

World Bank Training Program Managing Procurement and Logistics of HIV/AIDS Drugs and Related Supplies

Supply Chain Management

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Organization of Module

- Introduction to supply chain management and logistics
- Considerations in HIV/AIDS Supply Chain Management
- Inventory Management
 - Storage
 - Distribution
 - Inventory Control
- LMIS
- ARV Commodity Security
- Participant Country ARV Supply Chains



Learning Objectives

- To understand key concepts of SCM
- To understand the critical issues in SCM of HIV/AIDS commodities
- To appreciate the relevance of storage and distribution in HIV/AIDS programs
- To understand the key issues in and how to design inventory control systems for HIV/AIDS supply chains
- To understand the importance of LMIS in HIV/AIDS programs
- To share country experiences in SCM of HIV/AIDS commodities



SCM Problems

- Supply interruptions are a classical problem in all public health programs
- Stock outs and expirations are common in all public health programs
- There is critical need to predict and carefully manage potential supply chain interruptions
- There is a multiplicity of causes of supply chain interruptions



What is Supply Chain Management?

- No consensus on what supply chain or SCM is
- 1985, Jones and Riley introduced SCM as a tool to manage inventory for gaining competitive advantage
- Many definitions, theories and models proposed
- Supply Chain = linkages of organizations, people, procedures and systems involved in getting products to customers
- SCM is the management of the entire set of business processes that produces and delivers products/services to the final customer

