Certification in Humanitarian Medical Logistics Practices (MedLog)
Competence Model

Final Version – 2008

COPYRIGHT STATEMENT

Fritz Institute
50 Fremont Street
Suite 1150
San Francisco
CA 94105
United States of America

Competence Model Context

The competence model contained in the following pages has been written to support the Certification in Humanitarian Medical Logistics. The interpretation of the various parts of the model should only be made by referring to the content of this context statement.

Logistics and supply chain management is a “customer” oriented service. It is managed within a frame of administrative and financial rules, national and international laws and regulations, and technical requirements. To deliver the right thing, at the right cost, at the right time, to the right place in conflict and stressful contexts is the day-to-day challenge for the humanitarian logistician.

Humanitarian logistics and supply chain management covers a wide range of activities including:

- Procurement
- Warehousing
- Transport
- Fleet Management
- Import and export.

Humanitarian logisticians have to provide response in a variety of situations. These include emergency response to natural and man-made disasters. Sometimes such events can be planned for, but equally they can happen suddenly. Typically such situations require an ability to construct a supply chain and operate it to provide relief to those in need quickly.

Additionally, response is also made in situations requiring development and/or reconstruction. In some circumstances this might be for a short or long period of time. Here there is frequently the opportunity to be able to build more permanent supply chains.

In recent years we have seen that such requirements for a humanitarian response can occur anywhere in the world. Usually the circumstances will create an environment where communications and “normal” relationships are at best strained and frequently completely broken. Often the protection of the security of people and the goods being moved will be at risk. In some situations the infrastructure can be damaged or destroyed rendering existing or planned supply chains redundant.

As well as ensuring that the response provides the relief to the target population efficiently and effectively, the logistician must also ensure that adequate records are kept to enable transparency and accountability to be demonstrated to donors.

Many different people contribute to the management and operation of the supply chain and success will depend on their ability to work together.

Whilst the above holds true for all types of humanitarian supply chains there are specific challenges associated with medical logistics. These challenges require that different groups of people think in a way that recognises the characteristics of the unique items being handled so that the flow of products and equipment through the supply chain is smooth.

All of these organisations and people are united in a common aim of wanting to reduce the suffering of the affected people. They will be attempting to do this in many different ways that makes the job of the logistician a complex one. The ability to form relationships and work together with other people is therefore a critical success factor.

The model that follows has been designed to support this challenging operating environment and it is important that its interpretation is made within this context.

OUTCOMES OF EFFECTIVE PERFORMANCE

On completion of this programme logisticians and medical personnel will be able to contribute to the planning and operation of a humanitarian aid medical supply chain through the following outcomes of effective performance:
1 & 2 scope the SC and the product characteristics
3, 4, & 5 Normal conditions to ensure SC flow, documentation of the flow, and then constraints to the normal flow
6, 7, 8, 9, - functional aspects of the SC
New titles for each of the units
This structure gives students a list of what will be covered, and where they start and where they will end.

1. **Identify the supply chain requirements associated with medical programmes**
2. **Identify the product characteristics of items used in medical programmes that have supply chain implications.**
3. **Identify the conditions needed to maintain supply chain flows and avoid common performance problems**
4. **Identify the information and documentation needed to service/manage an efficient and effective medical supply chain**
5. **Identify supply chain characteristics, barriers, and constraints that can impact medical programmes.**
6. **Specify the requirements for procuring medical items.**
7. **Specify the requirements for storing medical items.**
8. **Specify the requirements for transporting medical items.**
9. **Specify the requirements for disposing of medical items.**
10. **Specify the requirements for medical supply chain quality assurance**

The key learning points and coverage for each outcome is described on the following pages.

