

SUPPLY/LOGISTICS
MANAGEMENT SYSTEM
ASSESSMENT

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MANAGEMENT SYSTEM ASSESSMENT

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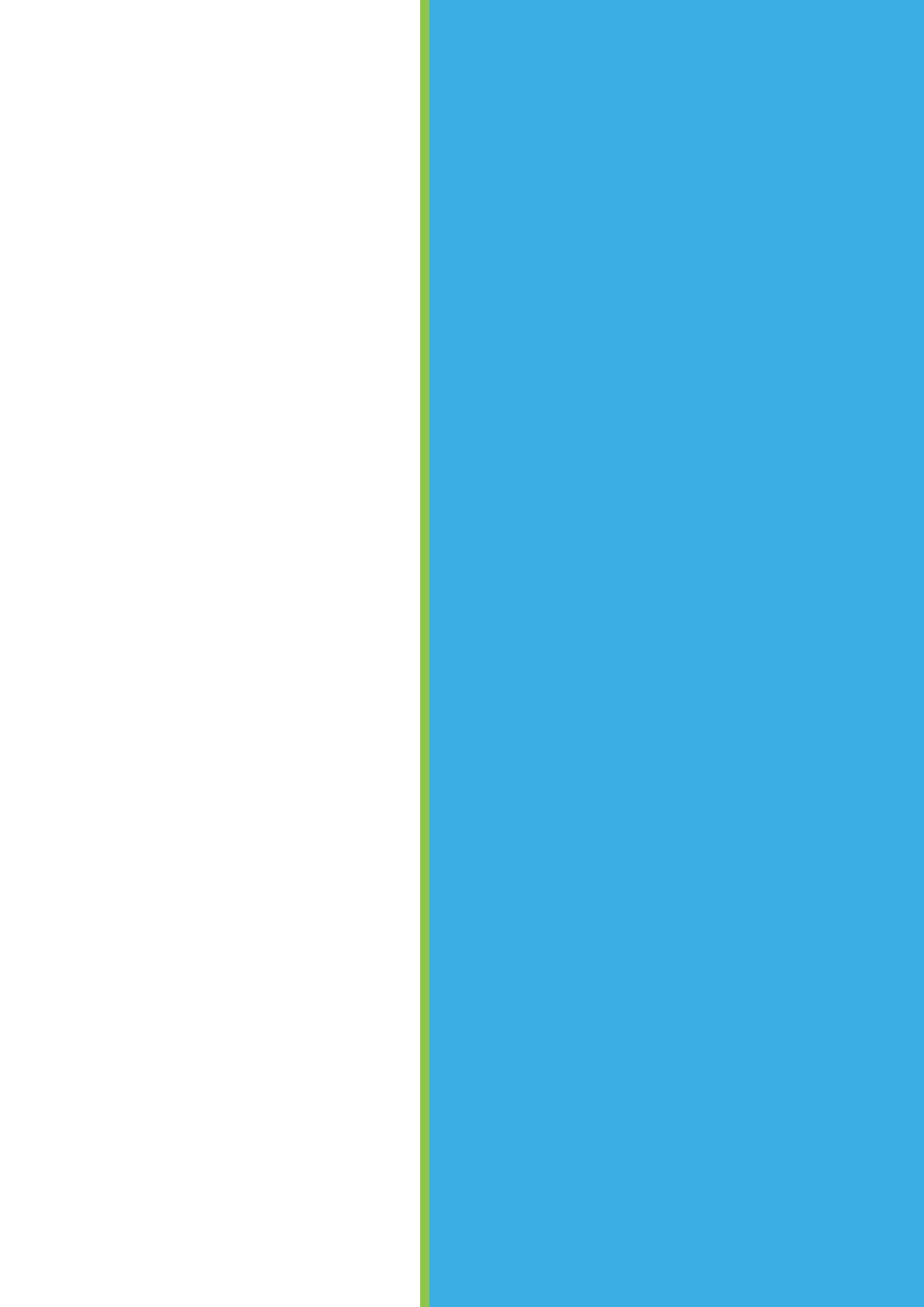
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ACKNOWLEDGEMENT

I would like to express my appreciation for the contribution and cooperation of all of those who were interviewed and whose health facilities were assessed. This Supply / Logistics Management System Assessment would not have been possible without the support of representatives of Federal Director General Health, Secretary Health Punjab and Sindh, Department of Health Balochistan, Department of Health FATA, Department of Health KP, Department of Health Sindh, Primary and Secondary Healthcare Department Punjab, Specialized Healthcare and Medical Education Department Punjab, Planning and Development Department Punjab and Sindh, Drug Regulatory Authority of Pakistan, Integrated Reproductive Maternal Newborn Child Health and Nutrition Program, Maternal, Newborn and Child Health, World Health Organization, USAID, John Snow Inc, Peoples Primary Health Care Initiative, Integrated Health Services , Health and Nutrition Development Society, Nutrition International, Pakistan Pharmaceutical Manufacturer's Association, and stakeholders who participated in inception and dissemination.

I would also like to thank UNICEF Pakistan for their guidance and support in developing this report.

Fuad Hamid



ACRONYMS

ACRONYMS

AAT	Award/Advance Acceptance of Tender
ADR	Adverse Drug Reaction
ARI	Acute Respiratory Infection
BHU	Basic Health Unit
CEO	Chief Executive Officer
CPOES	Computerized Physician Order Entry Software
DHIS	District Health Information System
DHO	District Health Officer
DHQ	District Head Quarter Hospital
DDHO	Deputy District Health Officer
DOH	Department of Health
DOS	Days of Stock-out
DRAP	Drug Regulatory Authority of Pakistan
DT	Dispersible Tablet
DTL	Drug Testing Laboratory
EDL	Essential Drug List
EMA	European Medicines Agency
EML	Essential Medicines List
EPI	Extended Program of Immunization
FATA	Federally Administered Tribal Areas
FP	Family Planning
FP&PHS	Family Planning and Primary Healthcare Services
GAPPD	Global Action Plan for Pneumonia and Diarrhea
GMP	Good Manufacturing Practices
HANDS	Health and Nutrition Development Society
HF	Health Facility
HIMS	Health Information Management system
HISDU	Health Information and Service Delivery Unit
iCCM	Integrated Community Case Management
IHS	Integrated Health Services
IRMNCH&NP	Integrated Reproductive Maternal Newborn Child Health & Nutrition Program
KP	Khyber Pakhtunkhwa
LMIC	Low and Middle Income Countries
LMIS	Logistic Management Information system
LMU	Logistics Management Unit

Lo-ORS	Low Osmolarity Oral Rehydration Solution
LSAT	Logistic System Assessment Tool
LP	Local Purchased
LHW	Lady Health Worker
MICS	Multiple Indicator Cluster Survey
MOU	Memorandum of Understanding
MEA	Monitoring and Evaluation Assistant
MIS	Management Information System
MNCH	Maternal, Newborn and Child Health
MSH	Management Sciences of Health
MO	Medical Officer
NEML	National Essential Medicines List
ORS	Oral Rehydration Solution
P&SHD	Primary and Secondary Healthcare Department
PITB	Punjab Information Technology Board
PPPs	Public Private Partners
PPHI	Peoples Primary Health care Initiative
PPHSS	Punjab Public Health Sector Strategy
RHC	Rural Health Center
RMNCAH&N	Reproductive Maternal Newborn Child Adolescent Health & Nutrition
SCMS	Supply Chain Management system
SDG	Sustainable Development Goals
SHC&ME	Specialized Healthcare and Medical Education Department
SOP	Standard Operating Procedure
SRO	Stringent Regulatory Ordinance
THQ	Tehsil Head Quarter Hospital
U5	Under 5 years
UN	United Nations
USFDA	Unites States Food and Drug Administration
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WHO LIS	World Health Organization Library Information System

01

EXECUTIVE SUMMARY

01

EXECUTIVE SUMMARY

1.1 BACKGROUND

UNICEF and Bill and Melinda Gates Foundation established a partnership to contribute to increase the child survival in Pakistan. MG (Melinda Gates) Foundation achieved their goal by improving the process of diagnosis and treatment of Pneumonia and Diarrhea in children less than 5 years of age. The Project “Accelerating policy change, translation and implementation for Pneumonia and Diarrhea commodities in Pakistan”, is to be implemented in close coordination of the Government of Pakistan and relevant stakeholders to ensure sustainable changes.

Pakistan has the third highest rate of maternal, Fetal, and child mortality in the world¹. According to the research in 2010, the mortality rate of children under five (U5) is 89 deaths per 1,000 live births, with 1 in every 11 Pakistani children not surviving to his fifth birthday. Each year, approximately 91,000 children die of Pneumonia and 53,300 children die of Diarrhea. According to Demographic Health Survey of Pakistan 2012-13 a low proportion of children is receiving appropriate treatment. Only 38% of children suffering from Diarrhea are properly treated with Oral Rehydration Solution (ORS) and 1.5% received Zinc. Nearly half of children suffering from Pneumonia received suitable antibiotic. One out of nine children receives no treatment for Diarrhea and 59% of them remain untreated for Pneumonia.

1.2 PURPOSE

The pharmaceutical logistics assessment of Pakistan was carried out through UNICEF and Bill Melinda Gates Foundation. The assessment was particularly conducted for DoH Sindh and Punjab. The provincial level assessment has been conducted for Khyber Pakhtunkhwa, Balochistan and FATA for advocacy purpose.

The main purpose of the assessment was to provide the quantitative data on the supply of selected medicines and commodities at public health facilities and private pharmacies. The assessment was conducted to provide an in-depth situation analysis of pharmaceutical supply chain management system at all levels i.e. National, Provincial, District and Sub-district levels. The health service delivery levels include central warehouse (at provincial and district level), health facility and medicines store (at sub-district level). Vertical programs (IRMNCH, LHW program, PNC, and MNCH) were also assessed to provide the baseline information to track changes and improvement in pharmaceutical supply chain management system. To attain sustainability of availability of Diarrhea and Pneumonia medicines certain measures should be taken for local level production. The study also provides the base line knowledge for the registration of new formulations (Amoxicillin DT and combo pack of ORS & Zinc supplementation) with Drug Regulatory Authority of Pakistan.

DoH and development partners required this information to explore national/provincial drug requirements and to measure the performance of logistics supply chain system. Moreover, they wanted some basic information regarding the duration of availability of essential medicines for Diarrhea and Pneumonia at health facilities and the reasons of stock outs.

¹Reproductive, maternal, newborn, and child health in Pakistan: challenges and opportunities: Health Transitions in Pakistan, The Lancet Volume 381, No. 9884, p2207-2218, 22 June 2013



1.3 OBJECTIVES

The supply chain management system assessment has following objectives:

- To analyze the current supplies logistic system for Pneumonia and Diarrhea management through in-depth situation analysis for public sector health facilities and vertical programs dealing in management of Diarrhea and Pneumonia.
- To consult with key opinion leaders, decision makers and other stake holders to discuss the existing logistic systems for the procurement and distribution of Pneumonia and Diarrhea medicines within the country especially in - Sindh and Punjab provinces.
- To give practical and logical recommendations to the stakeholders on how updated logistic management information system (LMIS) can be introduced in supply chain management for forecasting, procurement, inventory management, warehousing and distribution and also on linking of revised DHIS tools with LMIS.

1.4 METHODOLOGY

The methodology of assessment is based on mixed analysis that is quantitative and qualitative. The quantitative analysis is established on the data derived from the Logistics System Assessment Tool (LSAT) developed by USAID Deliver Project and recommended by WHO for the assessment of logistics / supply chain management of medicines. However, the qualitative analysis was based on the information gathered through semi structured in-depth interviews.

1.5 KEY FINDINGS

In accordance with the scope of work for this assessment, the pharmaceutical LSAT was used to obtain baseline data for the indicators. The data collected for selected indicators is presented in various tables while the key findings are as follows;

1. All the Provincial procurement cells have facilitated the districts by providing central rate contract with prequalified firms except in Balochistan. The health

department of Balochistan has central procurement of medicines. WHO recommended method of forecasting was not implemented in provinces.

2. The teaching hospitals (health facilities) where computerized inventory management software were implemented under the supervision of SHC&ME have shown better result in inventory management based on LSAT assessment i.e. 92%, comparing with DHQ hospitals of Sindh, which were not facilitated with such interventions, have shown 52% results only.
3. In Sindh in LHW-LMIS it has been observed, where the definition of SCMS has been modified like the definition of availability of stock was “% of LHW who did not have logistics item available” , definition of opening stock balance was “% of LHW who did not have opening balance available for logistic item”. Even the DHIS does not give the clear picture of the stock status of tracer elements. Furthermore, the LMIS from health facilities was not web based. The LMIS program of LHWs does not report the stock status of Amoxicillin suspension and Zinc supplement.
4. In the public health supply chain system, frequent stock outs were reported. Medicines forecasting was based on consumption methodology which does not fulfill WHO recommendations. Khyber Pakhtunkhwa, however, has adopted mix method approach of medicines forecasting that is consumption + morbidity based forecasting. In Punjab, E-procurement cell has developed the medicines forecasting which is also based on consumption method. By and large, in the vertical program the reasons for stock out were common in all provinces.
5. Bulk orders were given to the prequalified manufacturers who were responsible to supply the medicines to all the districts simultaneously. The supplies, however, were not made within agreed time which was one of the contributing factors of stock out.
6. In Sindh, the medicines samples were not sent to the Drug Testing Lab for quality assurance on frequent basis. They assumed that prequalified manufacturers do not require laboratory analysis. Another reason was time required by the DTL for submission of analytical reports.
7. WHO and NEML 2016 recommend solid oral dosage form of Zinc in the treatment of Diarrhea rather Zinc syrup. In government procurement Zinc Syrup is common as compared to Zinc tablet that was only available at DHQ hospital Bahawalnagar Punjab. Commercially, this syrup was only available in large pharmacies. Zinc syrup contains sugar as sweetening agent which is not recommended by WHO in Diarrhea because it can cause osmotic Diarrhea and hypernatremia. The gap of availability of amoxicillin suspension was observed during the assessment.
8. The drug registration process takes 3 to 4 years. Commercial market of Amoxicillin DT and Zinc DT was not established yet. This situation, therefore, could not motivate manufacturer to take interest and get their product registered with DRAP. The drug law “Procedure for Registration of Drugs” clause 2. (v) states “Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.” And clause 2. (ix) further states “Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.”

1.6 CONCLUSION

1. The public health supply chain system was predominantly mixture of “push” and “pull” system. But in case of unavailability of demanded medicines it becomes “Push” system
2. The issues of report submission could be resolved with computerized inventory management system
3. During the process of LMIS and revised DHIS integration difficulties may occur. These difficulties may be due to different master sheets and SoPs of data entry and results.
4. The medicines forecasting and quantification should be based on the WHO recommendations to minimize the stock-outs.
5. The storage capacity of medicines at health facility level was not enough. The staff who is handling the pharmaceuticals needs WHO recommended technical knowledge.
6. The medicines distribution system from district warehouse to health facility were not based on any forecast criteria. Department of health does not have suitable vehicles for pharmaceutical transportation which creates hurdle in distribution plans
7. The process of prequalification of manufacturers was not up to the mark. It does not accurately judge the production capacity of manufacturers. Delays in supplies has been observed from manufacturers.

1.7 RECOMMENDATIONS

1.7.1 Immediate Recommendations

1. The inventory of medicines of health facilities should be managed by computerized inventory management system.
2. The medicines forecasting should be based on comparison of morbidity and consumption method.
3. Immediate steps should be taken for strengthening of DTL of Sindh; for quality assurance of medicines procured for public health facilities.
4. The basic technology for integration of LMIS with revised DHIS should be planned for comprehensive data mapping, system synchronization, software updates and aligned with continuous financial and technical support.
5. Based on WHO recommendations, Zinc DT should be used instead of Zinc syrup for the treatment of Diarrhea.
6. The distribution of medicines should be in the form of complete courses or Kits so that the STG should be followed.

1.7.2 Medium term Recommendations

1. Memorandum of Understanding (MoU) should be developed among stakeholders for daily data sharing interface between LMIS & revised DHIS.
2. During the consultation with the stakeholders, key performance indicators should be finalized and should be regularly monitored.

3. In integrated LMIS and DHIS, STG should be incorporated to develop an automated morbidity based method for medicines forecasting.
4. The process of registration of Amoxicillin DT and Co-packing of Lo-ORS and Zinc DT with DRAP should be considered according to the provisions of law; as stated in 2.(v) and 2.(ix).

1.7.3 Long term Recommendations

1. The software like “Prescription management Information System” has advantages over inventory management system but it should be modified and upgraded to computerized physician order entry software (CPOES) approach.
2. Considering the number of outpatients or services delivered from RHC, pharmacist should be provided for pharmaceutical activities.
3. The capacity of warehouses and technical knowledge of staff should be improved.



02

INTRODUCTION

02

INTRODUCTION

2.1 BACKGROUND

UNICEF and Bill and Melinda Gates Foundation established a partnership, to contribute to increase child survival in Pakistan. This goal was achieved by improving the diagnosis and treatment of Pneumonia and Diarrhea in children less than 5 years of age. The Project “**Accelerating policy change, translation and implementation for Pneumonia and Diarrhea commodities in Pakistan**”, aimed to implement the policies to ensure sustainable changes. The M.G. Foundation worked with close coordination with the Government of Pakistan and the relevant stakeholders. It had an overarching goal to ensure that relevant national policies are revised, understood, and adhered to in order to ensure quality treatment and availability of the essential commodities for improving management of childhood Diarrhea and Pneumonia and increasing child survival by the end of 2019. The project also focused on incorporating Pneumonia and Diarrhea management commodities into essential medicines lists and advocates for increased resource allocation for commodities; it also catalyzed the initial stages of the commodities procurement process with the government authorities and pharmaceutical manufacturing stakeholders. Moreover, the Foundation concentrated on updating and strengthening supply chain and logistics management systems to track the respective commodities. This was done to further supplement the planned work of the project. The commodity availability targets were developed to determine its success, and the results will be documented and disseminated as learning for contemporary in-country initiatives and long-term sustainability. The primary outcomes that are likely to be achieved through this project include the following:

Outcome 1: Policy Change

Existing national/provincial policies and guidelines are updated in line with global recommendations (WHO/GAPPD) for management of Diarrhea and Pneumonia; among children under five in Pakistan by the end of 2019.

Outcome 2: Policy Translation

Translation of the revised and updated Pneumonia and Diarrhea treatment guidelines, into relevant action plans, by all provincial/areas health departments, in Pakistan by the end of 2019.

Outcome 3: Policy Implementation

Availability of essential commodities such as Amoxicillin DT, Zinc DT, co-packed ORS and Zinc suspension, oxygen, ARI timers, and pulse oximeters. It was required for the treatment of childhood Pneumonia and Diarrhea in Pakistan by the end of 2019.

Outcome 4: Knowledge Management

Translation of lessons learned from this investment, to other settings/broader geographical areas within Pakistan. This four year Project has completed its first six months inception phase (Jan-June 2016). The implementation activities for this project are planned for the remaining period of 2016 and onward.