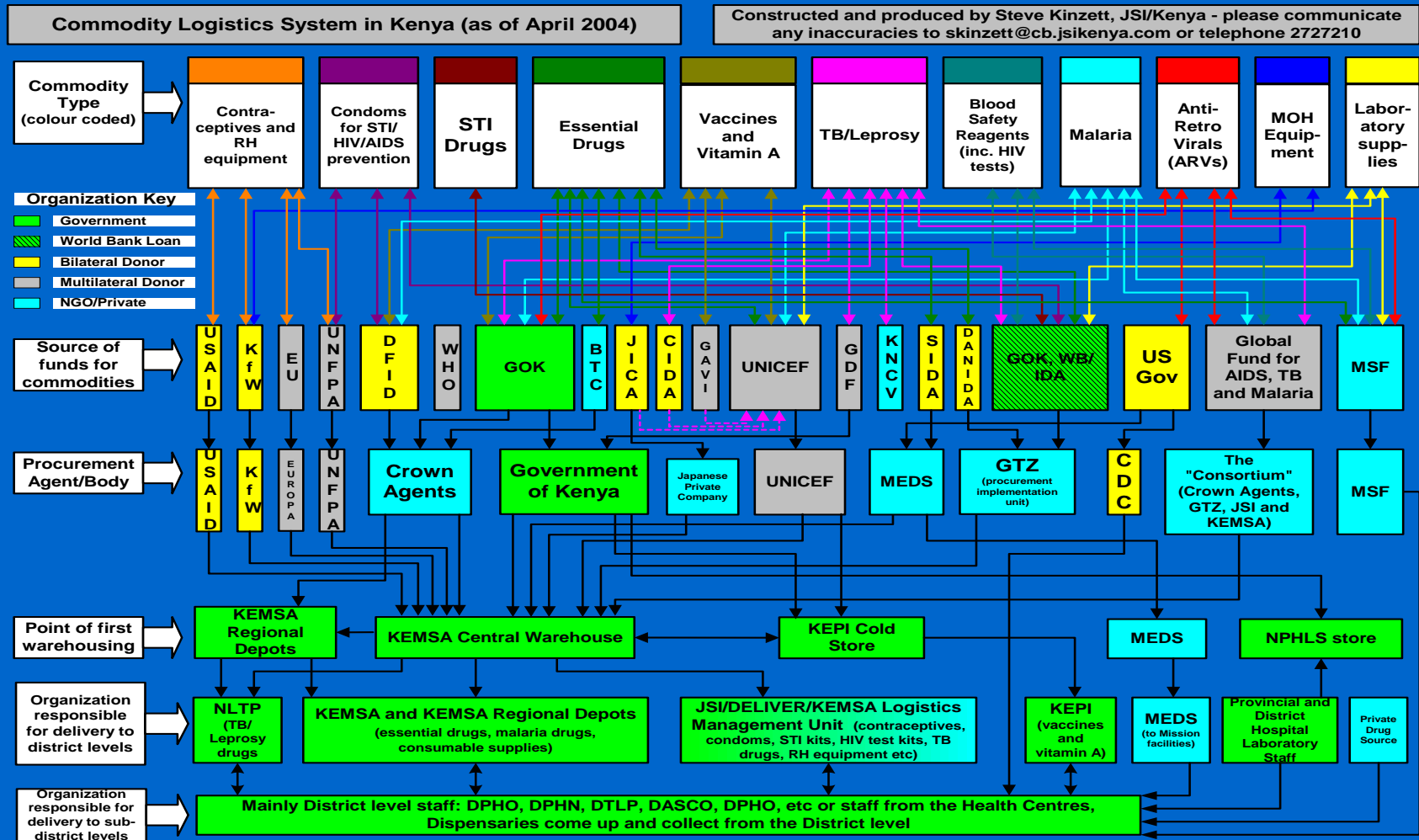


What is a Supply Chain?

- Supplier of raw materials
- Manufacturer
- Central Decision Makers and Funders
- Central Medical Stores
- Warehouses
- Regional stores
- SDP
- Clients



Supply chains in health are complex



Source – John Snow Inc.

Logistics

- Changed rapidly during past 40 years
- In 1960s logistics was synonymous with physical distribution
- In 1970s German business administration professors introduced the concept of “Betriebswirtschaftliche Logistik” defining logistics as integrated management of the flow of goods and related information



Setting Scene For Effective SCM

- Enabling environment
- Coordination
- Planning framework
- Financial resources
- Human resources

