issues for each drug and the total in entered in the form used to track consumption for each month. • Computer available but only used to email daily requisition to the pharmacy store. Constraints reported— • All dispensing records are manual. Need software to capture data.
Medication counseling and monitoring adherence	Pharmacists give some basic information (name of ARV and dose) to the patient, who then returns to ART clinic for in-depth counseling. Adherence monitoring: adherence monitoring is performed at the ART clinic.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. Longtan Hospital did not report submitting this report. • Monthly report. Longtan Hospital did not report submitting this report. • Requisition report. In addition to needs, Longtan Hospital submits information on the number of patients taking each product, current stock on hand, and estimated number of patients expected to be on treatment in the next quarter. Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Constraints reported— • Inventory management and dispensing are all managed manually. Need software to capture data and transactions.
Monitoring and supervision	No regular supervision, but CDC staff visit the ART treatment clinic and pharmacy two or three times a year for follow-up monitoring.
Human resources	Staff are currently managing ARVs on a part-time basis and have many other responsibilities. Funding is needed to support pharmaceutical management operations. Staff requested more training in forecasting needs and especially in developing assumptions about future scale-up.

Recommendations

In general, many pharmaceutical management operations appear to be working well. Key recommendations include the following.

- **Policies and guidelines**: At the provincial level, develop and field-test written SOPs for key pharmacy operations including ordering, forecasting needs, inventory management, dispensing, information management, and reporting. Provide training in pharmaceutical management to support the implementation of tools and SOPs.

- **Storekeeping:** At the local level, introduce procedures and charts for monitoring the temperature in the Liuzhou CDC ARV Store and the CDC ART clinic room where the ARVs are stored. Monitor the temperature at the hottest part of the day. If temperatures exceed the maximum recommended for ARV products, either air-condition the rooms or relocate the ARVs to an air-conditioned area. At Longtan Hospital, ensure that the ARVs are moved to a store that is air-conditioned and with adequate space to allow ordering for three months at a time, as needed.

- **Forecasting annual needs and order quantities:** At the provincial level, improve forecasting by strengthening and standardizing methods for analyzing data, developing assumptions, and estimating needs, and by providing appropriate tools and training. At Longtan Hospital, consider involving one or two physicians from the ART clinic in the forecasting process. Prescribers can assist in developing assumptions on prescribing trends and rate of scale-up. Also, they will be better informed and able to communicate issues that affect forecasting to their colleagues, for example, to encourage other prescribers to inform the pharmacy about changes in prescribing trends, including regimen switches.

- **Requisitioning ARVs:** At the provincial and national levels, address the procurement delays to resolve supply shortages and ensure that orders from lower levels are filled in full. At the local level, work with the provincial CDC to develop a budget and identify funding to cover transportation costs.

- **Inventory management:** At the provincial level, introduce standardized tools for capturing transactions (receipts, issues, losses) and monitoring inventory.

- **Dispensing:** Provide tablet counters and appropriate bags (resealable, moisture-proof plastic bags or bottles). Replace labels with errors with correctly printed ARV labels at all ART treatment centers.

- **Medication counseling and monitoring adherence:** At the provincial level, strengthen and standardize medication counseling practices and procedures for monitoring adherence and addressing adherence problems.

- **Pharmaceutical management information system:** At the provincial level, streamline record-keeping and reporting tools to facilitate data collection, analysis, and reporting, and improve information flow between each level. For Longtan Hospital and other

hospitals with more than 200 patients on ART, software is needed that can process data from dispensing encounters and inventory transactions to generate information for forecasts, order quantities, and reports.

- **Monitoring and supervision:** At the provincial level, develop standardized procedures and a supervision tool for CDC monitoring visits to ART treatment and PMTCT sites.

- **Program management:** At the local level, work with the provincial CDC to develop a budget and identify funding to support ARV pharmaceutical management operations. At the provincial level, provide training in pharmaceutical management and link activities with the implementation of tools and SOPs. At the local level, ensure that all pharmacists dispensing and managing ARVs receive training in pharmaceutical management. Include prescribers involved in estimating needs in training on forecasting.