2.2 COUNTRY BACKGROUND

The Islamic Republic of Pakistan consists of Punjab, Sindh, Baluchistan, and Khyber Pakhtunkhwa, Azad Jammu and Kashmir (AJK), and the territories including FATA and province of Gilgit-Baltistan. The total land area of Pakistan is 796,095 km with an estimated population of 207.8 million². Approximately 64% of the population lives in rural areas (Economic survey of Pakistan, 2013-14, Pakistan Demographic and Health Survey 2012-13) The country is a lower-middle income country with a GDP of US \$ 1,368 per capita (Pakistan Economic Survey 2013-14).

2.3 PURPOSE

Pakistan has the third largest rate of maternal, fetal, and child mortality in the world³. As of 2010, the mortality rate of children under five (U5) is 89 deaths per 1,000 live births. This explains that one of the 11 Pakistani children does not survive to his fifth birthday. Acute respiratory infections (ARIs) and dehydration caused by severe Diarrhea are major causes of childhood mortality in Pakistan. Every year, approximately 91,000 children die from Pneumonia and 53,300 children death is caused due to Diarrhea. In total, Diarrhea, Pneumonia, collectively becomes the major cause of death among children in Pakistan⁴. According to Demographic Health Survey of Pakistan 2012-13, a less number of children are receiving appropriate treatment: only 38% of children suffering from Diarrhea receive adequate treatment with Oral Rehydration Solution (ORS) and only 1.5% receives Zinc; only half of children suffering from Pneumonia receive an appropriate antibiotic. Statistically, one out of nine children suffering from Diarrhea receives no treatment, and 59% receive no treatment for Pneumonia. The prevention of these illnesses; nevertheless, is ideal but it is critical to treat them correctly and timely.

Hence, the situation requires a focused revision of the high-level policies; strengthening the training and knowledge of the health care providers, supporting production and procurement of relevant commodities, and improving the supply and logistics systems to track commodity stock and utilization. This study is a corollary to the study on “Budgetary gap analysis of Diarrhea and Pneumonia commodities at provincial/region level”.

²Pakistan Bureau of Statistics Government of Pakistan 2017. <http://www.pbscensus.gov.pk/>

³Reproductive, maternal, newborn, and child health in Pakistan: challenges and opportunities: Health Transitions in Pakistan, The Lancet Volume 381, No. 9884, p2207-2218, 22 June 2013

⁴Interventions to address deaths from childhood Pneumonia and Diarrhea equitably: what works and at what cost? The Lancet, Volume 381, No. 9875, p. 1417-1429, 20 April 2013.

2.4 OBJECTIVES

The objectives of the analysis are as follows:

- Review the existing supply management system at National, Provincial, District and Sub district levels.
- To analyze the current supplies logistic system for Pneumonia and Diarrhea management, through in-depth situation analysis. For the public sector health facilities and the vertical programs dealing in management of Diarrhea and Pneumonia.
- To consult with key opinion leaders decision makers and other stake holders to discuss the existing logistic systems for the procurement and distribution of Pneumonia and Diarrhea medicines within the country especially in Sindh and Punjab provinces.
- To give practical and logical recommendations to the stakeholders on how to upgrade logistic management information system (LMIS); that can help in forecasting, procurement, inventory management, warehousing and distribution and also on linking of revised DHIS tools with LMIS.
- To review the process of registration of pharmaceutical items by Drug Regulatory Authority of Pakistan. It also aims to submit recommendations to get this process expedited for registration of essential drugs for management of Pneumonia and Diarrhea.
- To document all above objectives in detail with in-depth situation analysis.

2.5 SCOPE OF EVALUATION

In-depth situation analysis of commodities and supplies of logistic system at national, provincial, district and sub-district levels, related to Pneumonia and Diarrhea, has helped to determine the situation of SCMS. It also defines the existing policies and their relevance with recommendation of GAPPD, gaps in SCMS which include; product selection, situation of staffing, LMIS, forecasting & quantification, procurement, inventory management, warehousing, distribution of medicines, organizational support for logistics, rational utilization of drugs and situation analysis of private sector in Diarrhea and Pneumonia management.

The role of Public Private Partners (PPHI, IHS and HANDS) is strengthening of department of health. Strengthening of Public Private Partners was considered as strengths of concerned department of health. Individual assessment of PPPs was not included in the scope of the study.

2.6 INTENDED AUDIENCE

The intended audience includes policy makers, government officials, stakeholders and not-for-profit organizations who deal with strengthening and capacity building of SCMS and integration of LMIS with revised DHIS. Report will also facilitate those stakeholders and firms who require new product registration from DRAP.

2.7 STUDY'S CONTRIBUTION TO THE THEORY OF CHANGE FOR PNEUMONIA AND DIARRHEA PROJECT

- WHO has defined logistics as an art of supply and maintenance. It involves a scientific discipline and utilization of the management principles. Logistics for peripheral health facility as provision of activities including planning, budgeting, receiving and inspection, storage, inventory control, supply, distribution. Besides it includes the transportation, maintenance and repair, communications, environmental

management of health facilities, record and reporting, supervision and logistics training⁵.

In LMIC, lower buying power of patients, hinders the access to essential medicines; leading them to opt alternate therapies especially in rural areas. It has also observed, that inappropriate prescription and dispensing of medicines; creates the gaps to access the essential medicines⁶. WHO, described, that one of the key component of the functioning health system; is provision of access to affordable, appropriate and high quality medicines. The access of essential medicines; is the outcome of integration of finance, planning, service delivery, and information management and governance system⁷.

The studies conducted in different areas of Pakistan have also referred the issues of the supply chain management of medicines in public sector. The access to medicines is a big challenge for poor in Pakistan. One of the issues regarding the access to essential medicines, as reported in different studies; is, that the government spends very little on health sector. It has also been reported, that such issues include lack of policies legislation and regulation, wastage of resources, mismanagement, lack of knowledge and capacities and infrastructures etc.

The in-depth situation analysis of the supply chain management of medicines, will help in analyzing the SCM system of public sectors through WHO's recommended procedures and guidelines. The results of the analysis, will support the recommendations for policy or procedures change; to improve the access of essential Medicines to combat Diarrhea and Pneumonia.

2.8 RESEARCHER'S INTRODUCTION

The study has been conducted by Public health consultant who is pharmacist by profession. Previously he has worked for WHO, TRF plus, GAIN and other multinational pharmaceutical industries.

⁵Battersby, A., & World Health Organization. (1985). **How to assess health services logistics with particular reference to peripheral health facilities.**

⁶World Health Organization. (2008). **Medicine prices, availability, affordability and price components: a synthesis report of medicine price surveys undertaken in selected countries of the WHO Eastern Mediterranean Region.**

⁷World Health Organization. (2004). **WHO Medicines strategy 2004-2007: countries at the core.**

03

METHODOLOGY

03

METHODOLOGY

The methodology of assessment is mixed analysis that is quantitative and qualitative analysis. The quantitative analysis is based upon the Logistics System Assessment Tool (LSAT) developed by USAID Deliver Project and recommended by WHO⁸ for the assessment of logistics / supply chain management of medicines. As per the recommendation of LSAT for devolved health system, all provinces to be studied should be assessed separately; with recommended modifications of health service delivery levels, as described in the tool. The qualitative analysis is semi structured in-depth interviews based upon the desk review.

The provincial level assessment has been conducted for Sindh, Punjab, Baluchistan, KP and FATA. The district and sub-district level assessment has been conducted only for Sindh and Punjab because the project funding was for these two provinces. The other provinces were assessed for advocacy purpose.

The details of the methodology is as follows

3.1 PHASE I: METHODOLOGY FOR DESK REVIEW

The methodology adopted for the extraction of research papers from internet was as follows

TABLE 1: METHODOLOGY OF DESK REVIEW

Online Search	Search Terms	Research Inclusion Criteria
<p>Electronic databases searched: PubMed, Cochrane, Cinahal, WHOLIS, MSH, ELDIS, Google Scholar.</p> <p>Websites searched: Provincial Departments of Health, WHO Pakistan, WHO-EMRO and Pakistan Consumer Protection Network.</p>	<p>Pharmaceutical Supply Chain Management, Drug Supply and Pakistan, Rationale Drug Use and Pakistan; Drug Financing and Pakistan; Drug Affordability and Pakistan; Drug Access and Pakistan; Drug Availability and Pakistan; Drug Policy and Pakistan; Pharmaceutical Policy and Pakistan. Searches conducted during last five years period.</p>	<p>Primary research studies, reviews, case reports. Excluded: opinion pieces, commentary articles, bio-efficacy studies.</p> <p>Grey Literature: Policy Acts, Policy Guidelines, Policy or strategic frameworks, National formulary.</p>

⁸World Health Organization. (2010). **Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies** (p. 20). Geneva: World Health Organization.



Using the PubMed search engine “Pharmaceutical Supply Chain Management” 144 results were found, six from Cinahal and operational framework from WHOLIS. Abstracts and summary reports were reviewed. There were 86 studies that were further shortlisted for detailed study. Free full text researches and documents shared by government in their websites were studied and referred in the desk review. Complete desk review and references are shared in Annex 1.

3.2 PHASE II: METHODOLOGY OF DATA COLLECTION

The indicators for the assessment have been divided into following levels

- Assessment at National Level
- Assessment at Provincial Level
- Assessment at District and Sub-District Level

Following are the categories of the indicators based upon the LSAT Tool. As per the recommendations of LSAT the scoring of sub-indicators were modified for devolved healthcare system. A complete set of indicators of modified scores are attached in Annex 2.

TABLE 2: CATEGORIES OF INDICATORS

Section #	Categories of Indicators
1	Policy, Legislation and Regulation
2	Product Selection
3	Organization and Staffing
4	Logistic Management Information System
5	Forecasting
6	Obtaining Supplies / procurement
7	Inventory Control Procedures
8	Warehousing and Storage
9	Transport and Distribution
10	Organizational Support for Logistics
11	Product Use
12	Patient Exit Interviews
13	Private sector; Availability of services and medicines

3.2.1 Key Informants

The selection of key informant was based on the role of the informant in public health department. Special care was taken in selecting the most suitable person to respond to the questionnaire.

TABLE 3: LIST OF KEY INFORMANTS AT NATIONAL LEVEL

Sr. #	Key Informants	National Level
1	DRAP	X
2	EM WHO	X
3	MNHS R&C	X
4	Federal DG Health	X

TABLE 4: LIST OF KEY INFORMANTS AT PROVINCIAL LEVEL

Sr. #	Key Informants	Punjab	Sindh	KP	Baluchistan	AJK	FATA
1	DG Health	X	X	X	X	X	X
2	Director MSD	X			X		
3	Director IRMNCH & NP for FP & PHC	X	X	X	X	X	X
4	Chief Pharmacist (Purchase cell)	X	X	X	X	X	X
5	Store keepers	X	X	X	X	X	X
6	PPHI / HANDs / IHS		X				
7	Specialized Hospital / DHQs	X	X				

TABLE 5: LIST OF KEY INFORMANTS AT DISTRICT AND SUB-DISTRICT LEVELS

Sr. #	Key Informants	District Level				Sub-District Level			
		CEO / EDO (H)	Central Warehouse	Coordinator LHW Program or IRMNCH & NP	Warehouse or IRMNCH & NP	DHQ hospital	THQ hospital	RHC	BHU
1	CEO / DHO	X		X					
2	Head			X					
3	MS					X			
4	HF in-charge						X	X	X
5	Pharmacist		X			X	X		
6	Store keepers		X		X	X	X	X	X
7	LHW & CMW								X
8	Patient exit interview					X	X	X	X
9	Private sector doctor and pharmacy						X	X	X

3.2.2 Criteria for Selection of Districts

On the basis of the data of disease episodes provided by the Bureau of Statistics of Pakistan Multiple Indicator Cluster Survey (MICS) Sindh, 2014⁹ and the Multiple Indicator Cluster Survey Punjab, 2014¹⁰ following district has been selected for the assessment. For Sindh, the criteria for the selection of districts was as follows

- One district from each division has been selected for comprehensive review of supply chain management system of the province except in DG Khan Division of Punjab where an additional district (Rajapur) was selected on the request of the DoH.
- Districts showing high percentage of disease episodes of Diarrhea & ARI, for example, symptoms in MICS 2014.
- Districts administered through Health Department of Sindh, Public or private partnership, in order to get the comparative situation of supply chain management cycle.
- Good performing districts and bad performing districts; based on the treatment of Diarrhea and ARI, for example, symptoms taken from public sector.

TABLE 6: CRITERIA FOR SELECTION OF DISTRICTS

Province	Divisions	Districts	Percentage of episodes of	
			Diarrhea	ARI symptoms
Sindh	Larkana	Kashmore	32.4	16.9
	Sukkur	Sukkur	33.8	20.3
	Hyderabad	Tando Muhammad Khan	31.2	9.0
	Mirpur Khas	Tharparkar	23.4	9.5
	Karachi	Karachi Malir	28.8	10.8
	Shaheed Benazirabad	Shaheed Benazirabad	26.9	5.8
Punjab	Bahawalpur	Bhawalnagar	11.5	3.2
	DG Khan	Muzaffargarh	18.8	5.0
	DG Khan	Rajapur	22.8	5.5
	Sahiwal	Pakpattan	19.4	3.8

⁹Sindh Multiple Indicator Cluster Survey (MICS) 2014, Final Report. <http://sindhbos.gov.pk/wp-content/uploads/2014/09/01-Sindh-MICS-2014-Final-Report.pdf>

¹⁰Punjab Multiple Indicator Cluster Survey (MICS) 2014, Final Report. <http://www.bos.gov.pk/mics2014>

3.2.3 Public Health Facilities

A District Headquarter hospital, a Tehsil Headquarter Hospital, RHC and two BHUs have been visited to assess the medicines supply chain management system. The selection of BHUs was based on the distance from the central medicines distribution point, to assess the bottlenecks of medicines distribution and lead time.

3.2.4 Warehouses

Provincial central warehouse, district central warehouse, district warehouse of vertical program, health facilities medicine store of above mentioned districts have also been visited for the assessments of the storage conditions of medicines.

3.2.5 Patient Exit Interviews

Caretakers of the children with Diarrhea were interviewed to evaluate the provision of medicines and dispensing practices of the hospitals. Five caretakers of Pneumonia or Diarrhea patient from each health facility were planned.

3.2.6 Private Hospitals and Pharmacies

Five private practitioners and pharmacies were selected based upon the information provided by the respondents of households

3.2.7 Health Facilities & Warehouse visited

Apart from the provincial offices, sample size for the collection of the data was 64 including warehouses and health facilities out of which 38 from Sindh and 26 from Punjab were visited.

3.3 PHASE III: METHODOLOGY FOR ANALYSIS

The data of the quantitative indicators has been analyzed using LSAT analytical score. The LSAT recommended scores as mentioned in Annex 2

3.4 STUDY MANAGEMENT

The study was managed by the preparation of "Inception Report" which was reviewed by UNICEF and presented to stakeholders in quarterly meeting of "Technical Working Group on Child Survival". The suggestions were incorporated. The Government was taken on board for the collection of data. Official letters from the government were issued. Data was collected and analyzed. Draft report was presented to UNICEF which was reviewed internally and suggestions and comments were incorporated. Findings of the report were presented to the stakeholders in "National Technical Working Group on RMNCAH & N".

3.5 STUDY LIMITATIONS

The time for data collection and key informant interviews was limited. The patient exit interviews were limited to the availability of caretakers of patients at the time of assessment. As described in the scope of the study, the assessment was limited to department of health. The contributions of PPHI, IHS, HANDS and Micronutrient Initiative (now called Nutrition International) were considered as strengths of department of health. The district of Punjab in which Nutrition International was working was not included in the study. Their financial contributions were described in budgetary gap analysis study.

3.6 ETHICAL STANDARDS

The study will follow strict ethical guidelines associated with undertaking quantitative and qualitative research. The consent has been taken from key informants before starting the interview. During the interview socio-culture context were kept in view. No interviews were planned or conducted from children. The study has ensured that the research should not in any way harm the respondent. The report has not included any direct or indirect identification information of research participants. All ethical standards of UNICEF were followed.

04

RESULTS & ANALYSIS

04

RESULTS & ANALYSIS

The main focus of the assessment findings were Policy, legislation and regulation, Product selection, Organization and Staffing, Logistics management information System, Forecasting, Procurement, Inventory management, Warehousing. Moreover, the assessment of storage, Transportation & Distribution, Organizational support for logistics and Rational utilization of medicines, registration of new formulations of amoxicillin dispersible tablet with Drug Regulator Authority of Pakistan. The major findings of the assessment were as follows.

1) National Essential Medicines List:

Pakistan has National Essential list based on which provincial EML were prepared. Provinces have procurement rules of medicines which restrict the DoH to procure the medicines only from the Provincial Essential Medicines List, or, if required, from NEML. The strict rules for medicines selection from NEML, have strengthened the product selection of SCMS.

2) Logistic Management Information System:

The status of LMIS was more or less similar in Sindh and Punjab. The situation of vertical program was also same in both provinces.

3) Forecasting:

The quality of forecasting is based on the availability of data. The impact of LMIS on forecasting gave the same results.

4) Procurement:

At the districts of Sindh and Punjab, procurement process was similar LSAT scoring that is 53%. While the score of Specialized healthcare and medical education (SH&ME), was 70%, which was the highest percentage in the public sector.

5) Inventory control:

The inventory control procedures of SH&ME hospitals i.e. DHQs of Punjab has shown better results of assessment that is 92%. It was mainly due to the development and implementation of medicines Inventory management software. The situation of the districts in Punjab was also better; due to the introduction of e-procurement system.

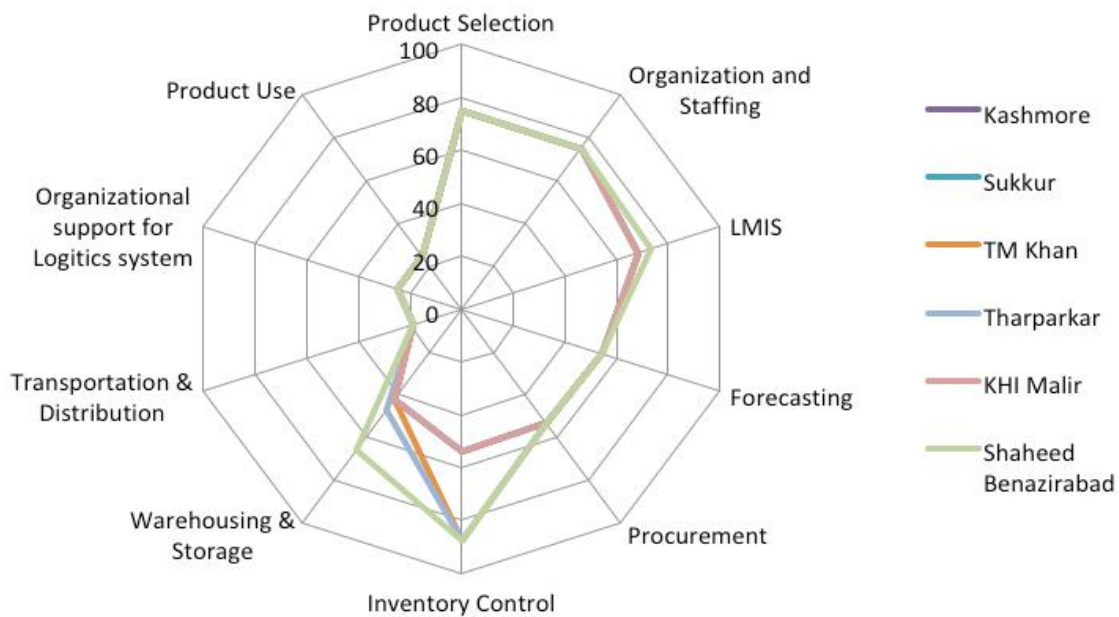
6) IRMNCH & NP:

IRMNCH & NP has totally changed the routine method of medicines distribution. They had outsourced the transportation process of medicines to a courier company.