OUTCOME OF EFFECTIVE PERFORMANCE

1 Identify the supply chain requirements associated with medical programmes.

KEY LEARNING POINTS	COVERAGE
Types of medical programmes	Definition of medical Medical aid Material aid Steady state Emergency Crisis Outbreak Type of disaster and impact on health Vaccination Immunisation Objectives of programmes Therapeutic feeding
Characteristics of medical programmes	Range of medical items plus supporting supplies Number of medical items Impact on beneficiaries Expertise needed Unpredictability of demand Variety of services required Characteristics of the items distributed Number and range of expertise to deliver Management of excess or inappropriate supplies “Standardised” response package
Organisations and people involved In medical programmes	NGO’s UN Agencies World Bank, WTO, IMF Local NGO’s Red Cross Movement Health professionals (international and local, private, traditional healers) Experts Logisticians/ Medical Logisticians Programme managers Ministry of Health and local authorities

	Social mobilisation actors, e.g. Community based organisations Religious organisations
Sources of funds and resources	Individual donors Private sector In-Kind Donations solicited/unsolicited Institutional donors e.g. governments Other agencies
Scope of supply chain and Its main components	Scope of supply chain process What is supply chain management Types of humanitarian supply chain Physical, financial and information flows Meeting customer needs Identifying the customer Order Mgt Procurement Transport and distribution ImpEx Storage Reporting
Role of supply chain	Initial assessment of situation Initial response team Advising programme mgr Jointly planning with programme mgr Advising medical personnel Providing information to customers and donors Managing push and pull Order management process Right items in right place at right time at right cost in right condition
Characteristics of medical supply chains.	Quality assurance throughout SC Manage diverse range of medical items Manage characteristics of medical items Legal requirements Network design Medical knowledge in the supply chain Clarity of responsibilities for tasks Environmental control and cold chain Reverse logistics Hazardous goods Demand distortion

	Need for higher service levels Managing surges in demand Supporting beneficiary service programmes Provide after-sales services

OUTCOME OF EFFECTIVE PERFORMANCE

2. Identify the product characteristics of items used in medical programmes that have supply chain implications.

KEY LEARNING POINTS	COVERAGE
Product characteristics that impact supply chains	Temperature Mechanical damage Humidity Sterility Tolerance to light Toxicity and hazard classification Value, regulation and security requirements Kits Packaging requirements Sources of supply (QA) Labelling requirements Value Dependant items Units of purchase Susceptibility to damage
Characteristics of drug products	Expiry dates Shelf life Tolerance to heat, light, damp, radiation, Importance of specifications Controlled substances Fake drugs (counterfeit and substandard) Generics and specialities (brand) Need for traceability Microbiological contamination and cleanliness National regulations (in addition to international regulations) Local production protection

Biological samples	Risk and safety Short shelf life Tolerance to heat Regulation Infectious and hazardous classification
Characteristics of disposable medical devices	Sterile requirements Risk and safety Fit for purpose specifications Shelf life Tolerances to heat, light etc Inflammable items Standard and non standard items Disposal requirements specifics Preferences of medical users
Characteristics of medical instruments, equipment and devices	Range of sizes, shapes weight etc Spares plus maintenance Fit for purpose specifications User instructions Dependable items Key components Requirements of compatibility Installation, calibration, and commissioning

OUTCOME OF EFFECTIVE PERFORMANCE

3. Identify supply chain characteristics, barriers, and constraints that can impact medical programmes.

KEY LEARNING POINTS	COVERAGE
Organisation rules and procedures	Procurement rules – local sourcing and procurement - standard item lists - order mgt procedure Principles and ethics Preparedness procedures and practices National lists Rules for donor donations Procedures for tracking and tracing
Country rules and regulations	Import and export regulations (international, national and sub-national)

	Controlled substance requirements and procedure Customs and excise procedures and lead times Rules for donations Hazardous goods regulations Administrative procedures
Availability of supply chain resources	Availability of suitable storage facilities and equipment Availability of suitable transport resources Availability of suitable transport providers Medical knowledge of people managing the supply chain and of medical people Behaviour and competence of people managing the supply chain Impact of monopolies & political pressures Information and telecommunications systems (e.g. IT tracking and tracing)
Availability of medical items	Lead times Sources and constraints of supply Zero stock policies, JIT, Orphan drugs Ownership Running out of funds