HENG COUNTY

ART Distribution and Treatment Sites Visited

- Heng County CDC: county-level distribution site
- Heng County People's Hospital: county-level ART treatment center

Both sites were visited on December 3, 2008.

Persons Met

MSH/SPS and WHO would like to thank Heng CDC staff and staff from the ART treatment center at Heng County People's Hospital for their tireless and exceptional cooperation during the visit.

- Dr. Lu Chanjian, Vice Director of Heng CDC
- Dr. Ma Guanghui, Director HIV/AIDS Department of Heng CDC
- Mr. Lu Wei, Medicine Manager of Heng CDC
- Ms Deng Fuqiu, nurse at ART clinic of Heng County People's Hospital
- Dr. Liang Feili, Director of Internal Medicine Department, chief doctor at ART clinic of Heng County People's Hospital
- Mr. Su Yisheng, Director of Medical Administrative Department, in charge of ARV procurement, Heng County People's Hospital

Key Observations and Findings

Heng County CDC

Topics	Observations/Findings
ARV flow at the distribution site	ARVs are requisitioned from Nanning City CDC Store. ARVs are stored at Heng CDC and distributed as needed. Facilities served (1)— • Heng County People's Hospital
Availability of ARVs	Stock-outs— • No stock-outs reported, but EFV was in short supply once in 2008. No treatment interruptions for patients have occurred. Expired stock—

Topics	Observations/Findings
	• No stock expired in 2008.
Policies and guidelines	Written SOPs for ART program not developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products distributed (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	• ARVs are stored in lockable cupboards in a room in the CDC building. Storage space is adequate. • The room is air-conditioned. Information not collected on temperature monitoring practices. • The cupboard is tidy, and products are organized according to expiry date. Staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	Work closely with Heng County People's Hospital staff to forecast needs. • Use consumption-based calculation to estimate needs for existing patients and a morbidity-based calculation to estimate needs for new patients. • For each product, the highest monthly consumption in the last 3 months recorded in the CDC store inventory records is multiplied by 12 to estimate needs for the annual forecast and by 3 to estimate quarterly procurement quantities. Estimated needs for new patients are added. • Work with ART clinic staff to develop assumptions for new patients. • Stock on hand is not deducted and no additional buffer is added. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Constraints reported— • A tool would be helpful but needs to be simple. • Need software that captures consumption data and also links to the patient reporting system.
Requisitioning ARVs	Requisition quarterly using pull system from Nanning City CDC Store. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 2–7 days. Heng CDC covers transport costs. Constraints reported— • Orders are often not filled in full. One emergency order placed in 2008 to date.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent

Topics	Observations/Findings
	with supplies. • Delivery list is endorsed and one copy is sent back with the driver to Nanning City CDC Store. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping	Use a "homemade" inventory book to record receipts, issues, and stock on hand. Also record batch number and expiry date. Entries are made at the time stock is received or issued. A computer is available. Data from the manual tool are entered into an Excel spreadsheet and used to generate data on monthly consumption for reporting and forecasting.
Inventory control	Buffer stock held: generated by using the highest monthly consumption to estimate order quantities. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed every 2–3 months. No discrepancies were reported in the last stock-take performed in November 2008.
Monitoring expiry dates	Information not collected.
Distributing ARVs	The nurse at the ART Clinic at Heng County People's Hospital orders supplies by telephone as needed (approximately every 20 days). No formal requisition is used. Nurse endorses a *Medicine Warehouse Delivery List* form when she collects the ARVs from Heng CDC.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. Heng CDC did not report submitting this quarterly report of receipts, issues, balance, and losses. • Monthly report. Heng CDC works with the ART clinic to prepare a monthly report on the number of patients on treatment, regimens used, and losses to follow-up using *Adults ARV Monthly Report Form* and *Children ARV Monthly Report Form*. Heng CDC forwards the reports to the city level. • Requisition report. In addition to needs, Heng CDC submits information on the number of patients taking each product, current stock on hand, and estimated number of patients expected to be on treatment in the next quarter. Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Constraints reported— • CDC and hospital staff report that there are "too many reports."
Monitoring and supervision	No regular supervision.
Human resources	No information collected