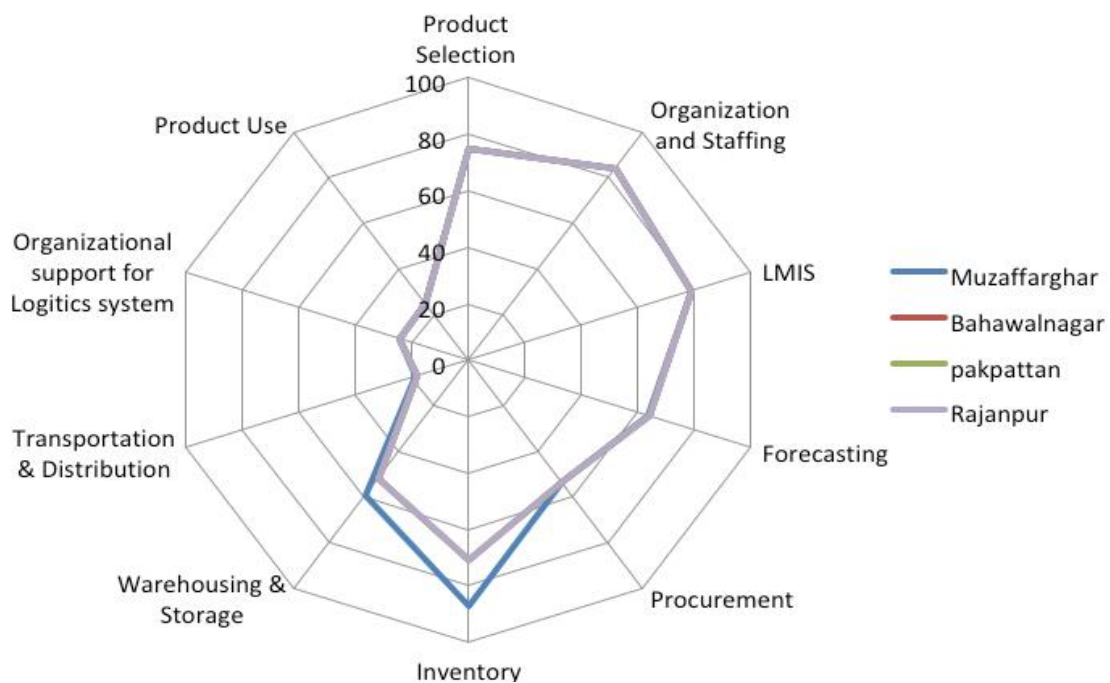
GRAPH 1: COMPARISON OF LOGISTICS SYSTEM OF DEPARTMENT OF HEALTH AMONG DISTRICTS OF SINDH

Comparison of Logistics Systems among Districts in Sindh



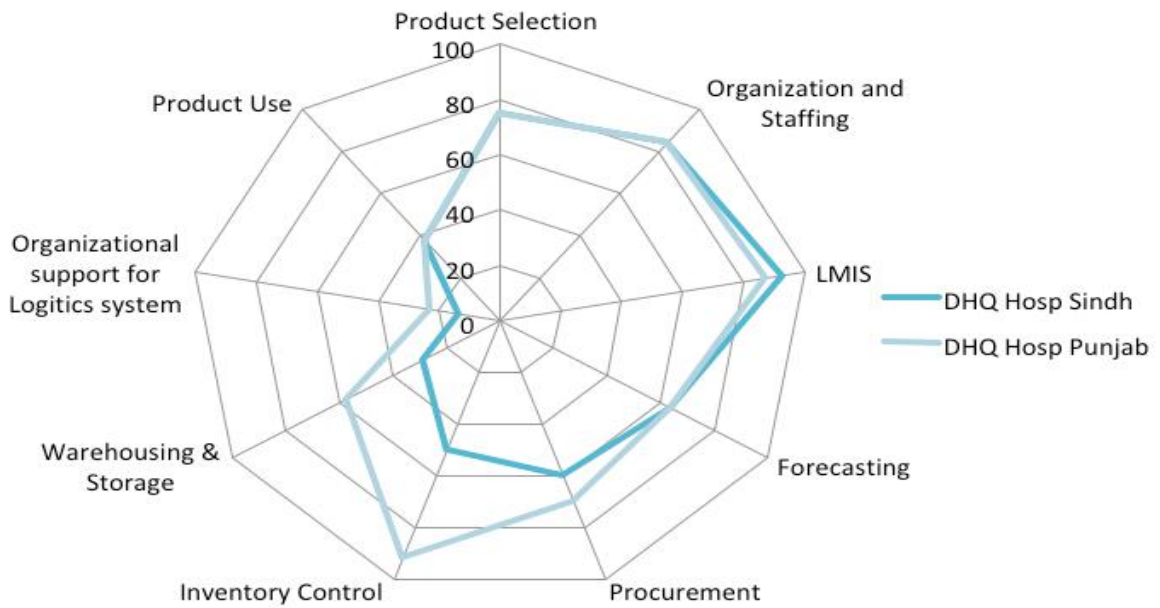
GRAPH 2: COMPARISON OF LOGISTICS SYSTEM OF P&SHD AMONG DISTRICTS OF PUNJAB

Comparison of Logistics Systems among Districts of Punjab



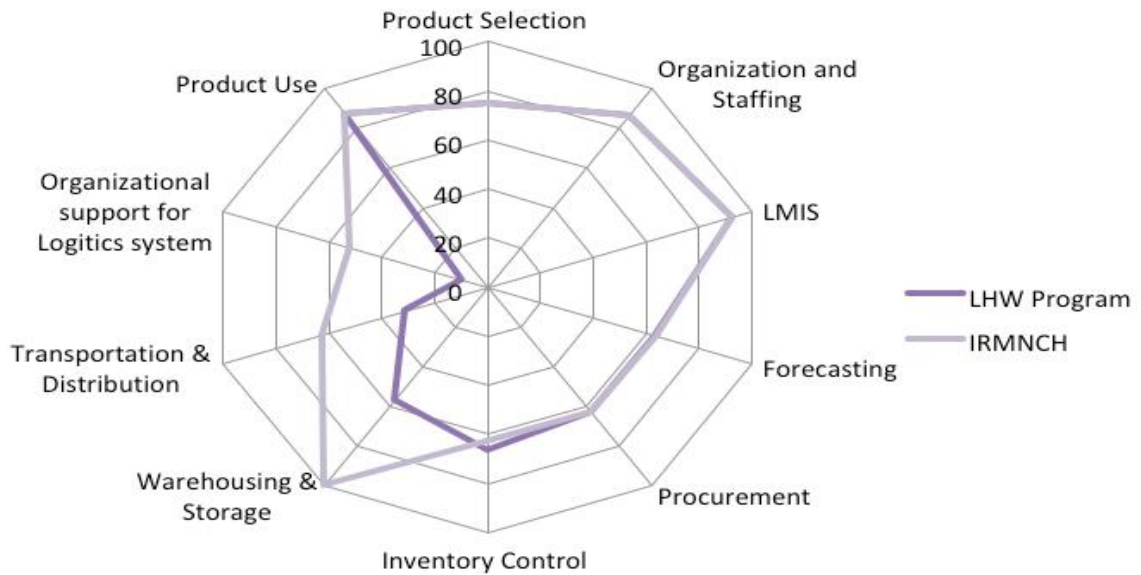
GRAPH 3: COMPARISON OF LOGISTICS SYSTEM OF DHQ HOSPITALS OF SINDH AND PUNJAB

Comparison of Logistics System of DHQ Hospitals of Punjab and Sindh



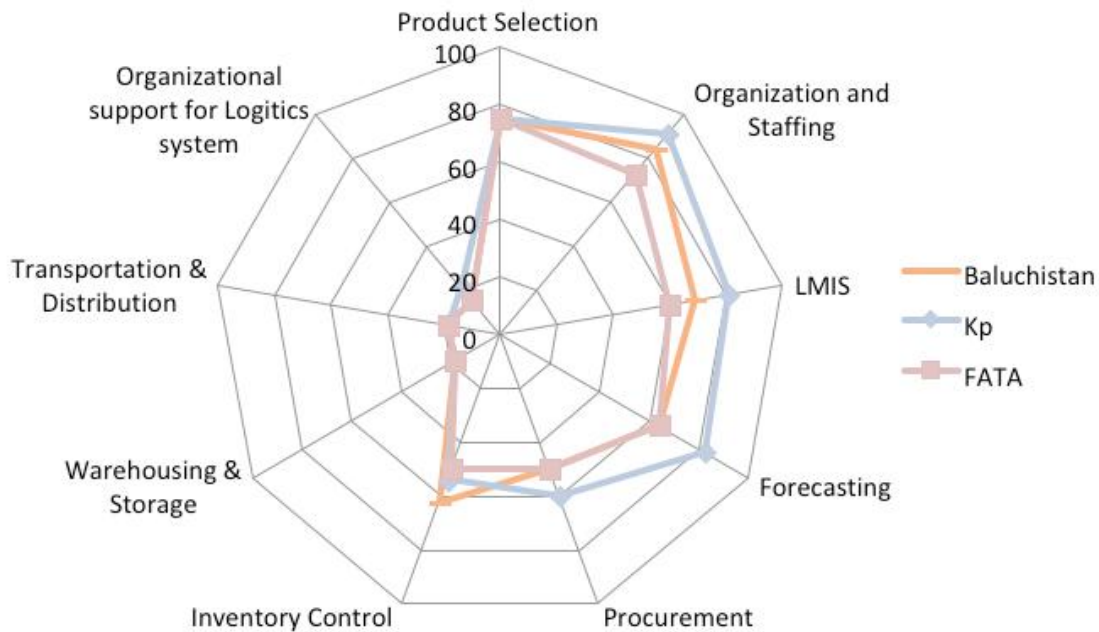
GRAPH 4: COMPARISON OF LOGISTICS SYSTEM BETWEEN NP FP&PHS AND IRMNCH&NP

Comparison of Logistics Systems among Districts of Punjab



GRAPH 5: LOGISTICS SYSTEM OF BALUCHISTAN, KP AND FATA

Logistics System of Baluchistan, KP and FATA



4.1 DRUG REGISTRATION PROCESS FOR LOCAL PRODUCTION

Diarrhea and Pneumonia are major causes of mortality among children under five in Pakistan. The availability of first line therapy, is one of the major challenges to the management of such diseases. Pharmaceutical industry is one of the growing industries of Pakistan.

The medicine essential for the management of these diseases are

- i. Low osmolarity ORS already registered and frequent in production.
- ii. Zinc Dispersible Tablet already registered but not frequent in commercial market
- iii. Amoxicillin Dispersible tablet not registered in Pakistan
- iv. Co-packing of Low osmolarity ORS and Zinc Tablet not registered in Pakistan.

The production of Lo-ORS and Zinc DT is easily available, while the drugs like, amoxicillin DT and Co-packaging, required registration with Drug Regulatory Authority of Pakistan (DRAP) for local production. Any manufacturing industry having capacity to manufacture “tablet” and “powder” can apply for the registration of co-pack.

Drug Act 1976, regulates the import, manufacture, storage distribution and sale of the drugs. These drugs are registered under section 7 of drug act 1976. Registration board is the authority of registration of drug.

It was observed that period of 3-4 years is required by the DRAP for the completion of registration. Already many applications, committee meetings, industrial inspections are still pending and the number is increasing day by day. For the registration of these medicines, the shortest possible time and the helpful provision of rules of drug registration should be considered. These rules are described in clause 2 (v) and 2 (ix).

Recently 7.1% chlorhexidine digluconate gel has been registered with DRAP. The process of registration was based on the morbidity needs which were described by the UNICEF. Details of the process has been shared by DRAP in minutes for 247th meeting of Registration Board held on 4th February 2015¹¹. The process of the registration of the Drugs is briefly described here; while detail is mentioned in Annex 3.

Clause 2. (V)

The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions: Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.

Clause 2. (IX)

Where it is necessary in the public interest, so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

4.1.1.1 Steps for registration of new formulation

1. The process of registration, for the new formulation, particularly Amoxicillin DT and packaging of ORS & Zinc supplementation consists of the following steps: Collection of reference material, preparing the desk review of impact analysis of Amoxicillin DT and ORS and Zinc co-packaging in other countries.
2. It also involves the consultation with Pharmaceutical Bureau, Pharmaceutical Manufacturing Association, Research & development of DRAP and other stakeholders, for preparation of comparative study of different formulation of the subjected medicines in Pakistan. The stakeholders include UNICEF, WHO, R & D of DRAP, Health Department of all Provinces, Pharmaceutical Bureau, Pharmaceutical Manufacturing Association of Pakistan, Pakistan Pharmacist Association, United State Pharmacopeia Pakistan and Nutrition International.
3. With consultation of PMA, selection of those pharmaceutical industries that are already registered with DRAP for manufacturing of Zinc DT and ORS for Co-packaging of ORS and Zinc supplementation. Amoxicillin DT needs bilateral discussion with DRAP and other stakeholders.
4. Preparation of bilateral meeting documents including invitation letters agenda, and studies, that has to be shared with participant etc.
5. Coordinate lobbying / Advocacy Bilateral meeting
6. Submission of final report of lobbying / Advocacy bilateral meeting (including minutes, conclusion and recommendations)

4.1.1.2 Potential Manufacturer for Registration

In discussion with Pakistan Pharmaceutical Manufacturers Association (PPMA), a manufacturer has been introduced, who is interested in registration of Co-package of ORS and Zinc DT and Amoxicillin DT. The manufacturer was already registered for Zinc DT with DRAP and soon they will receive the registration of ORS.

¹¹Minutes of 247th Meeting, Registration Board held on 04th February, 2015.

4.2 FINDINGS

4.2.1 Section I: Policy, Legislation and Regulation

Pakistan has National Drug Policy, but does not clarify the duty taxes on import of donated items. The SRO notification of Government of Pakistan through DRAP, MNHS R&C, explains the exemption of the duty and taxes on import of drugs for donation in Gazette of Pakistan.

The law and regulation of Pakistan promotes the local manufacturing of medicines, rather than, the import of finished drug from other countries; but in public interest, the import is allowed. The drug policy encourages the access of medicines at health service delivery sites. It also promotes or encourages the access of patient for utilizing the services by improving the availability of medicines at HF. In Punjab, on the other hand, public awareness has also been created through TV and print media. Provincial details are as follows

4.2.2 Section II: Product Selection

The product selection of medicines for procurement and availability at the service delivery site were based on the National Essential Medicines. All the products except Zinc solid oral dosage form selected for the procurement were from National Essential Medicines List, which was available on official website of DRAP. NEML, has been used for the development of provincial essential medicines list, and the list of medicines for central rate contract. The criteria for the selection of any product for essential medicines list, was WHO recommendations and disease burden. It has been observed that Zinc syrup was procured rather Zinc solid oral dosage form. The essential packages for health services were available for Punjab, Sindh and Khyber Pakhtunkhwa. The services included in EPHS were: Immunization, Antenatal , Natal and Postnatal care, Inter-natal care, prevention of STI and RTI, FP service, Major Micronutrient deficiencies, mental health, screening, outreach services for all levels of health facilities. The survey conducted, was primarily for assessment of Diarrhea and Pneumonia medicines which include ORS, Zinc supplementation, and Amoxicillin suspension which were part of essential medicines list for all the provinces.

Diarrhea and Pneumonia are vaccine preventable diseases. Rota virus was the major contributor of deaths of children suffering from Diarrhea in Pakistan. In Punjab vaccine for Rota virus and Pneumonia were included in routine EPI while in Sindh Pneumonia vaccine is included in routine EPI.

4.2.3 Section III: Organization and Staffing

Logistics Management Unit (LMU):

According to WHO, LMU, is a management structure that can be used to organize, monitor and support all the activities within the logistics system. Through the lens of continuous improvement; LMU identifies the Supply Chain problems, develop solutions and implement those interventions. LMU is an important link between the different organizations, levels, and actors within the supply chain.

LMU were available in all provinces. It was responsible for managing and using the logistics management information system, forecasting, procurement, inventory management and distribution. The selection of product was in consultation with the Districts. It was also responsible for the supervision and development of logistics staff.

- Although, at the provincial level, the activities were facilitated by specific units, for the procurement of the medicines; like: Procurement cell / Procurement Committee in all provinces and Medicines Coordination Cell like the one in KP. The key logistics tasks were assigned to either of it. The activities used to coordinate key logistics tasks among those responsible for logistics were official letters, meeting and joint work plans etc.
- Such staff members (who are employed for other departments and had other departmental responsibilities as well) had to perform logistics tasks. It was observed, that the system lacks the dedicated HR, to carry out key logistics task with powers and authority and make prompt decisions. The logistics activities could be best performed by a qualified person with pharmaceutical as well as SCM knowledge. The DHQs hospitals, were facilitated with the sufficient number of Pharmacists. It was, therefore, observed that the logistics system was better at DHQs as compared to the hospitals like RHCs, where the pharmacist was not available. The vertical programs have dedicated logisticians but SCM tasks were not achieved. It was observed that Standard Operating Procedures were also not available at all service delivery levels. The logistics system has one year plan in all provinces. The smooth functioning of the supply chain system was affected by transporters strikes, resulting in the delays of supplies from manufacturers and eventually, it led to the delay in the budget release.

Sindh:

LMU was available at provincial level but it was not integrated as in Punjab. It was fully responsible for managing and using LMIS, procurement, inventory management, product selection, supervision and logistics staff development. The product selection and forecasting were mainly done at district level under the supervision of DHOs. A single line budget was available with DHO and some HF who could exercise DDO authority. . They are capable of managing their logistics budget from it. Health facilities with DDO power also have single line budget.

- SoP or guidelines for medicines forecasting and quantifications were not provided at the district levels.
- The Central Level Position, dedicated for logistics is mainly in the district. The logistics officers can exercise the same authority as any other functional unit head can.
- The logistics responsibilities were managed by DHO, store keeper at the district level while at DHQ Hospital there are Hospital Pharmacist and Store Keepers.
- The Public Private Partners (PPHI, IHS and HANDS) of the Sindh, have LMUs, which were indirectly supporting the government health facilities within their scope of work as described in their contracts. In Sindh, almost all the BHUs are handled by PPP except in the District Shaheed Benazirabad and Karachi. They facilitated the government for the product selection, forecasting, procurement, distribution inventory management, storage, staffing for logistics, financing for logistics and supervision. The government of Sindh procures medicines for THQ / RHCs (not handed over to IHS). As PPP, is facilitating the government so their strengths and capacities were reflected as government services. Their SCM activities were under the supervision of the dedicated logistics staff, showing best performance in their work. Although, they are facilitating the government, in terms of services and access to medicines. All indicators, were applied on these organizations as well, in order to explore the strengths of the system and to compare it with the government supply chain system. Such comparisons will help the government to adopt the strengths of service delivery standards; so that, at the time of exit of PPP service delivery, the standards will remain the same, especially in terms of SCMS.