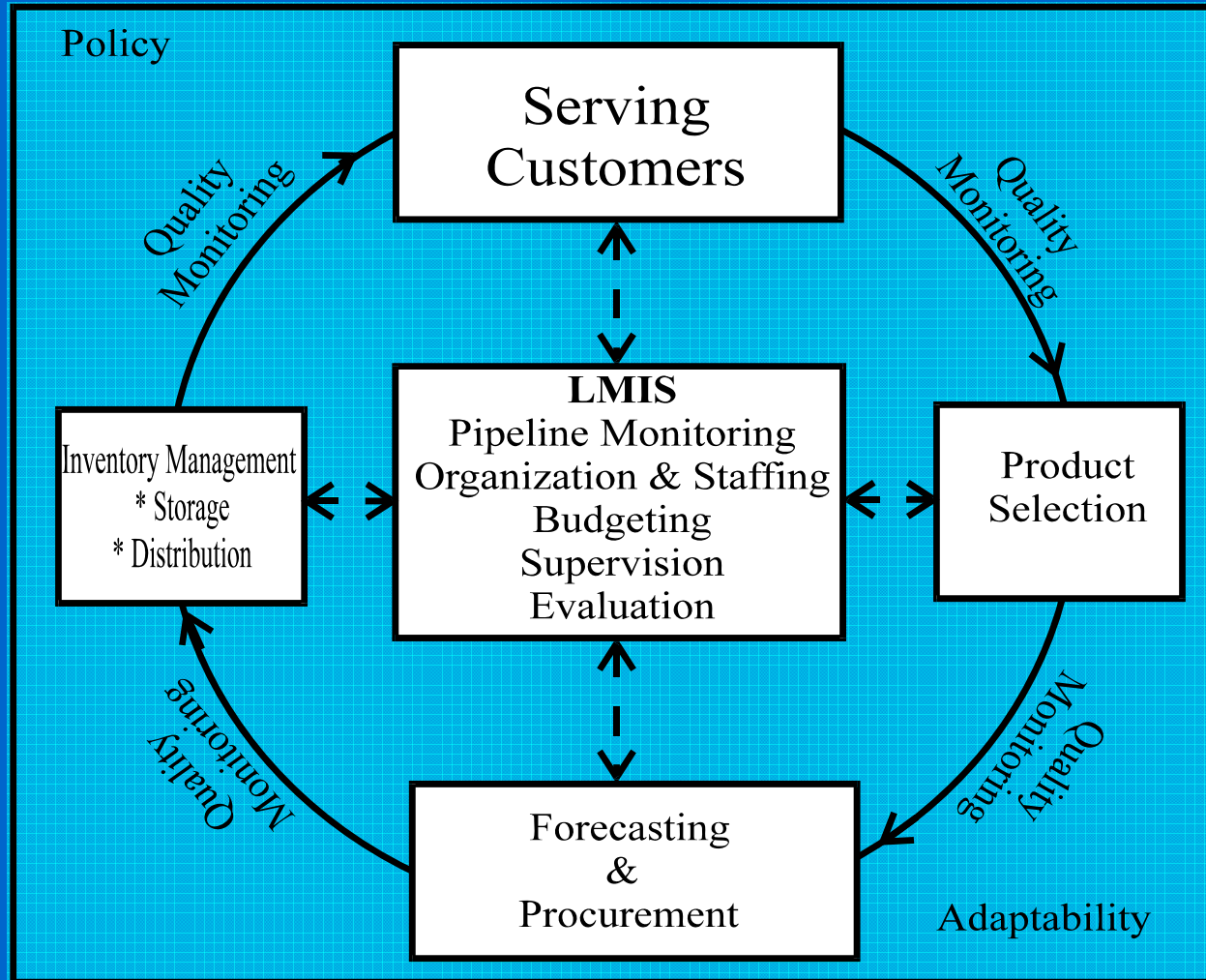


Types of SCM

- Full supply – supply matches demand
- Limited supply – demand exceeds supply
- Integrated supply chain
- Vertical supply chain



Logistics Cycle



(Source – John Snow Inc.)



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Goal of Supply Chain Management



(Source – John Snow Inc.)



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SCM Acid Test

- The barometer of effective SCM is the availability of
 - The Right medicine
 - In the Right quantity
 - For the Right patient
 - At the Right time
 - In the Right condition
 - At the Right price

Six rights of logistics adapted from John Snow Inc.



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Logistics Cycle – Group Exercise

- Allocate the different activities in the logistics cycle to small groups
- Each group to discuss the importance of the activity in supply chain management of HIV/AIDS drugs
- For each activity identify possible causes of inefficiency



Product Selection

Importance

- Specifies products
- Ensures compatibility with guidelines & laws
- Ensures safety, quality and cost-effectiveness

Sources of inefficiency

- No policy, guidelines or STGs
- No transparency
- Inadequate human capacity



Quantification/Forecasting

Importance

- Estimates short, medium and long term requirements
- Ensures uninterrupted supply

Sources of inefficiency

- No reliable consumption data
- No reliable stock status data
- No human capacity



ARV Quantification or Forecasting

- Rising demand
- New program
- No reliable past consumption data
- Changing treatment guidelines
- Introduction of new drugs
- Changing pricing



Procurement

Importance

- Ensures that products are purchased

Sources of inefficiency

- Poor specifications
- Unclear procedures
- No reliable quantification
- Supplier uncertainty
- Technology change



Storage

Importance

- Ensures that products are kept in a manner that maintains quality and efficacy
- Ensures that products are available when needed

Sources of inefficiency

- Lack of knowledge about storage conditions
- Lack of ideal storage facilities
- Poor communication between SCM and program managers



Distribution

Importance

- Ensures products are transported to dispensing sites

Sources of inefficiency

- Unclear procedures
- Unreliable mode of transport
- Lack of dedicated transport
- Poor coordination between distributor, SCM and program managers



Inventory Control

Importance

- Ensures stock status monitoring

Sources of inefficiency

- No system
- No tools
- Tools not collecting essential data
- Lack of human capacity



HIV/AIDS SCM Challenges

- HIV/AIDS is a disease of major public health importance
- Comprehensive HIV/AIDS Programs include more than 200 products
- Rapidly changing treatment regimens and introduction of newer drugs and related commodities
- Unmet global treatment gap (WHO 3X5 target)
- Multiple often uncoordinated supply chains within countries
- Inadequate personnel with skills in SCM and logistics



Goals of ART

- Maximum and durable viral suppression
- Restoration and preservation of optimal immune function
- Reduction of morbidity and mortality
- Improvement of quality of life
- Achieving these goals using the initial treatment regimen requires sustainable and uninterrupted access to efficacious, high quality ARV drugs



Inventory Management

- Storage
- Distribution
- Inventory control



Storage & Distribution (1)

- Ensure constant supply of medicines
- Maintain medicines in good condition until they reach the client
- Minimise losses due to damage and expiry
- Prevent theft and fraud