Heng County People's Hospital

Topics	Observations/Findings
Status of the ART program	County-level hospital. ART program started in September 2005. Number of patients is growing rapidly. Number of patients receiving ART— • 147 as of December 3, 2008 (approximately 40–50 at end of December 2007) • Percentage increase in patients from 2007 to December 3, 2008: 227 percent (approximately) • Children on ART: 0 • Second-line ART: 0 (3–5 patients are waiting to start when second-line ARVs become available)
ARV flow at the ART treatment center	ARVs are requisitioned from the Heng CDC Store as needed (approximately every 20 days). ARVs are delivered to, stored by, and dispensed by the ART clinic. Stocks are held in one area: at the ART clinic.
Availability of ARVs	Stock-outs— • No stock-outs, but EFV was in short supply once in 2008. No treatment interruptions for patients have occurred. Expired stock— • No stock expired in 2008.
Policies and guidelines	Written SOPs for ART program not developed. ART clinic request SOPs. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	Dispensing area— • ARVs are stored in a locked cupboard in the ART clinic dispensing room. Space for storage is adequate. • The clinic room is air-conditioned. Information not collected on temperature monitoring practices. • The cupboard is tidy and the room is secure. • Products are stored according to expiry date.
Forecasting annual needs and order quantities	Staff work closely with Heng CDC staff to forecast needs. See report for Heng CDC for forecasting process including methodology and constraints reported by staff.
Requisitioning ARVs	The nurse at the ART Clinic at Heng County People's Hospital orders supplies by telephone as needed (approximately every 20 days). No requisition form is completed.

Topics	Observations/Findings
Receiving ARVs	Process— • Nurse endorses a *Medicine Warehouse Delivery List* form when she collects the ARVs from Heng CDC. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping at storage area	ARVs are held only at the dispensing area.
Inventory control	Buffer stock held: generated by using the highest monthly consumption to estimate order quantities. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed every month.
Monitoring expiry dates	Information not collected.
Internal distribution	ARVs are held only at the dispensing area.
Prescribing	Most common first-line regimen used is d4T/3TC/NVP. Second-line: no patients on second-line as yet; 3–5 patients are waiting for second-line ARVs to be made available. Official prescription form is used. Two-thirds of patients collect ARVs monthly, and one third collect refills every 2–3 months.
Dispensing	ARVs are dispensed at the ART clinic by a nurse. Tablet counters are not available. A plate is used to count ARVs. Packing and labeling: Preprinted ARV labels are used to label dispensed medicines. Printing error on labels is corrected by hand. All ARVs are reportedly labeled before issue. Record keeping— • Use a “homemade” form to maintain a daily record of patients seen and ARVs dispensed and quantities issued. Consumption for each product is calculated by adding up the issues for each product every 2–3 months. • No inventory records are kept at the ART clinic. • Maintain a longitudinal record for each patient including ARVs and quantities dispensed. • Use a form to track appointments. • Computer available but not used for ARV record keeping. Constraints reported: “Too many forms.”
Medication counseling and monitoring adherence	Nurse provides counseling to the patient in the dispensing room in the clinic. Adherence monitoring: self reports on adherence are recorded at the clinic.
Pharmaceutical management information system	The reports submitted by the ART clinic are described in the Heng CDC section on Pharmaceutical Management Information System.
Monitoring and supervision	No regular supervision.
Human resources	No information collected

Recommendations

In general, many pharmaceutical management operations appear to be working well. Key recommendations include the following.

- **Policies and guidelines**: At the provincial level, develop and field-test written SOPs for key pharmacy operations, including ordering, forecasting needs, inventory management, dispensing, information management, and reporting. Provide training in pharmaceutical management to support the implementation of tools and SOPs.