Punjab:

LMU comprises “e-Procurement and Inventory Management Unit” which was an integrated system of medicines procurement. It has established central level position of logistics management in which districts procurement, drug testing labs and prequalified manufactures were involved. It also facilitates the medicines forecasting or preparation of rational demand based on the availability of the budget and the manufacturer’s capacity. The responsibilities of logistics, other than procurement, such as, inventory management, staffing and the product selection were served by the district team, under the supervision of CEO.

- SoP of medicines forecasting and quantification (based on WHO guidelines) has been provided to all districts through PSPU with the support of TRF plus in the form of forecasting and quantification tool. While after the establishment of Primary and Secondary healthcare Department, the system has been modified and incorporated in the e-procurement.
- The activities used to coordinate key logistics tasks, besides those responsible for logistics were official letters, meeting including online meetings and joint work plans.
- In DHQs, mainly Pharmacist was responsible for logistics management, while hiring of logistics officers at DHQ and THQ was in progress.

Balochistan:

MSD and PPHI collectively takes the responsibility of LMU. The role of MSD in the procurement of medicines while rest of all the responsibilities like distribution, inventory management etc. has been done by PPHI.

- The MSD, acts as central level position for the procurement of medicines, while handling and inventory management is being done by the store keepers.

Khyber Pakhtunkhwa:

In Khyber Pakhtunkhwa, at provincial level, LUM was Procurement cell and Medicines Coordination cell (MCC). The districts were facilitated with logistics staff.

- The MCC, provides the central rate contract list of prequalified manufacturers, while the product selection and forecasting is done at districts level. Handling, inventory management and warehousing is mainly done by logistics officers and storekeepers at district level.
- The logistics officers have the same level of authorities for decision making as the other functional unit heads

FATA:

The procurement is managed by procurement committee / cell. Forecasting of medicines is consumption based, which does not fulfill the WHO recommendations.

The central level position of logistics is managed at agencies. The activities used to coordinate key logistics tasks among those responsible for logistics were official letters and meeting. The key logistics positions were DHO and Store Keeper, Agency, and the Store keepers.

FP&PHS / IRMCNH & NP

- The vertical programs have already selected products, so there is no role of LMU in selection of products. The activities used to coordinate key logistics tasks among those responsible for logistics were official letters, meeting and work plans. The logistics staff include Logistics Coordinator at provincial level, the Store Keeper at District level,
- In Punjab IRMNCH & NP has recently modified the SCM system and quantities of medicines for LHWs have increased. In future, Forecasting will be based on the updates of the modified quantities. The distribution of medicines has been planned through courier/ parcel system.

4.2.4 Section IV: Logistics management Information System (LMIS)

The logistics Management Information System in Public health facilities was manual and computerized. The computerized system does not show the complete flow of medicines; from the receiving till the consumption. In different provinces different efforts were made to get maximum information of the logistics management.

In all provinces DHIS gave the information of stock out status of tracer elements at health facilities. DHIS provides the status of stock out only in yes and no format. This is not sufficient as it should also provide information of stock levels. Due to an incomplete information stock status (functional stock out) were not reported. Vaccine LMIS (vLMIS) was available but data was not updated regularly from all districts.

In Sindh manual LMIS was implemented which gave the information of stock procured, issued etc. The sharing of manual stock reports; from HF to the District level was not regular. The health facilities should also be monitored to get actual situation of stocks.

In Punjab, Specialized Healthcare and Medical Education Department has developed a web based computerized software for medicines inventory management at teaching hospitals, DHQs etc. this software gave real time stock status. The software shares information of status of stock outs, near expiry medicines, stock in hand, stock issuance etc. with all logins.

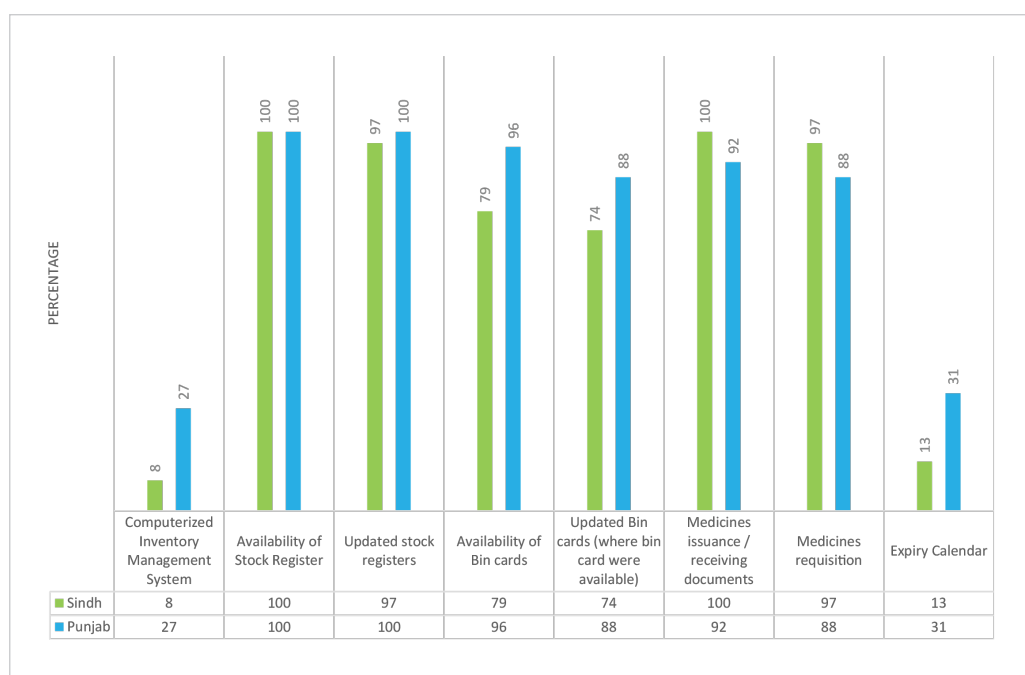
Health Information and Service Delivery Unit has launched Primary and Secondary Healthcare department. At the time of assessment, it was observed that online information including HR, logistics information of vaccines, contraceptive, TB, Information of DHIS etc. were shared at one dashboard. It was reported, that their next phase will be interlinking information from all segments, and making it more useful and result oriented. HISDU has also prepared a "Prescription Management Information System" which will track the medicines record from the receiving till the issuance to the patient. It will also link with inventory management system.

Simultaneously, the stock status was also monitored by Monitoring and Evaluation Assistants (MEAs) and they prepare monthly report of the stock status of very essential / tracer elements. The Health department, rely more on the reports of MEAs because it was considered as an external evaluation / physical count of stock status. This report indicates overall performance of health facility.

Vertical programs i.e. FP&PHS and IRMNCH & NP have their own MIS covering specific indicators and they depend more on their MIS rather DHIS. The LHW program reporting mechanism is both manual and computerized.

Ideally, the information provided by the LMIS; should be compiled and performed as automated functions of logistics activities. As observed the LMIS / DHIS / MIS focused the stock out status and report. There must be more automated systems to support the forecasting, resupply, transportation, monitoring of medicines dispensed to the patients as per WHO standards.

STATUS OF INVENTORY CONTROL IN SELECTED DISTRICTS OF SINDH AND PUNJAB



4.2.5 Section V: Forecasting

It has been observed that methodology adopted for the medicines forecasting and quantification was consumption based, in which, there was no adjustments of days of stock out. Stock for lead time, and time required for the laboratory analysis were not included. Buffer stock was considered; but the methodology for calculation of buffer stock was not correct. Review period for the forecasting was one year; which caters the seasonal variations. It was also observed, that the irrational use of medicines was due to the unavailability (stock out) of first line therapy which not only creates financial burden, but also was not appreciated and recommended by WHO. The activity of medicines forecasting requires financial support; it also depends on how much data is required to be collected and analyzed. It is one of the hidden costs of the supply chain management system. It was also discovered, that medicines forecasting need proper budget allocation. This situation was observed in all districts of Sindh, Punjab, Baluchistan, KP and FATA.

In Punjab, the Primary and secondary Healthcare Department has developed e-Procurement system, which is organized through software developed by Punjab Information Technology Board. It is a system through which the medicines were forecasted, based on the consumption based methodology provided by Policy and Strategic Planning Unit (PSPU). The system has improved the availability of medicines in tertiary care hospitals / teaching hospitals. The need to compare the consumption based methodology with morbidity based forecasting is still required to promote the rational utilization of medicines.

In Khyber Pakhtunkhwa, particularly in Health department, the medicines forecasting became a part of their agenda. They had developed the computerized tool for medicines forecasting and quantification. This tool developed for KP health department was able to conduct forecasting of all health facilities, with both techniques i.e. morbidity and consumption method based on WHO recommendations. It was observed that the data provided by the DHIS for morbidity

based forecasting and quantification had limitations which created hurdles for the morbidity based medicines forecasting and quantification methodology.

In Sindh, the Public private partners (PPHI, IHS, and HANDS), considered the importance of morbidity based forecasting and quantification. As per the recommendation of WHO, if there were no stock out, consumption based methodology can also be applied. The comparison of morbidity, consumption based method of forecasting and quantification; promotes the rational utilization of medicines. It was observed that PPP compared the consumption based and morbidity based forecasted data. Such techniques should be shared with the government staff for the capacity building.

4.2.6 Section VI: Obtaining Supplies/Procurement

Procurement is the process of purchasing supplies; directly from national or multinational, private or public supplier.

Procurement of medicines in public sector followed the government procurement rules. For larger quantities, the process of bids was followed. The bidding process is based on the estimated quantities from the districts. While with the estimating budget, special care is required for procurement of the medicine and equipment. This includes the actual expenditure incurred from Jan to May 2017, and the estimated needs for the remaining days of May & June, 2017. This will cater to the immediate need of payments, required for the medicine, procured at provincial level in “centralized procurement” mode. Following the government rules, the technical specification and financial specifications were acknowledged. The lowest bidders were contracted for the supply of medicines. It is stated, that the quality of the products should be according to the standards of drug act.

In Sindh: According to the “Bid Documents for Procurement of drugs by procuring agencies of Sindh,” in General Condition, it is stated that the chemical and physical examination of medicines shall be carried out through the provincial drug testing laboratories.

It has been observed and reported by health department Sindh; that the provincial drug testing laboratory is not properly functioning, hence, according to the government procurement rules “the batch release certificate” for test analysis report of quality control / quality assurance department, the manufacturers have to be relied upon.

Similarly, based on this situation, most of the public health facilities did not send their samples for quality assurance. The health facilities reported, that they have procured the medicines from prequalified firms or manufacturers, so the document was not required. And if they are required to send the document for DTL, then there will be more delay in availability of the medicines.

In Punjab: All the samples of medicines were sent to Drug Testing laboratories. In Punjab, particularly, there were five drug testing laboratories established at divisional level by the department of health; which covers the analytical requirements. The payments of the medicines were only made, when districts or hospitals receive the satisfactory reports from these laboratories.

In Punjab, it was witnessed, that despite putting in a lot of efforts in this case, the selection of the brand leaders, development of the new strategies for procurement, efficient follow up for pipe line status of orders, increase in budget to meet the gaps, timely submission of reports from DTL, timely payments to the manufacturer; an unacceptable delay in supplies

was observed due to which health facilities were in very bad shape. So much so that even the CEOs of the companies were expecting that if the manufacturers do not supply the medicine in time, there were high chances that the budget for procurement of the medicines will lapse. The prequalified manufacturer has less manufacturing capacities. During the visits of private pharmacies, in private sector, it was observed that there was no delay in the supplies of same manufacturer (GSK for Amoxicillin suspension). It shows that these brand leaders have more interest in their regular market.

Such attitudes of the manufacturers were also reported from Sindh province.

Balochistan: Central procurement system was introduced to ensure the procurement of quality products.

Note: It has also been noted that the IHS has been contracted as PPP for RHCs but their budget has not been released due to which the supply of medicines was affected. IHS has made an initial supply from their own budget. This needs to be replenished with the committed budget, for smooth operations of health facilities.

4.2.7 Section VII: Inventory Control

The Inventory control or inventory management is heart of pharmaceutical management system. It has been observed that the inventory management was considered as the simplest method, based on the receipt, store and issuance of medicines and record. The inventory control or management was not effective; mainly, due to the lack of pharmaceutical management knowledge or lack of qualified person i.e. pharmacist. One of the outputs of proper inventory management system is to create a reasonable balance between holding cost on the one hand and purchasing and shortage cost on the other. It could be achieved by applying the techniques, like; establishing minimum and maximum stock levels, establishing the reorder levels and determining how much to reorder. Organizing the data in effective manner supports the LMIS.

In Sindh, the inventory management system, used in public health facilities has shown many deficiencies in which push system of supplies was mostly observed. The medicines were distributed, based on the availability and request from HFs, rather than need. Most of the record keeping was manual and even the manual records were not fully updated. The concept and importance of bin cards were not fully understood. In some health facilities, either these bin cards were missing and in some, if available, were not updated. BHU Jaffer e Teyar of District Karachi Malir, stock register was not updated for Amoxicillin suspension. Moreover, the requisition for medicines was submitted with wrong information of physical quantities. In medicines requisition, stock in hand was reported as zero while physically bottles of Amoxicillin suspension were present in the health facility.

In Punjab, minimum stock level of tracer medicines for health facility has been established for the monitoring of MEAs which was considered as stock sufficient for next 45 days. The calculation for the average monthly consumption, was not dealing with all the WHO recommendation; but it helped in improving the availability of the stock in health facilities. The inventory control is required to balance the minimum and maximum stock levels. It was also reported that the excess stock of Amoxicillin suspension was distributed from Muzaffargarh. The e-procurement system, total maximum limit for the district was defined; because if the procurement exceeded the forecasted quantities, it was not possible to manage it with available budgets. In National program, and IRMNCH & NP, the minimum and maximum levels were demarcated. The Specialized healthcare

& Medical Education department has established its own medicines inventory management software, which gives the real time data of the health facilities under its supervision.

The **PPP**: The holding cost was managed by increasing the number of supply; which not only saved the holding and procurement cost but also the distribution or transportation cost. It provided sufficient space to organize the stocks in small store of public health facilities, especially in BHUS.

STOCK AVAILABILITY STATUS AT THE HEALTH FACILITIES DURING ASSESSMENT:

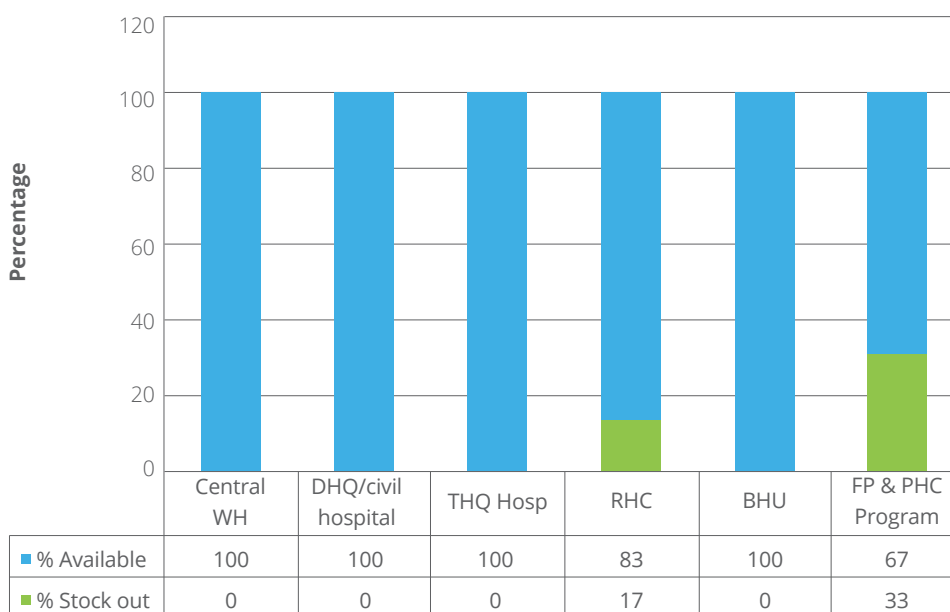
Any health facility that faced even a single day of stock out during one year period was considered as stock out. Even, at the time of assessment, the stocks were available but during one year period health facility faced the condition of stock out was reported under the stock out. It has been observed that the stocks of ORS were comparatively better than Amoxicillin and Zinc Supplementation. Mostly the stock outs were observed with LHW program.

Based on the observations during assessment following percentage of stock availability has been recorded. The total number of sample size was 50 out of which 38 service delivery levels were observed in Sindh and 26 were visited in Punjab. During the discussion with provincial managers of Sindh it was informed that procurement of all medicines were under process and within one month period the stocks will be available at the district levels.