OUTCOME OF EFFECTIVE PERFORMANCE

4. Identify the information and documentation needed to service/manage an efficient and effective medical supply chain

KEY LEARNING POINTS	COVERAGE
Programme requirements	Type of programme Programme objectives Timescales Type range and quantities of medical items required. Budget Specific standard lists linked to programmes Place (geography) of programme Access, maps, security, ethnic religious groups, infrastructure
Organisation and country rules and procedures	Procurement rules and procedures Import and export rules and procedures for medical items. Rules for import of controlled substances. Local NGO counterparts organigrams and key focal points Rules for import, movement, and storage of controlled substances
Information on medical items	Availability national & international Lead times National lists, local habits Composition, use, expiration of Health Kits Importance of stock levels, stock reports, pipeline, demand Characteristics of item
Information needed to process an order	Item code or specification/ specific regulations Purpose of item Item characteristics Item tolerances Dependent and dependable items Other players/coordination

	Quantities Stock levels, pipeline, demand, lead time, target delivery date Capacity to handle the order and infrastructure Logistics plan
Sources of information	Standard item lists National lists e.g. Ministry of Health Internet Product brochures Item code lists Medical experts Organisation head office Other organisations / counterparts Supplier Maps, catalogues, and guidelines
What records to maintain	Records on Expiry dates of items in supply chain. Temperature monitoring storage and transport Information to track and trace items through the supply chain. Items disposed Documents on controlled substances Tracing software (batch tracking) Consumption/demand data

OUTCOME OF EFFECTIVE PERFORMANCE

5. Identify the conditions needed to maintain supply chain flows and avoid common performance problems

KEY LEARNING POINTS	COVERAGE
Improving medical supply chains	Developing relationships Communication Tracking and tracing throughout total supply chain. Understanding item characteristics and their supply chain implications Clear responsibilities

	Use of non standard items particularly equipment with poor availability on installation, repair, service and parts. Sharing of information between medical professionals and logistics professionals. Establish and maintain systems and procedures Training
Common errors	Not understanding characteristics of medical items and supply chain requirements (e.g. bad storage) Poor communication on item specifications and stock information, lack of consultation with medical experts (e.g. products' expiry date, shortage, programme development) Ordering and supplying items not fit for purpose. Setting up unnecessary warehouses Product integrity and quality (and temperature control) not maintained throughout total supply chain Not monitoring shelf life/expiry dates Items being damaged through exposure to heat, light, inappropriate handling Responsibilities for certain supply chain tasks not clear. Systems, procedures, safety regulations and legal requirements not followed (e.g. locked storage) Decisions being taken by those without the expertise, and without appreciation of impact of errors Purchasing drugs locally Cannabalising Medical kits Lack of understanding there are more stringent government regulations Opening primary and secondary supplier packaging. No proper disposal around the whse (with recording)

OUTCOME OF EFFECTIVE PERFORMANCE

6. Specify the requirements for procuring medical items.

KEY LEARNING POINTS	COVERAGE
Definition of procurement	Procurement aims and objectives Procurement process Stages in procurement process Difference between sourcing and purchasing. Ethics
Sources of supply	Donors Drug donation guidelines Local International Importance of quality assurance and control. Types of supplier – manufacturer, distributor. Visits and validation of suppliers and the drug product Your own organization (upstream)
Requirements for medical items	Labelling Packaging Documentation – language, brand /generic names, patient information leaflet Spares Dependent items Sampling/ lab testing to ensure quality of supply – different reasons and means
Specifications	Types of specifications - Functional Performance Service Standard lists Non standard items
Information needed to process an order	Item code or specification Purpose of item

	Usage rates and buying quantities Supplier minimums & required delivery date Item characteristics Import and transport documents information required by the country Item tolerances Dependent items Order management process (security) Suitable substitutes Inventory data Programme requirements List of authorised products

OUTCOME OF EFFECTIVE PERFORMANCE

7. Specify the requirements for storing medical items in the supply chain.

KEY LEARNING POINTS	COVERAGE
The role of a warehouse in a humanitarian medical supply chain	Reasons for having a warehouse Role of warehouse – storage, assembly Location of warehouse/storage in a medical supply chain – e.g. medical centres, hospitals Permanent or temporary Activities carried out in warehouse Extended supply chain to beneficiaries
Specific storage requirements for medical items.	Temperature control Humidity control Security Quality control Sterile environment Cold chain Capacity Controlled substances under lock and key and legal documentation Hazardous or dangerous items Light and ultraviolet radiation Contamination Ability to store medical equipment, devices and instruments with range of weights, size, shape etc