Storage & Distribution (2)

- Maintain accurate inventory records
- Strategic storage points for timely delivery, quality maintenance and security
- Efficient use of transport
- Distribution – 20-25% cost of drug retail price (US pharmaceutical industry)



Strategies for ARV Distribution

- Integrated into essential drugs program or other existing system
- Vertical distribution system
- Mixed approach
- Contracting with the private sector
- Short supply chain improves effectiveness of distribution



Storage Considerations (1)

- Number of storage levels
 - Central
 - Intermediate
- Adequate space
 - Optimal use of existing space
 - Disposal of expired commodities
- Adequate security
 - High value drugs
 - Huge demand for drugs



Storage Considerations (2)

- Cold chain requirements
 - Rapid HIV test kits (Capillus)
 - Kaletra loses potency when stored $>25^{\circ}\text{C}$ for at least 2 months
- Short shelf life
 - Rapid HIV test kits – 6-18 months
 - Different shelf life for test (12-18 mnths) and chase buffer (11-13 mnths)
 - ARV drugs – 12-24 months



Inventory Control

- Stock status assessment
 - Tracking of quantity and use span of commodities in a supply chain/pipeline
- Purpose
 - To determine how long supplies will last
 - To detect potential stock outs/expirations and take appropriate and timely action
 - This is particularly critical in ART programs where there should be zero tolerance for stock out



What information is needed?

- Stock on Hand
 - Physical inventory
 - Stock card
- Average monthly consumption
 - Dispensed to user data (consumption data)
 - Issues data
- Calculating AMC
 - Trend – recent 6 months average
 - Fluctuation – last 3 months average
 - How about ART programs?
- Stock Status
 - $MOS = SOH/AMC$



Stock Status Assessment Challenges

- Too many products in EDL
- Staff shortages
- So what can be done?
- Prioritization
 - VEN = classification by medical need
 - ABC = classification by cost (Pareto analysis)
- ARV drugs are high priority in either system and therefore regular stock status assessment is critical



Inventory Control Systems

- When to order or issue?
- How much to order or issue?
- Determining and maintaining appropriate stock level
- Pull system
- Push system

- Goal: To avoid stock out and expiration
- How: By setting SL low enough to avoid S/O and high enough to avoid expiration
- Huge challenge and requires reliable LMIS data



Stock Levels

- Maximum – Minimum
 - Established range of stock level
- Maximum
 - Established maximum threshold
- Minimum
 - Established minimum threshold
- Different max-min levels may be set for each level of the pipeline



Useful concepts

- Review period/Order interval
 - Interval between stock status assessments
 - May result in an order or issue
- Safety stock level
 - Buffer of stock on hand needed to prevent unexpected stock out
- Lead time
 - Time interval between placing an order and receiving and having stock ready for use
- Emergency order point
 - Stock level threshold which triggers an order or issue irrespective of the review period



Determinants of lead time

- Manufacturer capacity
 - Zerit global demand
- Customs clearance process
- Reliability of distribution system in developing countries
- Length of the supply chain



Maximum – Minimum Systems

- Forced ordering
- Continuous Review
- Standard



Forced Ordering System

- Always retain maximum stock level at end of review period
- An Emergency Order Point is also set and an order must be placed whenever this threshold is reached at any time before end of review period
- Minimum level is not useful to the storekeeper
- Useful for systems managing few products



Setting Stock Levels (Forced Ordering)

- $\text{Min SL} = \text{Lead time SL} + \text{Safety SL}$
- $\text{Safety SL} = \text{at least half review period stock}$
- $\text{Max SL} \geq \text{Min SL} + \text{Review Period SL}$
- $\text{EOP} \geq \text{Longest emergency lead time stock}$



Forced Ordering

Advantages

- Simple decision rule
- Schedule transport

Disadvantages

- Possibility of small quantity orders



Forced-Ordering Delivery (1)

- Topping up system
- Same rules as the normal forced order system
- Deliveries made by a distribution or delivery truck system
- Truck goes round to replenish all sites at end of review period



Forced-Ordering Delivery (2)

- This system can either be pull or push
- Explain the difference
- Useful for ART programs
- Requires investment in transport system and trained delivery staff
- Reliable collection of logistics information
- Discuss other advantages of this system



Advantages of Forced-Ordering Delivery

- Lead time is eliminated
- Shortens pipeline
- Reduces costs of holding inventory
- Redistribution and collection of damaged or expired products possible
- Provides opportunity for support and supervision



Continuous Review System

- Assess stock status every time an issue is made and order back to max only when Min SL is reached
- No fixed review period
- Store keeper must know both max and min
- No EOP
- Example is a condom dispenser
- Is always a pull system (Explain why?)