Details are mentioned in graphs below:

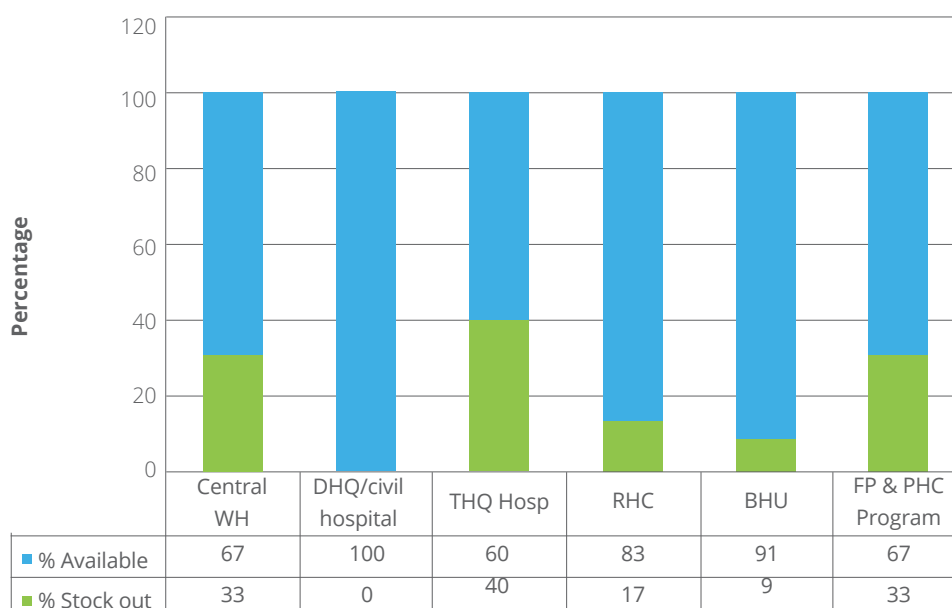
GRAPH 6: STOCK OUT STATUS OF ORS IN SELECTED DISTRICTS OF SINDH

Stock out status of ORS in Selected Districts of Sindh



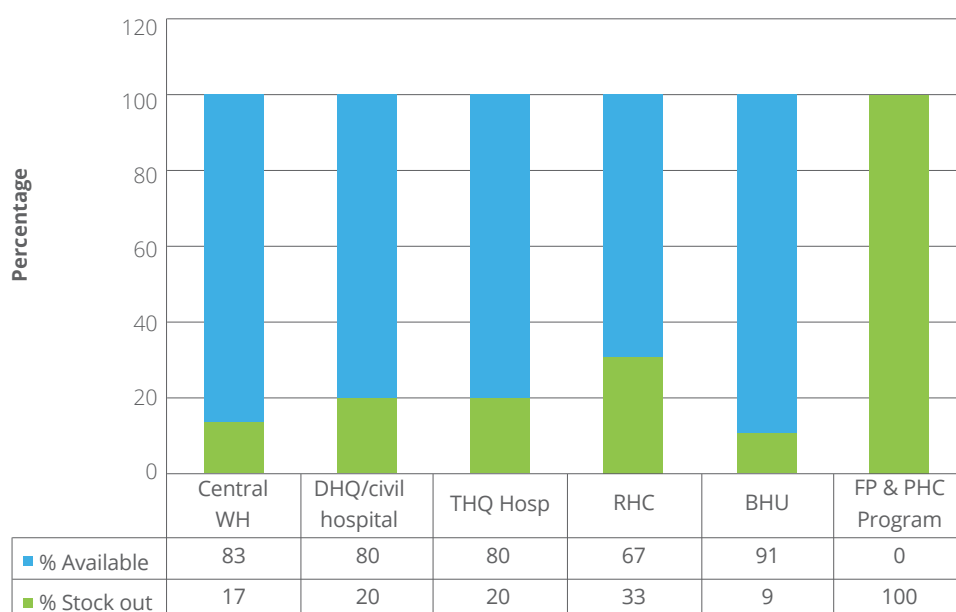
GRAPH 7: STOCK OUT STATUS OF ZINC SYRUP IN SELECTED DISTRICTS OF SINDH

Stock out status of Zinc Syrup in Selected Districts of Sindh



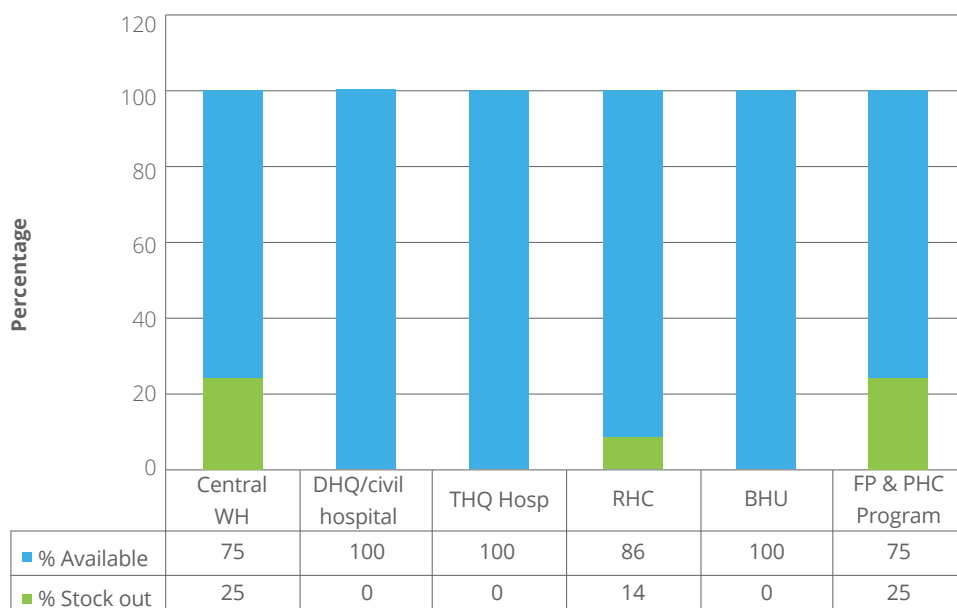
GRAPH 8: STOCK OUT STATUS OF AMOXICILLIN SUSPENSION IN SELECTED DISTRICT OF SINDH

Stock out status of Amoxicillin Suspension in Selected Districts of Sindh



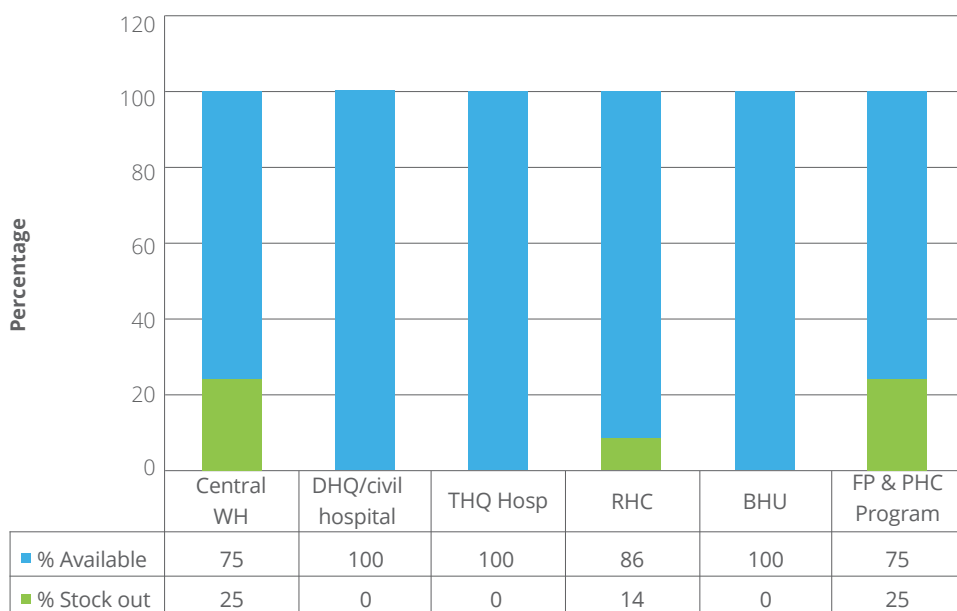
GRAPH 9: STOCK OUT STATUS OF ORS IN SELECTED DISTRICTS OF PUNJAB

Stock out status of Amoxicillin Suspension in Selected Districts of Punjab



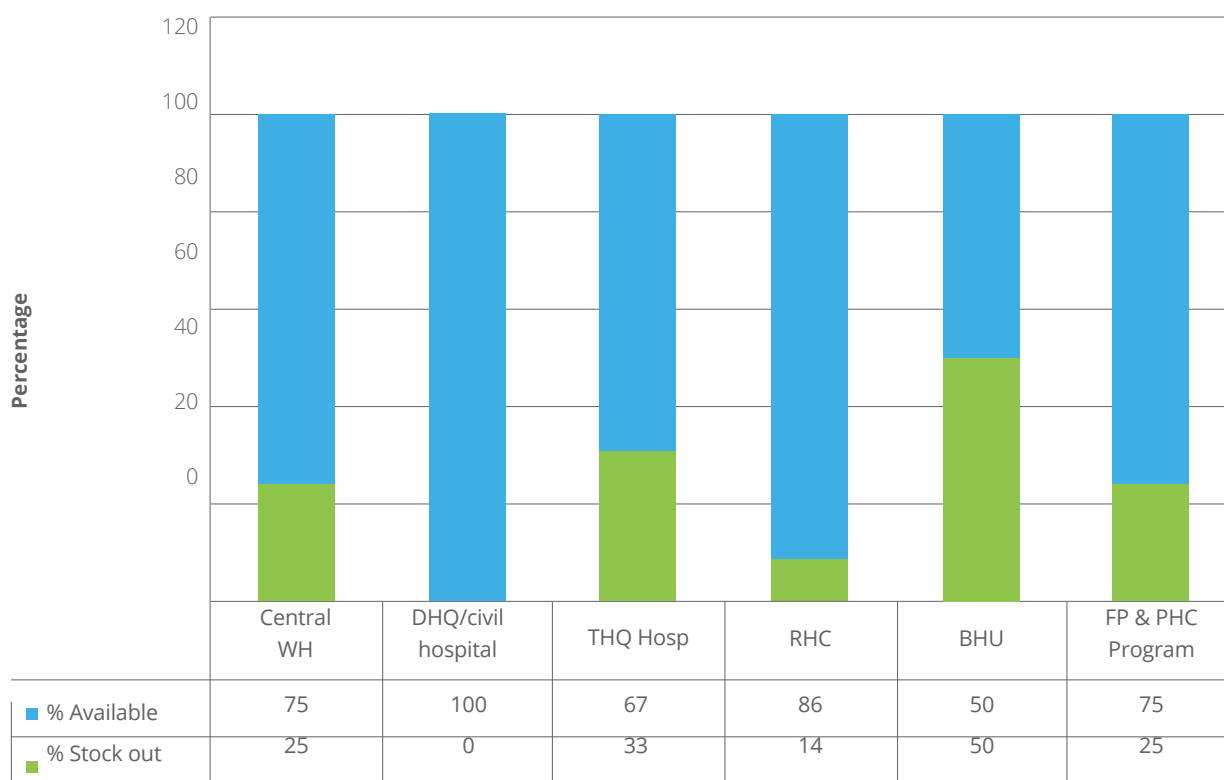
GRAPH 10: STOCK OUT STATUS OF ZINC SUPPLEMENTATION IN SELECTED DISTRICTS OF PUNJAB

Stock out status of Amoxicillin Suspension in Selected Districts of Punjab



GRAPH 11: STOCK OUT STATUS OF AMOXICILLIN SUSPENSION IN PUNJAB

Stock out status of ORS in selected districts of Punjab



4.2.8 Section VIII: Warehousing and Storage

The storage condition of the medicines has great impact on the service delivery. Among the storage conditions, the size of the store or warehouse has great importance. The availability of temperature controlling equipments like fridge and AC for maintaining room temperate, directly affects the efficacy of the products. The availability of racks, pallets, thermometers, fire extinguishers are essential for the storage of medicines.

The storage conditions of public health facilities need improvement. It includes the improved knowledge of the staff and the storage condition etc. Although, the Punjab health departments have improved the storage conditions and equipment like AC, fridge etc. have been provided. Such facilities were only provided at district level while the BHUs or RHC store also have need of these equipment. Vaccine was stored in recommended conditions. Chillers were provided at district level and ILR were provided at health facility level. Vaccine carrier boxes and ice packs were also provided to ensure the cool chain.

The government of Sindh, has planned to establish one warehouse in each division, to improve the storage capacity of the medicines.

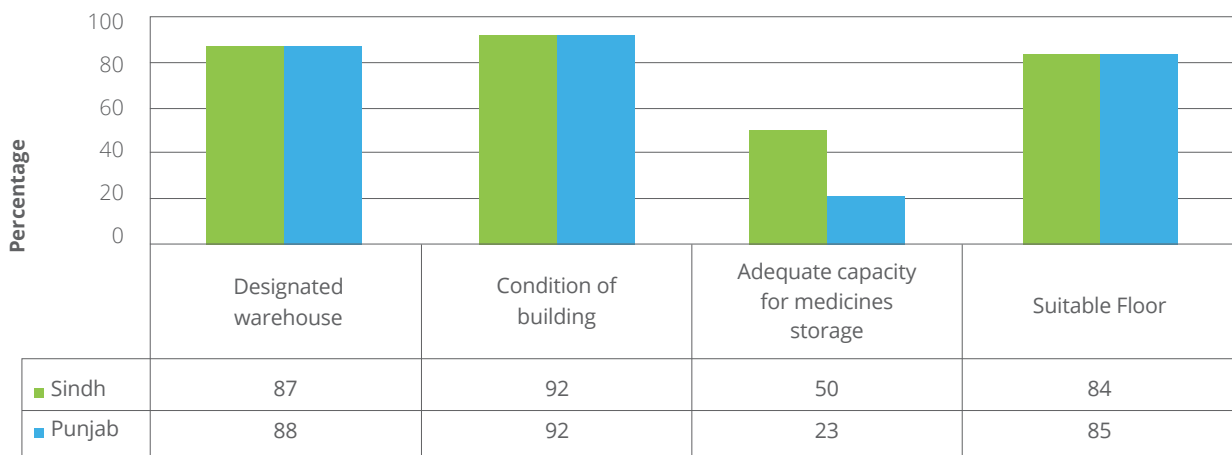
4.2.8.1 Infrastructure of warehouses

The medicinal warehouses have been assessed to provide the baseline information of the storage conditions. Purpose built stores were rare, mostly, rooms were allotted as storage sites. Capacity of store rooms, for the health facilities were not enough to store the medicines as per recommended procedures. The structure of medicines store of district Kashmore Sindh and Rajanpur were not suitable to store the medicines. EDO health, LHW program of Kashmore have arranged a temporary store while Rajanpur is still using the same store. The details are as follow:

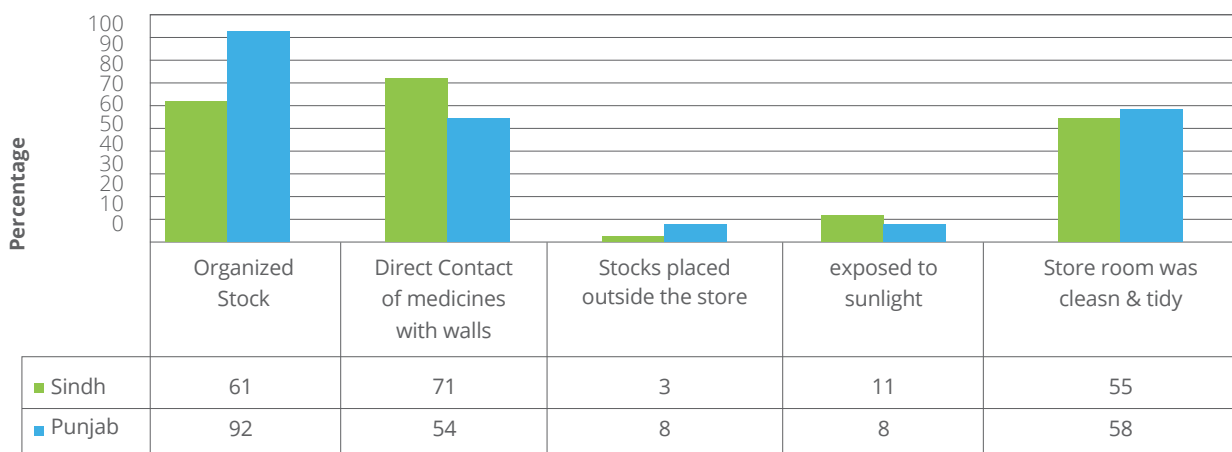
4.2.8.2 Good Storage Practices

The good storage practices, mainly depend upon the available resources and knowledge. The availability of a pharmacist for medicines management is a legal requirement. In Punjab, the Pharmacist are available in DHQ and THQ hospitals, where an additional charge has been given to “District Quality Control officer” who is a pharmacist by profession. The post of pharmacist on central warehouse was not filled. In Sindh, this responsibility is given to DDO or any doctor who is MBBS by profession. The details of good storage practices are as follows,

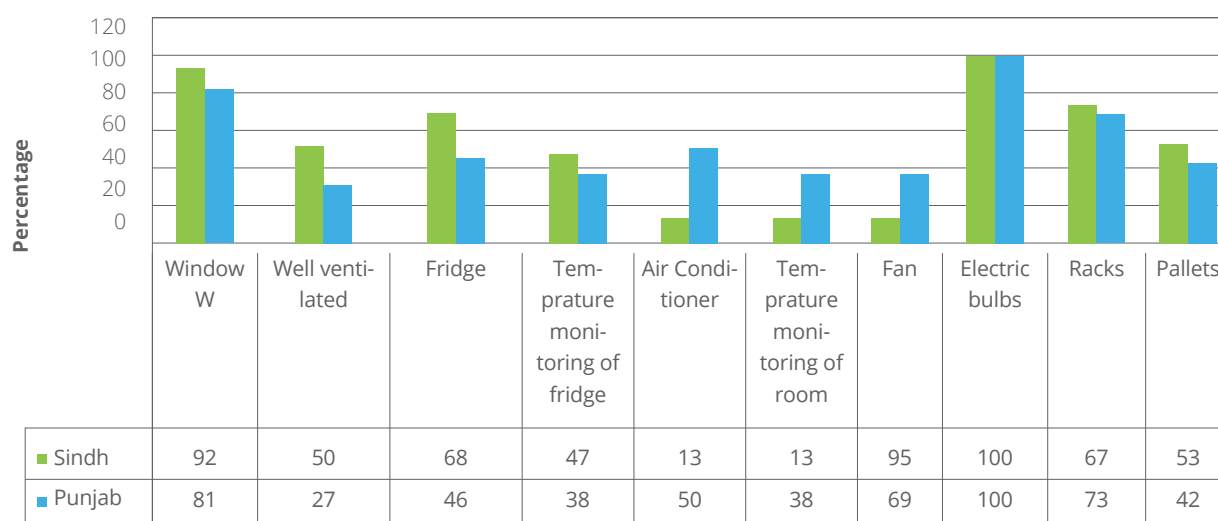
Status of Storage Infrastructure in selected districts of Sindh and Punjab



Stock Handling in selected Districts of Sindh and Punjab



Storage practices in selected Districts of Sindh and Punjab



4.2.9 Section IX: Transportation / Distribution

In Punjab and Sindh, it has been observed, that in the public health department, Supply chain mechanism and transportation of medicines was a challenge. Although, the health department, either arranges vehicle from LHW programs or provides rental vehicles for the transportation of medicines; but such situation could not be handled when there is an emergency stock delivery. The overall expense for the distribution of medicines increased considerably. The techniques to calculate the quantities, that are required to be distributed, were not understood by the store keepers. The quantities of medicines should be calculated on the basis of morbidity to provide complete therapy of a disease. It was observed that the health facilities have ORS in the stock, but Zinc Syrup was not present and if it was available, the quantities were very low. It indicates that morbidity or STG were not taken in considerations before the distribution of medicines. The distribution of vaccine was through recommended vehicle and vaccine carrier boxes.

In Sindh, PPP has arranged the private suppliers. They were responsible to deliver the medicines at district levels. At the district level, the organization managed medicines supplies from the district warehouse to the health facilities. The frequency of medicines supplies was based on the consumption and availability of space for storage, at each level. In the districts, the lead time of supply in PPHI was 2 to 3 days. PPHI, HANDS and IHS have its own vehicles (not specifically designed for medicines transportation) and medicines were distributed in the vehicle; especially, in the districts there were no specific routes for the distribution of medicines.

In Punjab, IRMNCH & NP has solved this issue by contracting a courier service for the supply of medicines. It was reported by the LHWs, that in the past they had to face the issues of medicines delivery. Delay was a common practice. The transportation of medicines through courier has reduced the time of delivery; thus, the medicines will reach its destination in time.