- **Storekeeping:** At the local level, introduce procedures and charts for monitoring temperatures and expiry dates in the storage area at Heng CDC and the dispensing room at Heng County People's Hospital, if not already in place.

- **Forecasting annual needs and order quantities:** At the provincial level, improve forecasting by strengthening and standardizing methods for analyzing data, developing assumptions, and estimating needs, and by providing appropriate tools and training.

- **Requisitioning ARVs:** At the provincial and national levels, address the procurement delays to resolve supply shortages and ensure that orders from lower levels are filled in full. At Heng County People's Hospital, use an official requisition to order stock from Heng CDC Store.

- **Inventory management.** At Heng County People's Hospital, introduce inventory records (e.g., bin cards or stock cards) to track issues, receipts, and stock on hand at the ART clinic. Record both the batch number and expiry date when receiving ARVs. Perform and record results of regular physical stock-takes.

- **Dispensing:** Make a tablet counter available at the ART clinic and appropriate bags (resealable, moisture-proof plastic bags or bottles). Replace labels with errors with correctly printed ARV labels at all ART treatment sites.

- **Medication counseling and monitoring adherence:** At the provincial level, strengthen and standardize medication counseling practices and procedures for monitoring adherence and addressing adherence problems.

- **Pharmaceutical management information system:** At the provincial level, streamline record keeping and reporting tools to facilitate data collection, analysis, and reporting, and improve information flow between each level. For Heng County People's Hospital, a software will be needed that can process data from dispensing encounters and inventory transactions to generate information for forecasts, order quantities, and reports once the clinic is dispensing ARVs to more than 200 patients.

- **Monitoring and supervision:** At the provincial level, develop standardized procedures and a supervision tool for CDC monitoring visits to ART treatment and PMTCT sites.

- **Program management:** At the provincial level, provide training in pharmaceutical management and link activities with the implementation of tools and SOPs. At the local level, ensure that all staff dispensing and managing ARVs receive training in pharmaceutical management.

LUZAI COUNTY

ART Distribution and Treatment Sites Visited

- Luzai County CDC: county-level distribution site
- Luzai County People's Hospital: county-level ART treatment center

Both sites were visited on December 5, 2008.

Persons Met

MSH/SPS and WHO would like to thank Luzai CDC staff and staff from the ART treatment center and the pharmacy at Luzai County People's Hospital for their tireless and exceptional cooperation during the visit.

- Dr. Qin Guiguan, Deputy Director of Luzai BOH
- Ms Qin Huiqun, Director of Division for Disease Control of Luzai BOH
- Dr. Fu Botao, Director of Luzai CDC
- Dr. Chen Xianjun, Deputy Director of Luzai CDC
- Dr. Yang Li, Director of Epidemiology Division of Luzai CDC
- Dr. Peng Wanfen, Epidemiology Division of Luzai CDC
- Dr. Qin Zhibin, Deputy Director of Luzai People's Hospital
- Dr. Luping, Director of Internal Medicine Department of Luzai People's Hospital
- Dr. Qin Daling, ARV Clinic for outpatients of Luzai People's Hospital
- Ms Wu Gezhen, Nurse of ARV Clinic for outpatients of Luzai People's Hospital
- Ms Liu Chengwen, Nurse of ARV Clinic for outpatients of Luzai People's Hospital