Continuous Review

Advantages

- Simple decision rule
- Orders can be placed any time (good for SDP)

Disadvantages

- Huge transport demand
- Work intensive
- Can be expensive



Two-Bin System

- Two equal bins of inventory
- Order when 1 bin is empty
- Simple variation of continuous review system
- No paper work, No calculations
- Min = 1 bin, Max = 2 bins
- Size of each bin is should be determined by AMC
- Useful for CBDs



Standard System

- Only order to bring to max SL products that are below Min SL at end of review period
- Emergency orders can be placed at any time
- Hybrid of forced order and continuous review systems
- Review period fixed
- Stock level set
- EOP is also set



Setting stock levels (Standard)

- $\text{Min SL} = \text{Lead time SL} + \text{Safety SL}$
- $\text{Safety SL} = \text{Buffer against uncertainty} + \text{Review period stock}$
- $\text{Max SL} \geq \text{Min SL} + \text{Review Period SL}$
- $\text{EOP} \geq \text{Longest emergency lead time stock}$
- EOP must ensure no S/O between review periods



Standard

Advantages

- No small orders
- No need to assess stock status continually, ideal for many commodities
- Regular order schedule

Disadvantages

- High buffer stock
- Discuss attendant problems of huge buffer stock
- Training of storekeepers



Group Work

- You are starting an ART program at four sites in your region/country. Each site has fairly reliable telephone/fax communication with the MOH head office. A dedicated distribution system has been proposed for the program. Funding has been committed for first and second line drugs for up to 1000 patients at each site during the first year.
- Would you recommend a pull or push system for 1st line drugs?
- Would you recommend a pull or push system for 2nd line drugs?
- Describe the type of inventory control system which you would recommend. Your recommendation should include the factors that should be considered in designing the system



Designing Inventory Control Systems

- Number of products
- Transport
- Training
- Reporting
- Push or pull
- Supervision
- Storage space



Logistics Management Information Systems

- Why should we collect data?
- What data should we collect?
- How do we collect the data?



What is LMIS?

- Collecting, collating and analysing data for decision making
- Critical for monitoring a supply chain
- What are the important questions which must be answered by an LMIS?



Essential LMIS Data Items

- Stock on Hand
- Consumption
- Losses and adjustments
- Service statistics - what are some of the important service statistics in an ART program?



Sources of LMIS Data

- Stockkeeping records
- Transaction records
- Consumption records
- Reports



Supply Chain Management Strategies

- Objective: **CREATE, ENHANCE and PROMOTE** uninterrupted supply of high-quality, low cost products that flow through an accountable system
- To rapidly scale up SCM to support HIV/AIDS treatment, prevention and care
- To develop capacity for sustainable procurement and distribution
- To ensure quality control of commodities
- To address IPR laws at international and national levels

Source: US Department of State - Supportive interventions for US Government Programs



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Strategies for Rapid SCM Scale up (1)

- Private public collaboration
- Set up vertical distribution and LMIS
- Technical assistance
- Improve storage conditions and capacity



Strategies for Rapid SCM Scale up (2)

- Improve inventory management systems
- Develop human capacity
- Collaboration between SCM and program managers
- Coordination of all donors and stakeholders



Sustainable Procurement and Distribution

- Use lessons learnt from other public health programs
- Develop and strengthen procedures and guidelines for product selection
- Develop and strengthen procedures and guidelines for distribution



Quality Control of Commodities

- Enhance country capacity to test and monitor quality of commodities
- Establish regional quality control facilities



Intellectual Property Rights

- Balancing IPR and public health
- TRIPS and flexibilities in Paragraph 6 of the DOHA Declaration
- To what extent have developing countries used these flexibilities?
- Is IPR a barrier to effective SCM of HIV/AIDS drugs in the MENA region?
- How is SCM affected by tariffs and duties?