4.2.10 Section X: Organizational support for Logistics system

The organizational support for the logistics activity is an important component for smooth operations of supply chain management system. It was observed, that the communication system among the public health facilities at the district levels was either weak or ambiguous. There were no routine meetings of the logistics staff. Mostly, the communication is through

the submission of reports and/or feedbacks. There was no capacity building of staff to develop the skills for better and more effective supervisory visits. The supervisors have an empathic behavior toward the departmental negligence. During health department's supervisors (DHO, coordinators etc.) visits, the coaching of health facility staff should be arranged. Such frequent coaching should be obligatory because it may help the on-job staff to develop the skills required for their employment.

In Punjab, monitoring of the stock out status was reported by two systems; one was DHIS and second was MEAs. Health department has more trust on MEAs data. The process of medicines forecasting was introduced in e-procurement software which was accessible at regional level. During the medicines procurement meetings at secretary health office, the demands of districts and health facilities were refined, rationalized and submitted to the manufacturers. The argument of health facilities staff, that they receive less quantity of medicines was still not denied. .

In Sindh, The Public health facilities lacked a well-defined system of medicines forecasting. It lead to irrational demand of medicines, and a common argument made by health facility staff was, that they do not receive the quantity of medicines according to their requisitions. Such issues were raised by the health facility staff during the supervisor's visits.

Conversely, the health facilities under the supervision of PPP, did receive the medicines according to their submitted demand. In the public and private partners, the health facilities did regular visits of higher levels, in which Hand on trainings / on job coaching has been done.

4.2.11 Section XI: Product use

All out efforts were made to improve the system, which ultimately, lead to the improvement of the availability of right drug, at right time in right dosage and frequency. Irrational prescribing practices of the physicians may influence the whole efforts that were put in to improve the SCMS.

The WHO always recommends and promotes the rational utilization of the drugs. In SCM, efforts made to promote the rational utilization of drugs are very important. There is a requirement to ensure the availability of STG at the service delivery site, to promote the understanding of STG, and increase the rational use of drugs. During the assessments, it has been observed that one of the major reasons of irrational use of medicines was, the unavailability of first line therapy. Physician has to move on to the second line therapy. It may increase the antibiotics resistance and the cost of therapy.

4.2.12 Section XII: Patient Exit interviews

Total number of caretakers interview conducted were 73. It has been observed that the patients have the understanding of preparation of ORS and on further inquiring an impression was given that they know the preparation of ORS before coming to hospital. The Patients know that they have to prepare the medicines in boiled and cooled water while a small number of patients skipped the word cool. The dose and duration was also understood by the patients, although, some patient have the confusion of daily interval of the administration of medicines.

District	Number of caretakers of patients interviewed	% of patient with correct understanding of	
		preparation of medicines	correct dose and duration
Kashmore	11	91	82
Sukkur	10	90	90
Tando Muhammad Khan	8	88	88
Karachi Malir	7	86	86
Saheed Benazirabad	11	91	91
Muzaffarghar	8	88	88
Rajanpur	8	88	88
Pakpattan	10	90	90

4.2.13 Section XIII: Private clinics and pharmacies

Prescribing practices (as asked from the physicians) was poly pharmacy. Physicians need complete understanding of the use of Zinc. There is no proper method defined for the disposal of clinic / hospital waste. It has been observed that the Zinc dispersible tablet was available in the market of District Pakpattan and Karachi. There was no shortage of medicines in the market especially in Punjab but there was a delay from the manufacturers in supply which indicates that the open market was the first priority area of the manufacturers.



05

CONCLUSION

05

CONCLUSION

1. The health system of Pakistan is now devolved. The supply chain system of medicines is totally provincial subject. It was observed that overall the public health supply chain system in Pakistan was predominantly mixture of “push” and “pull” system. But in case of unavailability of demanded medicines it becomes “Push” system.
2. Successful development and implementation of inventory management software will facilitate the LMIS and the barriers in report submission could be resolved. It will lead to better healthcare service delivery and access to medicine. In Punjab, prescription management information system, linked with LMIS is likely to produce more information for analysis including prescription behavior.
3. Many online links are required to develop LMIS and DHIS integration. In DHIS reports quantities of tracer medicines were not shared. On the other hand, DoH does not have web based / computerized inventory management system. As a result, different master sheets with different SoPs may create difficulties in synchronizing the data, particularly in converting it to useful information.
4. The medicines forecasting and quantification should be based on the WHO recommendations to minimize the stock-outs. The gap of availability of tracer medicines should be covered.
5. The capacity of medicines stores at health facility level are enough for medicines supplies. The staff members who were handling the pharmaceuticals were not capable enough to understand and implement the WHO recommendations. Pharmacists were not frequently available for handling the medicines as per WHO recommendations.
6. The distribution of medicines from district warehouse to health facilities were not based on any forecast criteria. Medicines were not distributed in the form of therapies / courses / kits rather unjustified proportions of medicines were distributed. Department of health do not have suitable vehicles for pharmaceutical transportation which creates hurdle in distribution plans.
7. The process of prequalification of manufacturers was not up to the mark. It does not accurately judge the production capacity of manufacturer due to which medicines were not supplied within the duration of sixty day time period. The delayed supplies, thus, exerts an extra burden on medicines SCMS.



06

LESSONS LEARNED

06

LESSONS LEARNED

The lessons learned from the study are as follows

1. Department of health and vertical programs have their own logistics management information systems which were designed according to their needs. The process of integration of LMIS with revised DHIS will be a challenging activity which require continuous technical and financial support.
2. The process of registration of new generic or formulation with DRAP is time taking process. The national pharmaceutical manufacturers are least interested in production of medicines whose market is not developed.
3. Supply chain activities are interdependent with each other. Performance of one activity affects the others.



07 |

RECOMMENDATIONS

RECOMMENDATIONS

7.1.1 Immediate Recommendations

1. The health facilities should be provided a computerized / android LMIS, for inventory of tracer elements on immediate basis. The data should be compiled on daily basis. The inventory software should be capable to provide an automated stock out reports, expiry calendar, medicines forecasting, distribution and reorders.
2. Based on the morbidity data and stock out reports, the medicines forecasting should use mix method to compare consumption method with morbidity method. Apart from that, the members of the procurement committee, physicians; with strong clinical knowledge and Hospital pharmacist should also be included for data collection and decisions.
3. Immediate steps should be taken for strengthening of DTL of Sindh; for quality assurance of medicines procured for public health facilities.
4. The basic technology and support process for integration of LMIS with revised DHIS should be planned and designed. It should be aligned with continuous financial and technical support for implementation and maintenance. The plan should comprehend data mapping, system synchronization, software updates and customization. It should address other system disruption and stakeholder's communication. The WHO definitions of "opening stock balance", "stock out" and "stock on hand" should be used to create harmony and synchronization of LMIS with revised DHIS.
5. As an interim measure, a master list of health facilities, commodities etc. of partners, stakeholder and others who support the cause for Diarrhea and Pneumonia should be shared and synchronized till the interoperability layer can be added.
6. Based on WHO recommendations, Zinc DT should be used instead of Zinc syrup for the treatment of Diarrhea. WHO recommendations should be followed, in LHW kits, Zinc syrup should be replaced with Zinc DT; along with easy handling of kit, and accuracy of dose will also be increased. It will help to reduce the transportation cost. The stock levels and consumption of Zinc supplement and Amoxicillin suspension should be monitored by LHW program LMIS.
7. The distribution of medicine should be in the form of complete courses or Kits so that the STG should be followed. Medicines transportation system should be outsourced to companies like IRMNCH & NP in Punjab.



7.1.2 Medium term Recommendations

1. The integration process should be launched in the meeting with the stakeholders and should continue to have the follow up meetings on regular basis in order to share the updates. Memorandum of Understanding should be developed among stakeholders for daily data-sharing interface between LMIS and revised DHIS. Stakeholders should be engaged with diverse expertise of clinical health practitioner, pharmacist and statistician representing all the level of health system to develop a knowledge base and make it available on the dashboard.
2. During the consultation with the stakeholders, key performance indicators should be finalized and should be regularly monitored. This can be more helpful for further investigation and integration.
3. In integrated LMIS and DHIS, STG should be incorporated to develop an automated morbidity based method for medicines forecasting.
4. The process of registration of Amoxicillin DT and Co-packaging of Lo-ORS and Zinc DT with DRAP should consider the helpful provision of law; as stated in 2. (v) and 2. (ix). The minutes of 265th meeting of Registration Board case no. 3 i.e. registration of 7.1% chlorhexidine digluconate gel. On submission of satisfactory documents by the firm 7.1% Chlorhexidine digluconate gel has been registered. United States Pharmacopeia (Pakistan) should be involved in the process of registration. It will be helpful for the firm to achieve GMP standards and submission of required stability studies.

7.1.3 Long term Recommendations

1. The software like "Prescription management Information System" has advantages over inventory management system but it should be modified and upgraded to computerized physician order entry software (CPOES) approach. Such software can inform the physician while prescribing medicines about the safety of medicine during pregnancy or lactation, therapeutic dose, drug allergy, side effects, drug-drug interaction, drug-food interaction etc. Adverse Drug Reactions Reports should also be included in it.

2. At DHQs and THQs, the availability of pharmacist showed better SCMS. Considering the number of outpatients or services delivered from RHC, Pharmacist should be provided to look after the pharmaceutical activities and facilitate the nearby BHUs.
3. The capacity of warehouses should be improved by purpose built warehouses or by providing racks suitable for large warehouse. Technical knowledge based on WHO recommendations of “Good Storage Practices” should be given to the warehouse staff for the handling of medicines.



08

ANNEXURES

ANNEX 1: DESK REVIEW

World health organization define logistics has developed from an art of supply and maintenance in to scientific discipline involving the utilization management principles. Logistics for peripheral health facility as provision of activities including planning, budgeting, receiving and inspection, storage, inventory control, supply, distribution and transport, maintenance and repair, communications, environmental management of health facilities, record and reporting, supervision and logistics training [4].

WHO estimates that in Low and middle income countries on an average there is about 35% in public health facilities and 65% in private sector, stated in Millennium Development Goals 2008. In LMIC where the buying power of medicines is very less which creates a barrier in access to essential medicines which led them to private informal sector of medicines especially in rural areas. It has also observed that inappropriate prescription and dispensing of medicines also prevails which also led to the gaps is access of essential medicines [5].

World Health Organization described that one of the key component of the functioning of health system is provision of access to affordable, appropriate and high quality medicines. The access of essential medicines is the outcome of integration of finance, planning, service delivery, and information management and governance system [6].

Pakistan's National Essential Medicines list has been prepared based on the WHO essential medicines list. EDL first version was published in 1995 and subsequently reviewed in 2000, 2003, and 2007 and now latest version has been published in 2016. It consists of 415 total molecules. 23 medicines were added as supplementary medicines which are based on the expert technical group recommendations to provide the wider range of medicines to meet the urgent needs. Selection of essential medicines for the Procurement is based upon the NEML 2016, for conveniences the list of EM has been arranged according to service delivery levels [7].

The access of essential medicines in public health facilities is of the major challenges [8]. The Generic Drug Act was introduced in 1972 to improve the access of essential medicines but it was opposed by the commercial sector [9]. The Drug Act 1976 currently regulates the pharmaceutical sector and is a comprehensive document setting out extensive stipulations for industry licensing, drug registration, quality control etc. However implementation of the act is loosely monitored and creates space for abuse [8]. Due to the weakness of the drug act malpractices of distribution chains has been observed [9] and it is also described in Pakistan Medical and Dental Council 2011 report that due to the absence of the drug act for the promotion of the medicines to the prescriber and its implementation. Receiving of gifts and benefits were not well covered. It has promoted the irrational use of medicines the procurement list of the public sector in Punjab is a Generic list which promotes the healthy competition in commercial sector.

The healthcare department of Punjab has been divided into two departments that is Primary and Secondary Healthcare Department (P&SHD) and Specialized Healthcare and Medical Education Department. P&SHD is responsible for vertical programs and health facilities including DHQ, THQ, RHC hospitals, BHUs and dispensaries. In principal for the procurement of selected essential medicines for the districts DGHS strictly followed the PPRA rules. District Government Punjab authorized the concern Health Department for the procurement of the selected medicines for DHQ, THQ, RHC and BHUs in Punjab and Additional Director Health Services (MS&DC) submitted their demand to DGHS which then advertised the invitation for bids in the Newspaper. DGHS on receiving the prequalification documents select analyze it and select the firm for bids. Than DGHS issued the notification of award/advance acceptance of tender (AAT) and subsequently contract and purchase order against the finalized rates by Health Department after the receipt of performance security in the form of an irrevocable bank guarantee. The upper limit of the ordered quantities should not exceed the demand submitted by DGHS and subsequently advertised in the bidding documents. On receiving the stock DGHS after confirmation of quantities and quality distribute the stocks in districts. The procedures strictly followed the PPRA rules; it is required to see in-depth situation analysis for the selection of medicines for the treatment of diseases, method of forecasting of demand and methodology of distribution of items. In districts purchase committee also exist which also follow the PPRA

rules for the purchase of medicines. The in-depth situation analysis is required to see the policies and regulations for the selection, procurement and distribution of essential medicines at provincial and district levels.

Specialized healthcare and Medical education department has also launched web-based medicines inventory management software which is temporarily share with the hospitals for learning purposes and instruction has been given for the entry of the medicines of local purchase (LP) of each tertiary care hospital at Lahore. Software is of basic level having "Medicines Dashboard" which gives quick access to near expiry medicines. The "Medicines Management" field keeps the inventory record of the medicines batch and expiry wise. It also facilitates the hospitals for transfer of stock from one hospital to another.

Health system of Pakistan provides care to children suffered from diarrhea and pneumonia also through Lady Health workers and Lady Health supervisors (LHS) programs. Even in presence of these services diarrhea and pneumonia causes 27% of all deaths in children under five in Pakistan. In project "Nigraan" a qualitative study has been conducted to explore the role of LHW's and LHS's motivation level in District Badin of Sind province of Pakistan and also to assessed the knowledge and skills regarding iCCM of diarrhea and pneumonia. It has been observed that there was lack of knowledge of diarrhea and pneumonia case management in which lack of knowledge to prepare the ORS was also reported. LHW has also reported that lack of availability of essential medicines and commodities for diarrhea and pneumonia case management is the major reason of their demotivation. They also mentioned that availability of essential medicines will improve their credibility in the community. Medicines management required effective inventory management reporting for the replenishment of the medicines. Feedback provided by the LHWs showed that they were not comfortable with written reports which may be cause hindrance in stock reporting. [10]

According to Multiple Indicator Cluster Survey (MICS) 2014 Sindh described that in diarrhea management many deaths can be prevented by use of ORS or recommended home fluid (RHF) and Zinc Supplementation reduces the reoccurrence of episodes. It has been reported that the overall period-prevalence of diarrhea in children under five years of age is 28.4% while the highest period-prevalence is seen among the children age 12 to 23 months which grossly correspond to weaning period. The care seeking behavior for diarrhea was more common for younger as compare to older children. 72.8% of children age 0-11 months received the treatment from HF compared with 62.6% of children age 48-59 months. Survey report stated that Children under five who received ORS were 54.5% while who received both ORS or RHF and Zinc were 11.6%. In Sindh 14% of children suffered from diarrhea do not received any treatment of diarrhea (MICS 2014, Sindh).

Punjab Public Health Sector Strategy (PPHSS) 2012-2020 stated that the public health facilities of Punjab have issues in supply chain, lack of quantification skills, procurement and budget issues, lack of storage spaces and delay supplies which results in frequent stock outs of essential medicines health facilities. The strategy has sets its goals to make sure that there must be periodic review of Essential Drug List (EDL) and system of essential medicines supplies should be improve at the level that there must be not stock out at BHU, RHC and SHC hospitals. Key performance indicators were also set for the inclusion of Zinc and pediatric formulation of amoxicillin in essential drug list of LHWs.

The use of ORS and Zinc Supplementation was well accepted for the reduction of use of antibiotics. The interventions such as diarrhea pack through community health workers in community settings. The effectiveness of the provision of the diarrhea pack has been reported as effective that it should be scaled up at national level. [11]

The study of Akbar Pardhan described that the Matiari district has sound implementation potential; however, bottlenecks at health care facility and at health care management level have badly constrained the implementation process. An interdependency exists among the constraining factors, such as lack of sound planning resulting in unclear understanding of the strategy; leading to ambiguous roles and responsibilities among stakeholders which manifest as inadequate availability of supplies and drugs at PHC facilities. Addressing these barriers is likely to have a cumulative effect on facilitating IMCI implementation. On the basis of these findings, we recommend that the provincial department of health and provincial Maternal Neonatal and Child Health (MNCH) program jointly assess the situation and streamline IMCI implementation in the district through sound planning, training, supervision, and logistic support. [12] "The Institutional Assessment of UNICEF Supply Division's Forecasting

Process” described in its final report that the demand planning plays a critical role in ensuring that supplies reach the right place, at the right time, in the right quantity and at the right price. Mostly used forecasting procedures are the demand from the government (government request) which comes in the form of bulk orders which stretched the supply chain system. According to the UNICEF report the forecasting of medicines become important component to manage the smooth supply chain operations. The forecasting at government level should be with sufficient timelines to support other SCM operations.

The USAID funded Deliver Project “Supply Chain Evolution” described the framework of the Supply Chain Strengthening of Developing countries Public Health Sector. The project report described that the development and improvement in the supply chain management system of the public sector of developing country it is necessary to describe the existing level of the supply chain management system which ranges from “ad hoc level” to “extended level”. In extended level of supply chain management system the extended stages, health system managers increasingly understand how their system operates, ways to use resources more efficiently, how to manage and align supply chain actors to achieve common goals, and, ultimately, ways to interact more effectively with the broader environment in which the supply chain is situated.

In Pakistan there is considerable work has been done for the policy legislation and regulation of medicines. Access of medicines is included the policy and regulation but still there are gaps that exist in policy and practices. These gaps are due to weak implementation and lack of monitoring procedures. It has also observed that one of the reasons of the lack of implementation on the policies is government traditional tilt of policies towards punitive actions rather than cooption of other stakeholders towards practitioner’s regulation [8] and it has also been observed in the recent drug act given by the Punjab government.

In pharmaceutical market of Pakistan commercial sector is considered as more active in terms of drug information rather than public sectors. It has been observed that on request of the doctors about the drug information from mix of 45 multinational and local companies only 26% letters has been received out of which only 15% met the WHO criteria for optimal drug information center [hafeez and mirza 1999].

The reporting mechanism of Adverse Drug Reactions (ADR) is considerably week. There are many parameters due to which the reporting of the ARD is not sufficient to support promote the drug information. Even in some studies it has been observed that the medical professionals are not well aware of the term or if aware were not know the process of reporting the ADR.