Key Observations and Findings

Luzai County CDC

Topics	Observations/Findings
ARV flow at the distribution site	ARVs are requisitioned from Liuzhou City CDC Store. No storage area so ARVs are distributed immediately on receipt. Facilities served (2)— • Luzai County People's Hospital • Luzai Mother and Children Hospital
Availability of ARVs	No stock held because there is no store.
Policies and guidelines	Written SOPs for ART program not developed. CDC staff requested that SOPs be developed. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products distributed (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	No storage area.
Forecasting annual needs and order quantities	ART treatment/PMTCT site staff prepare plans for both annual forecasts and quarterly orders, and CDC collates estimates and forwards to city CDC. See Forecasting section of report on Luzai County People's Hospital for information on methodology by the ART treatment center. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Constraints reported— • Developing assumptions is problematic. Because of the recent changes in national ART guidelines, prescribing practices are changing. Prepared annual forecast for 2008 based on first edition of guidelines, and now different regimens are in use. • A tool is needed to help staff estimate needs. Methodology needs to be simplified because staff have many other responsibilities and lack time for ARV pharmaceutical management activities.
Requisitioning ARVs	Requisition quarterly using pull system from Liuzhou City CDC Store. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* • *Children PMTCT Free HIV Antiviral Therapy Medicine Use Plan* Lead time is 2–3 days. Luzai CDC covers transport costs which are significant. Constraints reported— • Orders are often not filled in full (especially EFV, AZT, and 3TC) because of shortages at provincial level. As a result, six emergency orders have

Topics	Observations/Findings
	been placed in 2008 so far. • Transportation costs are significant. Luzai CDC suggests exploring the option of contracting transportation out to a logistics agency.
Receiving ARVs	Process— • Order is cross-checked with *Medicine Warehouse Delivery List* form sent with supplies. • Delivery list is endorsed and sent back to the Liuzhou City Store. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping	No inventory records kept because there is no storage area.
Inventory control	No inventory is held because there is no storage area.
Monitoring expiry dates	No stock held.
Distributing ARVs	No storage area. ARVs are distributed immediately on receipt. Both facilities served are nearby, so transportation is not a significant cost.
Pharmaceutical management information system	Pharmaceutical management reports produced on a regular basis— • Annual forecast or plan (see Forecasting section). • Medicine inventory report. ART treatment/PMTCT sites prepare a report of receipts, issues, balance, and losses every quarter using *Medicine Inventory List*. Luzai CDC forwards the report to the level above. • Monthly report. ART treatment/PMTCT sites report monthly on the number of patients on treatment, regimens used, and losses to follow-up using *Adults ARV Monthly Report Form* and/or *Children ARV Monthly Report Form*. Luzai CDC forwards the report to the level above. • Requisition report. In addition to needs, Luzai CDC submits information on the number of patients taking each product, current stock on hand, and estimated number of patients expected to be on treatment in the next quarter. Indicators to monitor ARV availability and performance of pharmaceutical management operations are not routinely calculated or tracked. Constraints reported— • CDC and hospital staff request that reporting be simplified.
Monitoring and supervision	CDC visits are scheduled monthly.
Human resources	CDC staff member responsible for managing ARVs received training in pharmaceutical management at MSH/WHO workshop in June 2008.

Luzai County People's Hospital

Topics	Observations/Findings
Status of the ART program	County-level hospital. ART program started in May 2006. Number of patients is growing rapidly. Number of patients receiving ART—

Topics	Observations/Findings
	• 260 as of December 5, 2008 (79 end of December 2007) • Percentage increase in patients from 2007 to December 5, 2008: 229 percent • Children on ART: 0 • Second-line ART: 0 • Approximately one-third of clients are estimated to be injecting drug users.
ARV flow at the ART treatment center	ARVs are requisitioned from the Luzai CDC Store. No storage area at Luzai CDC so ARVs are distributed to the treatment center immediately on receipt from the Liuzhou City CDC Store. ARVs are delivered to the pharmacy and dispensed at the ART clinic. Stocks are held in two areas: at the pharmacy and the ART clinic.
Availability of ARVs	Stock-outs— • Had no shortages in 2007 but 3–4 shortages lasting 1–2 days in 2008. No treatment interruptions for patients have occurred. • Have avoided treatment interruptions through good communication and careful monitoring of ARV stock levels. • Issued 2-week supply to patients when stocks were low. • Most shortages because of EFV. Receive EFV sufficient for only 20 percent of patients, but requirements are much higher. Expired stock— • Some ddI expired. Most patients who were taking ddI as first-line ART have now been switched to alternative regimens.
Policies and guidelines	Written SOPs for ART program not developed. ART clinic staff request SOPs. *Guangxi ARV Drug Management Protocol* forms used for operations and reporting.
Selection	ARV products and regimens used in line with *National China Free ARV Treatment Manual* (2nd edition, 2008). Products used (6)— AZT 300 mg tablet; d4T 15 mg capsule; d4T 20 mg capsule 3TC 300 mg tablet; NVP 200 mg tablet; EFV 600 mg tablet
Storekeeping	Storage area— • ARVs are stored in the general pharmacy store with other medicines. Space for storage is adequate; adequate shelving available, and no products were stored on the floor. • The store is not air-conditioned. Temperatures are not routinely monitored and recorded. • The storeroom was observed to be secure and tidy. • Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis. Dispensing area— • ARVs are stored in a locked cupboard in the ART clinic room. Space for storage is adequate. Staff expressed concerns about the security of this arrangement.