ARV Commodity Security

- Sustainable supply for life for patients on ART
- Pillars
 - Forecasting
 - Financing
 - Procurement
 - Distribution



Emerging Lessons on HIV/AIDS Commodity Security from Developing Countries



Forecasting

- ART program newness
- Lack of in-country expertise in forecasting and quantification
- Lack of skilled staff – No pharmacists at district hospitals
- Weak LMIS even in EDP
- Poor quality of logistics data - incomplete and inaccurate
- Lack of trust in the system – high prevalence of stock piling of essential drugs
- Demographic data based on DHS either not up to date or lacks HIV prevalence data
- Some countries not conducting HIV surveillance



Financing

- Huge treatment gap but not yet quantified
- Multiple donors and little coordination
- Competing priorities for Government expenditure
- Donor commitments usually limited to 1 year
- Variable degree of political and fiscal commitment in different countries
- Scope for more private sector involvement
- Approaches to cost sharing



Procurement

- Multiple procurement agents for various HIV/AIDS commodities with little coordination.
- Donor funded programs tend to have carefully considered procurement plans
- Lack of transparency and inefficiency of the procurement process remains a major issue



Delivery

- Weak LMIS for HIV related commodities
- Multiple donor funded programs with different and un-coordinated distribution systems
- Efficiency gained by outsourcing distribution of ARV drugs and other HIV products
- Dedicated distribution for ARV drugs
- Development of inventory management procedures and LMIS systems were frequently an after thought
- Varying degrees of political, civil society and community pressure to initiate and/or rapidly scale-up ART programs



ARV SCM Issues in the MENA Region

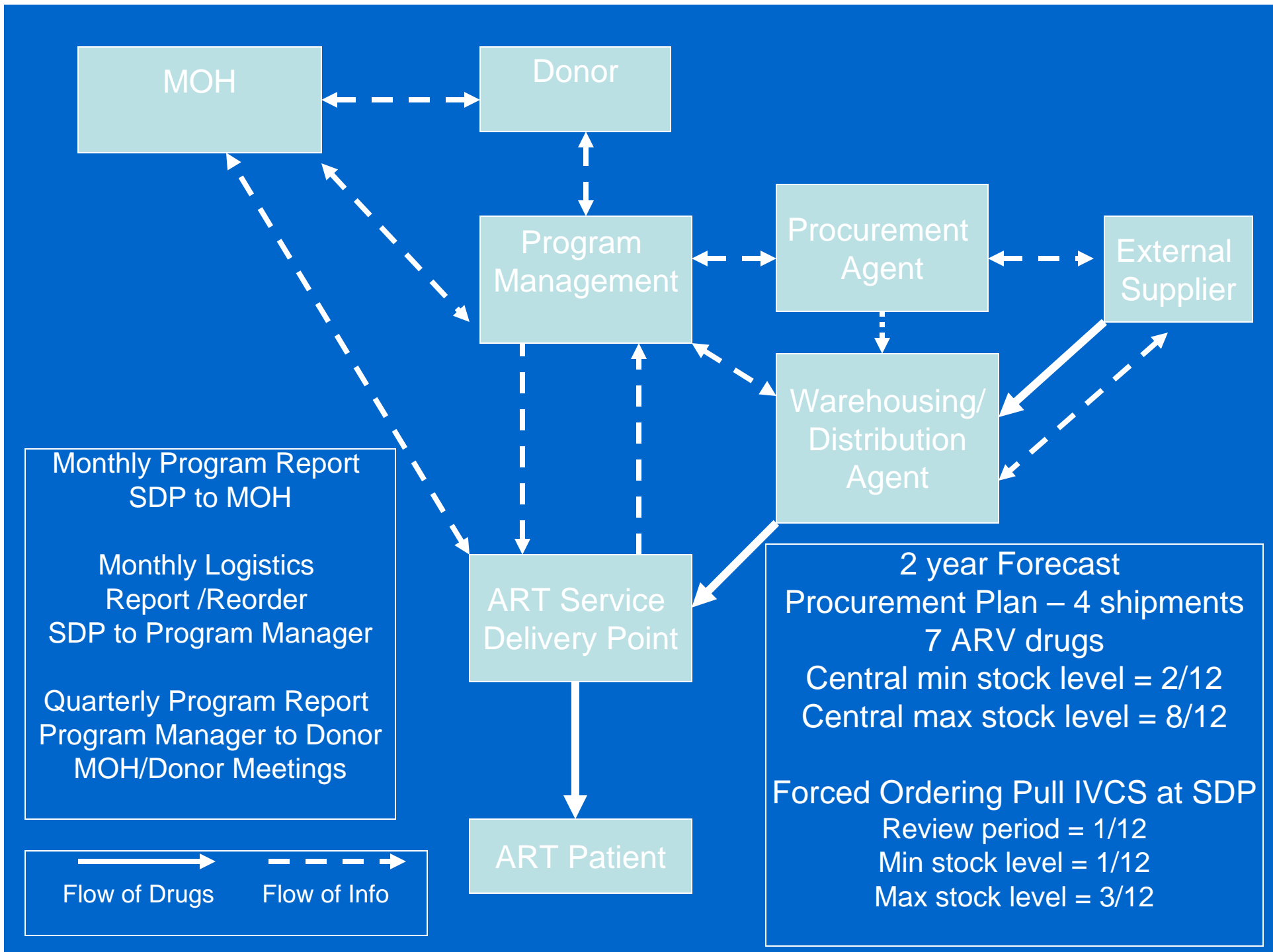
- Program initiation versus scaling up
- Stigma
- New markets for most manufacturers
- What is the role of private public collaboration?
- Is there a place for pooled procurement?
- Sharing experience with countries in other regions