A cross sectional study conducted to identify the influences of the availability of essential medicines for the community management childhood illness in Central Ugrnada has mentioned that the uninterrupted supply of medicines to treat children <5 years with pneumonia, diarrhea and malaria depends on the timely submission of the reports showing the utilization of medicines for the purpose of the replenishment. Innovative ways of monitoring of the stock levels may improve the monitoring and availability of medicines which is an important factor for the community health workers to manage the pneumonia and diarrhea. [13]

In achieving the Millennium Development Goals of UN lack of educated staff is one of the major barriers. The lack of pharmacist is one of the reason to achieve the goals of medicines supply chain management. MSC not under the supervision of pharmacist or even the person having required pharmacy knowledge has caused hurdles in operations of smooth supply chain management of medicines. The training of health personal on essential medicines supply chain management should be done to improve the availability of medicines. [14]

Maintaining of adequate supply of essential medicines at the health facility level is the backbone of the success of management of any particular disease. Maintaining the stock level in the health facility is a challenging task. An innovative idea to monitor the stock and timely and effectively reporting system contributes a lot to support the disease management. A pilot project for the improvement of the essential medicines supplies for the malaria has introduces the mobile text reporting system, named “SMS for life” has worked well to improve the availability of medicines for malaria in health facility. The study reports that good visibility of the stock level’s reports submitted timely has the major factor to reduce the stock-out conditions in the health facility [15]

Health system delivery systems like, Philippines, constantly challenged by the disasters and emergencies where existing laws, national policies and regulations covers critical aspects of medicines management including

quantification, warehousing, distribution, utilization monitoring and disposal of medicines even then due the lacking of the implementation is a hurdle in supply chain management of medicines. The additional supplies of medicines during the disasters increased the intensity of mismanagement [16]. Increasing the quantities of the medicines in the weak supply chain management of the medicines creates more SCM issues. It is necessary to improve the SCM hurdles and bottle necks for the better access of medicines for patients in the health facilities.

The Integrated Management of Childhood Illness (IMCI) was developed by the WHO and UNICEF aimed to reduce childhood morbidity and mortality. In Tanzania it was introduced in 1996 and then expanded to all districts of the country. The cross-sectional study with sample size of 95 healthcare workers described the improvement in the essential medicines supplies and monitoring of utilization has played a vital role in implementation of IMCI services [17]. It is necessary not only to improve the quantities of medicines but also the monitoring of rational utilization. Government of Punjab and Sindh has made many efforts to improve the access of medicines for patients, it is necessary to analyze the rational utilization of medicines.

Access to medicines from health system perspective was studied by Alliance for Health Policy and System Research, World Health Organization. The study states that the most health system strengthening interventions ignore the interconnections between system components specially the complex relationships between the essential medicines and health financing, HR, Health Information and health service delivery were not given sufficient considerations. Findings of the study recommend that the accesses to medicines barriers are complex and interconnected as they occur at multiple levels of health system. A holistic view of demand side constrains with multiple and dynamic relationship between medicines and other health system resources should be applied. It has mentioned that the determinants of access to medicines are in national, regional and international contexts. [18] The objectives of the consultancy will cover the aspects of National, Provincial, District and Sub-district levels of medicines supply chain management. The indicators used for the monitoring covers the interconnections of the SCMS.

The irrational or non-scientific forecasting and quantification of essential medicines leads to loss of medicines by over stocking or expiry or on other hand causes the stock out. This situation has been described by the study conducted in 2014 in Tanzania. It stated that the integrated logistic system was not adequately addressed accountability concerns under the "push" or kit system. The weaknesses of the quantification have led the frequent stock out of antimalarial medicines and ORS. The study proposed the regular reconciliation between the health information system and the medicines delivery system which not only improve the availability of essential medicines but also guide for the interventions for further improvement of access of essential medicines. [19]

Most common method of medicines forecasting is consumption based which is also used in public health facilities of Pakistan. To improve the access of medicines the consumption based methodology should be applied with its all technical aspects. Technical Resource Facility plus (TRF+) has developed the user friendly tool for medicines forecasting and quantification and training for 36 districts of Punjab has been conducted in which DDO, Pharmacist and computer operators were trained. Later Primary and Secondary Health Care Department of Government of Punjab has introduced its computerized logistic management information system and claim that system has ability to forecast medicines. In-depth situation analysis is required to see the efficiency of the forecasting and quantification.

The supplies of essential medicines under the supervision of pharmacist have shown better results. The access of medicines has been improved at rural hospitals of Australia. [20]

According to "Bureau of Statistics of Pakistan" about 22% population of Pakistan use Public health facilities to get health services. The high competencies of the services provided and the availability of essential medicines at health facilities played an important role in the utilization of health services and the as well as to promote the better clinical outcomes. [21]

The SDG 3 presented by UN emphasizes the need of access of quality treatment within the affordable cost. The price of medicines is one of the interventions to control the cost of the treatment. In Pakistan, the prices of hundreds of essential and life-saving medicines have increased greatly, making them unaffordable to residents with low and middle incomes. [22]

ANNEX 2: FINDINGS

1.1 Section I: Policy, Legislation and Regulation

	Indicators	Marks	Sindh	Punjab	Baluchistan	Khyber Pakhtunkhwa	FATA
1	Is there National drug Policy document		Yes, there is a Pakistan National Drug Policy document.				
2	Does the national drug policy contain the written guidelines for donation of the products?		No, the National drug policy has not clarified the guidelines for donation of the products.				
3	Is duty taxes imposed on imported drugs or products		No, the duties and taxes are not imposed on finished good of the pharmaceuticals.				
4	Are donated commodities exempted from duty taxes		<ul style="list-style-type: none"> Yes, the medicines for donation are exempted from duty and taxes. According to the Gazette notification SRO 586(1)/2015. In the exercise of powers, conferred by the section 36. of Drug Act, 1976(XXXI of 1976). Federal Government has exempted the duties and taxes on any drug imported as a donation by any agency from provision of sub-clause (vii) of clause (a) of subsection (1) of section 23 of said act, for a period of one year with effect from 16th April 2015. 				
5	How new product or formulation get registered?		Registration of drug with DRAP is based on the public interest, safety and efficacy guidelines. It also depends on the manufacturing capability of manufacturer who was submitting the documents for the registration of product.				
6	Are there laws and regulations that promote the importation or local production of the health commodities being assessed? If yes, give examples.	1	<ul style="list-style-type: none"> According to Gazette Notification "Any drug to be imported as donation by any agency in Pakistan, is conditionally exempted from section 23(1)(a)(vii) (import, manufacture and sale of drugs/Registration) for a period of 1 year with effect from 16.04.2015 vide SRO. 586 (I)/2015 dated 12.06.2015." Such exemption was notified earlier for a period of 5 years vide SRO. 334 (I)/2010 dated 13.05.2010, for 5 years i.e. 16.04.2005 vide SRO. 439 (I)/2005 dated 12.05.2005 and for 5 years with effect from 15.04.2000 was notified vide SRO. 260 (I)/2000 dated 08.05.2000. 				

	Indicators	Marks	Sindh	Punjab	Baluchistan	Khyber Pakhtunkhwa	FATA
		1	<ul style="list-style-type: none"> The notifications such as [including SRO. 330 (I)/95 dated 19.04.1995, SRO. 218 (I)/90 dated 04.02.1990, SRO. 1124 (I)/84 dated 20.12.1984 (each of 5 years' exemption) was provided on Clientele demand. Drug Act 1976, Chapter 4 "Administration and Enforcement" described "regulation and prohibition of import etc. of drugs" point number 2.b states that the drug or a class of drug specified in the notification shall not be import except by an agency of the Government so specified. Drug Act 1976, Chapter 4 "Administration and Enforcement" described "regulation and prohibition of import etc. of drugs". According to this drug act, only such drug shall be imported which are on sale in the market of any of the Western European countries, USA, Japan, Australia, or any other country as may be prescribed. Production of Amoxicillin DT and Combo pack of ORS plus zinc syrup has regulatory issues of production. 				
7	Are there laws and regulations that hinder the importation or local production of the health commodities being assessed?	1					
8	Are there policies or other restrictions that limit or encourage client access to services or commodities? <i>if no, skip to question 9.a</i>	1	Provincial health strategies encourage the client access to services and commodity availability.				
			The indicator is related to the Drug Regulator Authority of Pakistan and laws are implemented to all, so equal weightage is given to all.				
9	How are policymakers engaged in improving access to health commodities?		By improving the availability of medicines at health facilities (in all provinces) particularly, in Punjab, to inform the public through TV and Print Media. They should be informed about the availability of free of cost high quality medicines at public health facilities. Sindh government, has focused on improving the supplies of medicines and they had planned to establish one warehouse in each division to ensure continuous supplies.				

	Indicators	Marks	Sindh	Punjab	Baluchistan	Khyber Pakhtunkhwa	FATA	
		Marks	<p>In Baluchistan, the procurement of quality medicines has been focused. This goal was achieved by infiltration of spurious drugs. The process was strictly monitored; and information of arresting the culprits has been shared in the papers, to build the confidence of public.</p> <p>The efforts to put more medicines in the supply system at provincial level are as follows</p> <p>Punjab: The primary and secondary healthcare process, a high quality medicines procurement was major focus. The budgetary gap created, due to varied prices of previous manufacturers and currently manufacturers was filled. The temperature controlling system of the warehouses was upgraded, although, a lot of work is still required to maintain the standard. The supply process of IRMNCH & NP has improved. The morbidity of the hospitals were considered. The allocation of the budget for medicines procurement is accurately provisioned. DHQ & THQs, however, were still not satisfied with the distribution of the budgets. Improvement is observed in LMIS, prescription management information system, introduced by Health Information and Service Delivery Unit (HISDU) though computerized software in specialized healthcare department.</p> <p>KP: The medicines forecasting and quantification was focused, and the strengthening of supply chain management system was done through the staffing of logistics.</p> <p>Baluchistan: In order to ensure the procurement of quality medicine, government of Baluchistan, has procured the medicines centrally. These medicines, were later supplied to PPHI.</p> <p>FATA: as per the information shared, that, FATA agencies need strengthening and capacity building in terms of access to medicines. The department has requested UNICEF, to extend its services in FATA, in terms of provisioning of medicines and capacity building</p>					

1.2 Section II: Product Selection

Indicators	LSAT Marks	Sindh										Punjab					Baluchistan	KP	FATA											
		HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHO	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur				IRMNCH & NP	DHOS									
1		1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
a. Is there an essential services package?																														
b. If yes, what services are included?			The services are Immunization, Antenatal, Natal and postnatal Care, Inter-natal care, Prevention of STI and RTI, FP service, Major Micronutrient deficiencies, mental health, screening, outreach services for all levels of health facilities																											
2		1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3		1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
4		1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
5			The criteria for the selection of products are according to WHO guidelines which is disease burden.																											
6			The National Essential List is uploaded on the website of Drug Regulator Authority of Pakistan.																											
7			List is used to prepare the provincial list of essential medicines for health packages																											
8			The selected products are used for the preparation of Central rate contract list in all provinces																											

1.3 Section III: Organization and Staffing

Indicators	LSAT Marks	Sindh												Punjab					Baluchistan	KP	FATA		
		HANDS	I H S	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHOs					
1	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Does the provincial level have a logistics management unit?		<p>Logistics Management Unit (LMU): According to WHO, LMU, is a management structure that can be used to organize, monitor and support all the activities within the logistics system. Through the lens of continuous improvement, LMU can identify the Supply Chain problems, develops solution for those problems and implement those interventions. LMU is an important link between different organizations, levels, and actors within the supply chain.</p> <p><input type="checkbox"/> Sindh: LMUs are available at the district level under the supervision of DHOs. An Integrated LMU at Provincial level is not available, whereas, the PPP of the Sindh has LMUs which are indirectly supporting the government health facilities within their scope of work; as described in their contracts.</p> <p><input type="checkbox"/> Punjab: LMU is available (e-Procurement and Inventory Management Unit) it looks after the procurement and availability of the medicines at the district warehouse, however, it has not been established completely. It was done in order to establish the link and to monitor the work under progress. The rest of Logistics role is served by the district under the supervision of CEO.</p> <p><input type="checkbox"/> Baluchistan: MSD and PPHI collectively provide the responsibility of LMU. The role of MSD is in the procurement of medicines, while rest of all the activities like distribution, inventory management etc. has been done by PPHI.</p> <p><input type="checkbox"/> KP: Logistics management Unit is available and the district level staff is also provided.</p>																					

Indicators	LSAT Marks	Sindh										Punjab					Baluchistan	KP	FATA							
		HANDS	I H S	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur				IRMNCH & NP	DHQs					
		<p>medicines. The technical aspects, like, product selection was done by the MO of health facilities and forecasting by purchase committee under the supervision of DHO. In the Civil Hospitals or DHQs, such activities are under the supervision of purchase committee including Hospital Pharmacist</p>																								
3		<p>Are there documented guidelines for:</p>																								
a. managing and using the logistics management information system?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
b. forecasting quantities needed?	0.25	Y	Y	Y	N	Y	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
c. procurement?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
d. inventory management, storage, and distribution?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
e. product selection?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
f. staffing of logistics positions?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
g. budgeting for the logistics system?	0.25	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
h. supervision and staff development?	0.25	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		<p>The documented guidelines are in the form of official letters, LMIS templates, software information, training documents etc.</p> <p>Sindh: SOP or guidelines for medicines forecasting and quantifications were not provided.</p>																								

Indicators	LSAT Marks	Sindh												Punjab					Baluchistan	KP	FATA
		HANDS	I H S	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shaheed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMINCH & NP	DHQs			
		<p>Punjab: SOP (based on WHO guidelines) has been provided to all districts through PSPU with the support of TRF plus in the form of forecasting and quantification tool. And after the establishment of Primary and Secondary healthcare Department the system has been modified and incorporated in the e-procurement. IRMINCH & NP has recently modified the SCM system and quantities of medicines because LHWs have increased. In future, the Forecasting is planned to be based on the updates of the modified quantities.</p> <p>In Sindh almost all the BHUs are handed over to PPP (except in Shaheed Benazirabad and Karachi), they facilitate the government for the product selection, forecasting, procurement, distribution inventory management, storage, staffing for logistics, financing for logistics and supervision. The government of Sindh procures medicines for THQ / RHCs (not handed over to I H S). As the PPP are facilitating the government so their strengths and capabilities are tend to be reflected as government services.</p> <p>KP: Under the supervision of Procurement and MCC and with the support of TRF plus, the health department has developed the forecasting guidelines and computerized tool while the trainings are planned to be conducted in few months.</p> <p>In Baluchistan and FATA, the convention method of forecasting (consumption based) is used, which does not</p>																			

	Indicators	Marks	Sindh												Punjab					Baluchistan	KP	FATA
			HANDS	I H S	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQs			
6	Do LMIS or other information system reports received at the central level provide information on stock status at the health facility level? Please explain.		<p>The stock status means, that the central-level staff have accurate routine information on which facilities are stocked out, under stocked, adequately stocked, or overstocked</p> <ul style="list-style-type: none"> <input type="checkbox"/> According to the Logistics Management Information system, in the provinces, the health facilities have to submit their monthly stock status to the district office. Which is not a regular practice of many provinces. In routine, the health facility share the stock status at the time of submission of medicines requisition. Stock out status of very essential medicines (tracer elements) through DHIS. <input type="checkbox"/> DHIS: in all provinces report stock out status of tracer medicines <input type="checkbox"/> PPP are regularly (monthly basis) submitting their stock status. <input type="checkbox"/> Punjab: Health facility monitoring through MEAs, also report the stock out of tracer elements. <input type="checkbox"/> Percentage of report submission in Vertical programs was good. The regular follow up of the missing report has made it possible to achieve these results. <input type="checkbox"/> The Logistics report submission in public health facilities was not regular. It is next to the higher level, which was District office. No clear guidelines were provided for the submission of the reports. <input type="checkbox"/> In PPP the submission of report are quite regular. 																			
8	How do managers monitor reporting rates and follow-up to obtain missing logistics reports?		<ul style="list-style-type: none"> <input type="checkbox"/> Percentage of report submission in Vertical programs was good. The regular follow up of the missing report has made it possible to achieve these results. <input type="checkbox"/> The Logistics report submission in public health facilities was not regular. It is next to the higher level, which was District office. No clear guidelines were provided for the submission of the reports. <input type="checkbox"/> In PPP the submission of report are quite regular. 																			

	Indicators	Marks	Sindh												Punjab					KP	FATA					
			HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarhar	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQs							
	b. How often?																									
11	Is the information system automated at the following levels:																									
	a. central?																									
	b. regional?																									
	c. district?																									
	d. service delivery level																									
	If no to questions 11 a–d, skip to 13.																									
12	Briefly describe the functions and processes that are automated. Forecasting of medicines is automated, stock-out reports,																									

	Indicators	Marks	Sindh												Punjab					KP	FATA	
			HANDS	I H S	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHOs			
13	Is external assistance provided to manage the information system? Describe.		Punjab Information Technology Board, has provided IT assistance to developing the inventory management system software and its management.																			
14	Is the information system used to monitor and evaluate the program's performance?		Availability of Essential Medicines (stock out status) is one of the key performance indicators of the program.																			
15	How is logistics data recorded, managed, analyzed, and used at each level?		Detail is mentioned in table # 7.																			
16	What indicators related to logistics and/or product availability does the information system track (e.g., stock out rate, percentage of reporting, rational prescribing practices, etc.)? a. Who tracks these indicators? How often?		The available Information management system is mostly at initial / basic stages of analysis. System is capable for tracking stock outs (at district warehouse level), stock outs of very essential medicines (tracer elements) at the health facility levels and near the expiry medicines in DHQs or civil hospitals of Punjab. DHIS tracks indicators in all the provinces and the districts on monthly basis. Punjab: The Medicines Inventory Management software of Specialized Healthcare services for DHQs and Autonomous hospitals. The data was recorded and uploaded at real time. It has access to the district and regional																			

Indicators	Marks	Sindh												Punjab						Baluchistan		KP	FATA
		HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHOs					
c. district?	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N		
d. service delivery level	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
What feedback mechanisms are in place to channel logistics information back to lower levels?																							
Telephone reports (particular logistics report)	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Meeting	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Supervisory Visit	0.25	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
Are issues data or dispensed-to-user data cross-checked against other data sources (e.g., service statistics, demographic surveys, etc.)?		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		
<i>If no, skip to 22.</i>																							
a. What type of data are they checked against?		PPPs checked stock consumption against morbidity data																					
b. How often are they checked against each data type?		PPPs normally checked before the resupply																					
c. Who is responsible for cross-checking? District medical officer than		Initially the district managers and then at a later stage the regional officers																					