	Avoid damage to items and packaging Backup plans (eg cold storage goes down) Minimum competency of staff (eg must be a pharmacist) Increased complexity of reception procedure
Medical storage design	Specialised warehouse Storage area in 'general' warehouse Equipment needed to ensure- Security Temperature Humidity Cold chain equipment (see Tables of standards and different types of cold storage) Use of storage providers Power requirements Design to enable and manage FEFO policy and stock rotation. Picking and packing area/mechanism Kitting, and renewing expired items in a kit Quarantine and area for goods to be disposed Segregation of medical items from "regular" items
Use of warehouse providers	Selecting suitable providers Information required by providers Responsibility for actions and performance of providers. Visits and validation of providers
The monitoring and management of storage	Monitoring of temperature, humidity etc Maintenance of equipment Process, procedure and records required to track and trace items Security procedures e.g. responsibility for keys.
The role of inventory in a medical supply chain	Reasons for holding inventory Inventory in the total supply chain Replenishment policies and strategies Stock policies FEFO

		Replenishment policies Maintenance of inventory records Stock identification and classification Coding systems Process for recording stock movements Stock checks Reporting on stock levels Tracking shortages and anticipated excess

OUTCOME OF EFFECTIVE PERFORMANCE

8. Specify the requirements for transporting medical items through the supply chain.

KEY LEARNING POINTS		COVERAGE
The role of transport in medical supply chains.		Role of transport – movement, security, maintain quality assurance. Different movements through total supply chain.
Specific transport and handling requirements for medical items	&	Cold chain & temperature requirements Humidity control Security control Controlled substances Hazardous Inflammable items Biological samples Aware of IATA regulations (IATA for air DGR [Dangerous Goods regulations] for road transport) 'Specialised' transport or transporting with non medical items. Avoiding damage to items and packaging. Handling methods Contingency plans Quality,capacity & preparedness of port and airport storage and handling facilities
Suitability of various modes of transport		Weight and volume of items Speed of movement

	Security requirements Susceptibility to mechanical damage
Use of transport providers	Selecting suitable providers Information required by providers Responsibility for actions and performance of providers. Visits and validation of providers
Import and export procedures and transport documentation.	Country regulations Documentation needed Synchronisation of physical and information flows Quality capacity and preparedness of port and airport storage and handling facilities Controlled substances – Documents - Reports - Records - Procedure Role of National Food and Drug Administration.

OUTCOME OF EFFECTIVE PERFORMANCE

9. Specify the requirements for disposal of medical items

KEY LEARNING POINTS	COVERAGE
Reasons for disposal	Out of date/expired Counterfeit Not required Not suitable Unused at end of programme Ineffective Damaged Change of programme, and specifications
Disposal guidelines (used items/ handling of used healthcare waste)	Ethical aspects Legal aspects – country legislation Environmental aspects Sanitary aspects Organisation procedures Disposal methods for different items

	Donate, export/return items
Disposal process	Decision to dispose – involve medical personnel. Legal implications or requirements Involvement of relevant authorities Completed by relevant authorities Health and safety of disposal teams, and community Cost planning required Sensitivity of disposal (e.g. during a time of drug shortage)
Consequences of improper or non-disposal	Theft Resale Reuse Misuse Hazardous Impact on environment e.g. water supply Expired drugs can have adverse reactions if used.

OUTCOME OF EFFECTIVE PERFORMANCE

10. Specify the requirements for medical supply chain quality assurance.

KEY LEARNING POINTS	COVERAGE
Quality Assurance in Supply	Sources of supply Good Manufacturing Practice Sub standard drugs Supplier assessment/prequalification inspection and validation Product & producer prequalification WHO Certification Scheme Inspection/testing Packaging and labelling
Quality Assurance in Storage and Transport	Good distribution practice Documentation, Tracking and tracing Inspection Quality Control Storage requirements Damaged/expired items

	Monitoring Security Knowledge of workers Feedback on quality issues Transport packaging and labelling
Quality assurance in Handling and Delivery	Inspection Handling requirements Damaged items Identifying items Extended supply chain Knowledge of ‘users’ Feedback on quality issues