Example of an ARV Supply Chain

- Donor
- Primary implementer
- Procurement Agent
- Storage and Distribution Agent
- Service Delivery Points – 4 clinics
- End users – 1000 eligible ART patients





ARV LMIS

- Stock keeping records
 - Stock card for each drug at SDP level
 - Stock card for each drug at central level
 - Capture SOH/ and L/A
- Consumption records
 - Dispensing log at SDP level
- Transaction records
 - RIV
 - Issue note at SDP level
- Summary reporting
 - Monthly logistics and stock order form
 - Monthly ART report for service statistics



Strengths of the System (1)

- The LMIS forms at SDP level capture all 3 essential LMIS data items
 - Stock Card
 - Stock on Hand
 - Losses and Adjustments
 - Promotes accountability
 - Dispensing Log
 - Dispensed to user data
 - Reporting/reordering
 - Self balancing monthly logistics R/R
 - The review period for stock status assessment and ordering coincides with reporting
 - Efficient mailing system and email service for submitting report to central
- Short pipeline – 2 levels, lead time (SDP) = 1-2 weeks
- Reliable transport and distribution system (outsourced)



Strengths of the System (2)

- Adaptability – the logistics R/R was revised twice in less than a year
- Procurement plan is flexible – cancellation of planned second line ARV drug shipments permissible in supply contract
- On-going quality monitoring - monthly site support visits and supervision
- On-going collaboration with the MOH
- Ownership of the program by the sites



Challenges of the system

- High cost of treatment - branded drugs (US\$600 ppy)
- Many drugs in the supply chain compared to programs in same country using generic drugs
- Difficulty in maintaining constant supply and lead time for stavudine



Conclusion (1)

- SCM is often ignored in most public health programs
- SCM should be carefully planned at the beginning of an ART program
- Effective SCM is the key to effective comprehensive HIV/AIDS programs
- Coordination is imperative
 - Program and SCM managers
 - Program Funders



Conclusion (2)

- Effective supply chain management of HIV related commodities is central to the hope for a longer and improved quality of life of more than 6 million PLWHA in urgent need of treatment globally!
- Always remember that every stockout of ARV drugs within your pipeline contributes to the unnecessary and premature death of a child, woman or man somewhere out there.
- ***Our action must make a difference!***



Country Experiences (1)

- Participants from each country to form a group
- How many ARV supply chains are there? (different funders with different supply chains)
- Draw the ARV supply chain for your National Program highlighting the flow of drugs and flow of data
- Describe the strengths and weaknesses of the system
- Suggest recommendations to strengthen the system
- Describe problems which the system has encountered
- How were the problems resolved?



Country Experiences (2)

- Describe the LMIS forms in use
- Describe how SDPs order ARV drugs
- Describe the inventory control system that is in use
- Have there been any reports of ARV stock out? If so why
- Have there been any reports of ARV expiration? If so why
- What strategies have been put in place to ensure ARV commodity security?
- Are ARVs in full supply?



Thank You
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