Topics	Observations/Findings
	• The clinic room is air-conditioned. Staff report that temperatures are regularly monitored and recorded. • The cupboard is tidy. Products are stored according to expiry date, and staff report that ARVs are issued on a FEFO basis.
Forecasting annual needs and order quantities	Nurse at the ART clinic is responsible for forecasting annual needs and order quantities. • Uses morbidity-based methods for both annual forecasting and quarterly ordering. • Considers the number of patients currently on ART, regimens used, estimated number of new patients, and stock on hand. • Adds a buffer of 10 percent for both the annual forecasts and order quantities. • Consumption data are not used to cross-check estimates. Annual forecasts are submitted using— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* Constraints reported— • Developing assumptions on the number of new patients and regimens is problematic. The number of new patients is constantly more than expected, and there have been many regimen switches in 2008 in line with new national guidelines. • The nurse requests a simple tool (uses manual methods now) and a standardized method to calculate needs.
Requisitioning ARVs	Requisition quarterly using pull system. Forms used to order ARVs— • *Adults HIV Antiretroviral Therapy Medicine Use Plan* Lead time is 2–3 days from when CDC order. Luzai CDC notifies ART clinic when ARVs arrive. ART clinic collects all the stock ordered for the quarter. Constraints reported— • Orders are often not filled in full because of shortages at provincial level.
Receiving ARVs	Process— • Nurse at ART clinic crosschecks the order with *Medicine Warehouse Delivery List* form sent with supplies. • Expiry date and batch numbers are checked. • Delivery list is endorsed and returned to Luzai CDC. • A *Medicine Warehouse Entry List* is generated each time a delivery is received.
Record keeping at storage area	No inventory records are maintained at the pharmacy store.
Inventory control	Buffer stock held: 10 percent. Do not use reorder or minimum order levels to trigger resupply, but staff report that stock-outs are rare and that no treatment interruptions have occurred. Staff report that physical stock-takes are performed monthly.
Monitoring expiry dates	Expiry dates are monitored in the pharmacy storeroom. Stock with less than 3 months to expiry is recorded on a chart on the wall of the pharmacy storeroom.

Topics	Observations/Findings
	It is not clear if expiry dates are monitored at the ART clinic.
Internal distribution	ART clinic staff collect ARVs from pharmacy storeroom as needed. No system in place to track the movement of ARVs from the pharmacy storeroom to the ART clinic.
Prescribing	Most common first-line regimen used is AZT/3TC/NVP. Second-line: no patients on second-line yet. Official prescription form is used.
Dispensing	ARVs are dispensed at the ART clinic by a nurse. Nurse checks the prescription with the patient record before dispensing. Tablet counters are not available. A spoon is used to count ARVs. Packing and labeling: ARVs are dispensed in resealable plastic bags. Preprinted ARV labels are used to label dispensed medicines. Printing error on labels is corrected by hand. All ARVs are reportedly labeled before issue. Record keeping— • Use a "homemade" daily tally sheet to record issues to patients and to calculate monthly consumption. • No inventory records are kept at either the pharmacy or the ART clinic. • Maintain a longitudinal record for each patient including ARVs and quantities dispensed. • Use a form to monitor and report on patient adherence. • Computer available but not used for ARV record keeping. The computer is only used to enter data into standard reports. Constraints reported: "Too many forms."
Medication counseling and monitoring adherence	Nurse provides in-depth counseling, including information on side effects, to the patient in the counseling area in the clinic. Adherence monitoring: pill counts are performed and recorded at the clinic. However, the staff report that adherence monitoring needs to be strengthened.
Pharmaceutical management information system	The reports submitted by the ART clinic are described in the Luzai CDC section on Pharmaceutical Management Information System.
Monitoring and supervision	CDC staff visit the ART treatment center quarterly for follow-up monitoring.
Human resources	Staff trained in ARV pharmaceutical management have since been transferred. Nurses now responsible for managing and dispensing ARVs have not had any formal training in ARV pharmaceutical management.

Recommendations

In general, many pharmaceutical management operations appear to be working well. Key recommendations include the following.

- **Policies and guidelines**: At the provincial level, develop and field-test written SOPs for key pharmacy operations including ordering, forecasting needs, inventory management,

dispensing, information management, and reporting. Provide training in pharmaceutical management to support the implementation of tools and SOPs.

- **Storekeeping:** At the local level, introduce procedures and charts for monitoring the temperature in the pharmacy storeroom at Luzai County People's Hospital. Monitor the temperature at the hottest part of the day. If temperatures exceed the maximum recommended for ARV products, either air-condition the storeroom or relocate the ARVs to an air-conditioned area. At the ART clinic, improve the security of the clinic room to safeguard the ARVs held there. Introduce a system for monitoring expiry dates at the ART clinic if not already in place.

- **Forecasting annual needs and order quantities:** At the provincial level, improve forecasting by strengthening and standardizing methods for analyzing data, developing assumptions, and estimating needs, and by providing appropriate tools and training. At the local level, ART prescribers can assist the nurse at the ART clinic in developing assumptions on prescribing trends and rate of scale up if this is not already happening.

- **Requisitioning ARVs:** At the provincial and national levels, address the procurement delays to resolve supply shortages and ensure that orders from lower levels are filled in full. Explore the option of contracting out transportation to a logistics agency. At the local level, work with the provincial CDC to develop a budget and identify funding to cover transportation costs.

- **Inventory management:** At the provincial level, introduce standardized tools for capturing transactions (receipts, issues, losses) and monitoring inventory. At Luzai County People's Hospital, introduce inventory records (e.g., bin cards or stock cards) to track issues, receipts, and stock on hand at both the pharmacy storeroom and the ART clinic area. Use a double-copy requisition to track movement of ARVs from the pharmacy storeroom to the ART clinic. Record both the batch number and expiry date when receiving ARVs.

- **Dispensing:** Make a tablet counter available at the ART clinic. Replace labels with errors with correctly printed ARV labels at all ART treatment sites.

- **Medication counseling and monitoring adherence:** At the provincial level, strengthen and standardize medication counseling practices and procedures for monitoring adherence and addressing adherence problems.

- **Pharmaceutical management information system:** At the provincial level, streamline record keeping and reporting tools to facilitate data collection, analysis, and reporting, and improve information flow between each level. For Luzai County People's Hospital and other hospitals with more than 200 patients on ART, software is needed that can process data from dispensing encounters and inventory transactions to generate information for forecasts, order quantities, and reports.

- **Monitoring and supervision:** At the provincial level, develop standardized procedures and a supervision tool for CDC monitoring visits to ART treatment and PMTCT sites.

- **Program management:** At the local level, work with the provincial CDC to develop a budget and identify funding to support ARV pharmaceutical management operations. At the provincial level, provide training in pharmaceutical management and link activities with the implementation of tools and SOPs. At the local level, ensure that all nurses dispensing and managing ARVs receive training in pharmaceutical management.