1.5 Section V: Forecasting

Indicators	Marks	Sindh												Punjab					Baluchistan	KP	FATA						
		HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed	Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQs								
1	Describe the forecasting process	<p>In the government system, the Consumption based methodology of forecasting was observed. A complete compliance with the WHO recommendations were not observed in the forecasting process. The process of the forecasting is initiated at the regional level (provincial procurement cell) and the demand of the medicines were requested from the districts. The districts collect the demand of the health facilities in order to compile a report for submission. Based on the information provided in the report the district calculated the final quantities which were further sent for bidding process. Normally, the process is initiated at the start of fiscal year (July to June), and it takes 1 to 2 months for completion.</p> <p>a. Who initiates it? The Provincial department of health, calls for the forecasted quantities for opening of bids.</p> <p>b. When does it take place? June of every month</p> <p>c. How long does the process take? one month</p>																									
2	Are forecasts developed using:																										
	a. dispensed-to-user data? (consumption data)	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Indicators	Marks	Sindh										Punjab					Baluchistan	KP	FATA
		HANDS	IHS	PPII	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarhar	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQS	
5	How close have most forecasts been to actual consumption?	According to the requirement of the assessment the medicines (Amoxicillin, ORS and Zinc syrup) discrepancies observed are mentioned in the table below.																	
6	a. How many products had serious forecasts discrepancies in the past 2 years (+/- 25%)? c. Which products had the smallest forecast discrepancies?	Antibiotics and Analgesics																	
7	What other factors are considered in the preparation of forecasts	<p>It was observed that the ORS has smallest discrepancy.</p> <p>The other factors include; consolidating decentralized forecasts or quantifications, seasonal and regional variations, standard treatment guidelines, national essential drug list, stock-out periods, etc.</p> <p>In Department of health of all provinces, medicines for forecasting were selected from the NEDL. It takes one year stock consumption, which covers the seasonal variations. Normally, 5% of incremental is added in consumption of last year quantities. More incremental are added for medicines which remained out of stocks.</p>																	

Indicators	Marks	Sindh												Punjab						Baluchistan	KP	FATA					
		HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQS									
8	1	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y		
<p>The medicines required for the expansion of the programmatic plans were considered in forecasting. This consideration is based on the availability of the budget.</p> <p>In PPP, such decision like expansion of the health facilities, at all times, facilitate the increase in supply of the medicines.</p>																											
9	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PPP has not taken any external assistance / TRF /the delivery for the contraceptive, vaccine and TB																											
10		Lower level (health facilities) provides the data that is compiled for further processing.																									
11		The private sector do not participate in forecasting activity.																									
12	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Indicators	Marks	Sindh														Punjab				Baluchistan	KP	FATA
		HANDS	I H S	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHOs				
<p>b. If yes, who does this and how? And C. How effective has this monitoring been? Explain.</p>		<input type="checkbox"/> PPP it is the Procurement and logistics team. Mostly, PPP has established prequalified suppliers, who are responsible to supply the product in time. If there is delayed from manufacturer, they buy it from distributor or from retails to ensure in time supply. <input type="checkbox"/> Sindh In Sindh, at the district level, the procurement cell is present for each district. Whereas, in vertical program, the procurement cell is working at regional level. At DHQ hospitals the pipeline status is monitored by Pharmacist. <input type="checkbox"/> Punjab The Procurement cell monitor these activities on weekly basis at secretary office, in which DHO, Manufacturer, DTL and central procurement cell participate. IRMNCH & NP Logistics and procurement cell. While in DHOs the status is monitored by Pharmacist. <input type="checkbox"/> Baluchistan, KP and FATA status is monitored by procurement Cell.																				
11. Does the procurement unit or persons responsible for procurement in which a) write and issue tenders? B) evaluate the bids c) monitor supplier performance		Yes, in the public sector and PPP the procurement cell is responsible for the issue tenders, evaluate bids, and monitor supplier performance.																				
12. Does the program have written procedures for ensuring that products meet defined standards		The Programs have written procedure for the inspection of the quality of medicines supplied by the manufacturer. They perform physical verifications of the supplied stock. The procurement committee monitors the quantities supplied by																				

Indicators	Marks	Sindh												Punjab					Baluchistan	KP	FATA
		HANDS	I H S	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajampur	IRMNCH & NP	DHQs			
		the manufacturers as well as required laboratory confirmations of quality. Samples of all batches supplied by the manufacturer were sent to the government drug testing labs. On the basis of satisfactory report of the lab, the department can issue and distribute the medicines.																			
13	What are the procedures for quality assurance, who is responsible for it, and how often are they done?	According to the procurement rules, there is a requirement of quality assurance report from the government analytical lab, to ensure the quality of each batch of medicines procured. The Drug Inspectors are responsible to collect the samples of the medicines procured and submit for quality analysis.																			
14	Is there a procedure for recording and reporting complaints about product quality to suppliers? Please explain.	In case of any quality issue, the manufacturer is responsible to replace the medicines and the government has legal rights to prosecute the supplier, if required.																			
15	What other actions are carried out to ensure product quality?	Prequalified firms / manufacturers																			

Indicators	LSAT Marks	Sindh													Punjab				Baluchistan	KP	FATA			
		HANDS	LHS	PPH	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shaheed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQS						
12	Note the approximate quantities of products that expired within the past two years.	The details has been mentioned below tables 11, 12 and 13																						
13	13. Does the program have a system for tracking product losses and other adjustments?	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
14	a. Are there significant losses and adjustments?	The government system has the provision of damage and adjustment but number of reports of damaged and losses were not reported apparently to avoid the investigations. Due to less reporting the system has limitations to improve in such situations																						
15	How does each level of the system calculate resupply quantities?	<p>The District Level: The district implements the consumption based method of forecasting. The order level depends on the demand of health facilities and availability of budget.</p> <p>Service delivery Level: The resupply quantities are calculated consumption based methodology (not consideration of all the WHO recommendations) The health facilities with PPP receive the medicines in 2 to 3 days while the government health facilities when required collect the medicines (depending upon the availability of medicines) from district.</p>																						
16	Have stock outs occurred for any product in the last 12 months at the following levels:	Details of the stock out status have been mentioned in below table.																						

Indicators	LSAT Marks	Sindh											Punjab					Baluchistan	KP	FATA	
		HANDS	LHS	PPH	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shaheed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQS			
		<p>availability. NP: through LHS, the report to the District Coordinator, later he supplied the stock in monthly meeting. In case if unavailability of the medicines, the regional level office are requested for medicines supplies. This process is completed within 2 to 3 days. PPP provides the required medicines within 24 hours to HFs.</p> <p>Punjab: In the case of emergency the order (medicines requisition) is directly placed to the District office. The stock is issued on the same day, depending on the availability of the stock. IRMNCH & NP Punjab handles emergency order of LHWS through courier service. Total time taken from placing an order to receiving of order may take 3 days. The efficiency of courier system should also be monitored.</p>																			
b. How successfully are emergency orders filled for the following levels?		<p>In tertiary care hospitals, if medicines are in central rate list and the order has been placed to the manufacturer, they cannot procure the medicines from the LP. The delays from the manufacturer create issues.</p>																			

1.8 Section VIII: Warehousing and Storage

Indicators	Marks	Sindh										Punjab					Baluchistan	KP	FATA					
		HANDS	IHS	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQs						
1	1	Y	Y	Y	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	N	N	N			
2	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			
3		Does the program conduct at least one physical inventory of all products annually at storage facilities at the following levels:																						
	0.33	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
	0.33	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	A	Y	Y	Y	Y
	0.33	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
		LHW program Sindh: The District coordinator check the physical stock of LHS placed at health facilities during his/her visit: IRMNCH & NP Punjab: As the stocks directly moves from Provincial warehouse to LHW. Then there is no physical stock at district level. In HF, the custodian of stock is the store keeper and the In-charge of health facility, they randomly verify the physical stocks.																						

Indicators	Marks	Sindh												Punjab					Baluchistan	KP	FATA				
		HANDS	IHS	PPII	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	Pakpattan	Rajapur	IRMNCH & NP	DHQs							
4	Are there cold chain requirements in this supply chain?	<p>In Sindh, the vaccine has been used for the preventive approach of Diarrhea and pneumonia. In EPI 9, the vaccine preventable diseases were included (Polio, Hep-B, Meningitis, Measles, Diphtheria, TB, Tetanus, Pneumonia, pertussis while diarrhea due to Rota virus). The vaccine for Rota virus was also under discussion. The cold chain is required for the above mentioned vaccines. The storage conditions for the vaccine are much better than the routine medicines.</p> <p>Punjab: The cold chain rooms were available at the provincial and district levels. At health facilities ILRs were provided.</p> <p>The cold chain storage resources for vaccines were available at all levels. This includes cold chain rooms, special vehicles for transportation, ILRs, ice packs and vaccine carrier boxes.</p> <p>All the refrigerator provided were not equipped with thermometers, temperature log sheets etc. guidelines are available for the vaccines storage only.</p>																							
5	Are cold chain storage resources (e.g., refrigerator, paraffin/kerosene, and temperature chart) available at all levels of the system, where appropriate?																								
6	How is the cold chain monitored to ensure that products are consistently maintained at appropriate temperatures? (Check all that apply.)																								
7	Is the existing storage capacity adequate to handle the current quantities of products at the following levels:																								
	a. regional?	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N
	b. district?	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N

Indicators	Marks	Sindh												Punjab			Baluchistan	KP	FATA			
		HANDS	IHS	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Malir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQs				
d. service delivery point? Hospital waste management practices in the Sindh	0.33	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		<p>The Sindh Health Department, constituted a seven-member provincial committee to implement the Sindh Hospital Waste Management Rules 2014 and to ensure the provision of safe drinking water at public and private hospitals in the province. According to a notification by the health department, the committee was formed to formulate a strategy and to implement hospital waste management plans of all public and private hospital in the province in the light of the rules. The panel will supervise the district sub committees for the implementation of the hospital waste management rules.</p>																				

1.9 Section IX : Transportation / Distribution

	Indicators	Marks	Sindh												Punjab				Baluchistan	KP	FATA					
			HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajampur	IRMNCH & NP				DHQS				
1	How are products delivered between each level of the system (include frequency and means of transportation)? Specify between which levels. How are routes determined?		In the government designated vehicle, used for the medicines distribution were not available. But when a private vehicle is arranged for the distribution of medicines and the cost is paid by the district health office.																							
2	Do written procedures specify what type of distribution system should be used to distribute products between each level?	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
			The procedures for the transportation of vaccines has been clearly described and well understood by the service providers.																							
3	3. Is there a documented distribution schedule for all levels?	1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
			In the districts of Sindh and Punjab, a proper schedules is prepared for the distribution of medicines. These schedules were helpful in managing the workload of the warehouse. IRMNCH & NP program, in Punjab, is now distributing medicines through courier service. In DHQ , the distribution of medicines is by the sub-pharmacies and that is according to the set schedules.																							

indicators	LSAT Marks	Sindh										Punjab					Baluchistan	KP	FATA						
		HANDS	IHS	PPHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQs							
communication?		responsibilities was normally shared. Updates of budget release, medicines procurement plan, any new instruction, change in law or reporting mechanisms were shared in the routine meeting.																							
3 Is there a supervision system that covers logistics activities?		Monitoring of tracer elements at BHUs and RHC through MEAs facilitate the physical count of medicines and the online software of DHQ facilitate the inventory management in Punjab, the reports of stock out status shared in DHIS reports in all the provinces will facilitate the availability of the essential medicines.																							
4 How often is supervision conducted at the service delivery points?		In all public health facilities, apart from the external monitoring or reporting by MEAs, the health facility in-charge is responsible for first level of supervision of all the logistics activities. Any report / document submitted by Pharmacist at DHQ or to the store keeper from BHU or RHC is verified by the health facility incharge. The Vertical program is monitored by the District coordinators.																							
5 Is there a process in place for improving any gaps in the knowledge and skills of logistics personnel at the following levels? If yes, please describe process.																									
b. regional?	0.33	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N		
c. district?	0.33	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	
d. service delivery point?	0.33	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	
6 Are there written procedures and guidelines (e.g.,	1	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

indicators	LSAT Marks	Sindh												Punjab				Baluchistan	KP	FATA					
		HANDS	IHS	PPII	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP				DHQs				
d. service delivery point?		At the health facility levels, the size of stores are insufficient. The Pallets and racks are not provided in sufficient quantities. And also the bags for the dispensing of medicines.																							
a. Is external assistance (from other NGOs, donors, or partners) used to complete management and supervision activities?		The Monitoring and Evaluation Assistance (MEA) has facilitated the department of health in getting the stock status of very essential medicines. UNICEF and WHO facilitate in monitoring of vaccination (utilization of vaccines) stock status etc.																							
10 Are supervisory responsibilities described in written job descriptions?	1	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	N	N	N	
11 Are guidelines available for how the supervisor is to conduct the supervisory visit	1	No guidelines were available for the supervisor that describes him how to conduct the supervisor visits. How to create two way communications.																							
12 Are tools available that describe what to cover when conducting a supervisory visit specifically for logistics monitoring	1	Y	Y	Y	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
		Supervisory tools for the monitoring of vaccine storage MEAs tool of monitoring of health facility DHIS indicators give the information of stock out status.																							

indicators	LSAT Marks	Sindh										Punjab				Baluchistan	KP	FATA			
		HANDS	IHS	PHI	Kashmore	Sukkur	TM Khan	Tharparkar	KHI Mallir	Shahed Benazirabad	National Program	DHQ	Muzaffargarh	Bahawalnagar	pakpattan	Rajapur	IRMNCH & NP	DHQs			
inventory?																					
e. review logistics records and reports?																					
f. discuss budgeting for logistics activities?																					
g. review changes made since last supervisory visit?																					
h. on-the-job training to improve job performance?																					
i. discuss what is working and what is not working?																					
j. discuss what help is needed (staff, equipment, forms, etc.)?																					

The review of the stock registers, daily expense register, bin cards, medicines requisition records, were always reviewed.

It was reported that the discussion on budgets was more among the provincial and district level staff.

Anything which was under the control of health facility staff and supervisor, if it is considered as a negligence or the area for improvement; then these areas were shared and discussed in next visit. The supervisory visits at the health facilities, under the supervision of PPP were more frequent, so the impact of any observation made during the previous visit, helps to bring more chances towards improvement of the processes.

Anything that can be explained or demonstrated within the limited time was discussed in the visits.

During the supervisory visits of the public health facilities, anything not working well was reported. However, if the issue was from the departmental side, empathic behavior was adopted. The issues, like, storage conditions etc. were discussed with higher officials during high level meeting.

Any help, like, requirement of the stock register, daily expense register, bin cards were immediately resolved.

	indicators	LSAT Marks	Sindh	Punjab	Baluchistan	KP	FATA
16	Is there a documented schedule for supervision?	1	HANDS H S PHI Kashmore Sukkur TM Khan Tharparkar KHI Mallir Shahed Benazirabad National Program DHQ	Muzaffargarh Bahawalnagar Pakpattan Rajapur IRMNCH & NP DHQs			
			<i>If no, skip to question 21.</i>				
17	a. Are supervisory visits conducted according to the established schedule? If not, why not? b. How often do they take place?		In PPP, the supervisory visits were conducted according to their schedules. The other scheduled visits were also reported, if required.				
18	Are there any constraints to conducting supervisory visits?		In Sindh and Punjab, the major constrain of conduction the supervisory visits is the limitations of HR, availability of vehicle and POL.				
19	If a staff member's performance in logistics is not satisfactory, is the person provided with trainings?		The public sector, it was observed that the components of capacity building was not scientifically focused. It mostly depends on the trainings organized by the NGOs. No periodic staff development program by the health departments was organized.				
20	Has training been given to current staff at all appropriate levels, in the following areas:						

ANNEX 3

PROCEDURE FOR REGISTRATION OF DRUGS

1. Drugs Act, 1976 regulates the import, export, manufacture, storage, distribution and sale of the drugs. Drugs are registered under section 7 of the Drugs Act, 1976. Registration Board is authority for registration of drugs.
2. The Registration Board has been setup under section 7 of the Drugs Act, 1976. The Registration Board is comprised of 17 highly technical, professional and experienced members from Medical, Pharmaceutical, Biologicals, Pharmacy, Veterinary, Law (from Law & Justice Division), Drug testing, relevant Directors of DRAP and representative of Intellectual Proprietary Organization. Representatives of stake holder's i.e. Pakistan Pharmaceuticals Manufacturer Association, Pharma Bureau and Pakistan Veterinary Manufacturer Association are included in the Drugs Registration Board as observers. Composition of Registration Board is laid down under rule 24 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 framed under the Drugs Act, 1976.
3. Rule 26 & 29 of Drugs (Licensing, Registering and Advertising) Rules, 1976 prescribe procedure for grant of registration as follows:-
 - (i) An application for registration of a drug shall be made in Form 5 (for local manufacture), 5-A (for imported drugs), 5-D (for new molecule) or Form-E (for Patent Drugs) accompanied by fee in duplicate to the Registration Board addressed to its Secretary, and separate application shall be made for each drug.
 - (ii) The applicant shall furnish such further information and material as may be required by the Registration Board for proper evaluation of the drug.
 - (iii) The Registration Board may, if it considers necessary, cause the application for registration and the information and material supplied to it to be evaluated by a Committee on Drugs Evaluation consisting of experts related to the aspect of the drug (Expert Committee on Biological Drugs for biological drugs and Veterinary Expert Committee for veterinary drugs constituted under Section 10 of the Drugs Act, 1976) to be evaluated and obtain its report.
 - (iv) The Registration Board may, before issuing a registration, cause the premises in which the manufacture is proposed to be conducted to be inspected by itself or by its sub-committee or by a panel of Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardizing, if necessary, and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff employed. Where inspection is carried out by a Sub-Committee or panel of experts or Inspectors appointed, it shall forward to the Registration Board a detailed report of the result of the inspection.
 - (v) The Registration Board shall, before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, require the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions: Provided that under special circumstances to be recorded in writing, the Registration Board may register a drug and require such investigations and clinical trials to be conducted after its registration.
 - (vi) A new drug, where new method of manufacture is contemplated or a change is proposed in source, standard or specification of the active ingredient or the finished product may not require full investigations

and clinical trials except in so far as they are necessary for the purpose of establishing bio-equivalence, absorption, acceptability or other such features.

(vii) For imported drugs, GMP inspection of foreign manufacturer is also carried out prior to grant of registration. Experts in the relevant field inspect the foreign manufacturer to ensure that manufacturer fulfills the current Good Manufacturing Practices. However, pharmaceutical / biological products approved by United States Food and Drug Administration (USFDA), World Health Organization (WHO), European Medicine Agency (EMA) or regulatory bodies of Japan, Australia, Health Canada, Switzerland any of the regulatory bodies of erstwhile Western Europe or three stringent regulatory bodies of erstwhile Eastern Europe shall be exempted from the inspection of the manufacturing unit abroad.

(viii) If the Registration Board, after such further enquiry, if any, as it may consider necessary, is satisfied of its safety, efficacy, quality and economical value or where the public interest so requires, it may register the drug and issue a certificate of registration in Form 6, subject to such specific conditions as it may specify.

(ix) Where it is necessary in the public interest so to do, the Registration Board may register a drug on its own motion without having received any application for registration.

(x) If the Registration Board is not satisfied as to the safety, efficacy, quality or economic value of a drug, or where the public interest so requires it may reject the application for registration and inform the applicant of the reasons for such rejection in writing.

(xi) The Drugs Registration Fee vide S.R.O 1117(I)/2012 is as follows:

		Fee (Rs.)	Renewal Fee (Rs.)
(a)	New drug or molecule / drug not manufactured locally	50,000/-	20,000/-
(b)	Any other drug for import	100,000/-	20,000/-
(c)	Drug for local manufacture	20,000/-	10,000/-
(d)	Drug for import	---	40,000/-
(e)	Drug for local manufacture	---	20,000/-
(f)	Variance to registration application i.e. changes in inactive raw materials, method of manufacture, testing methods or quality specifications, product specification, packing materials including changes of labeling specification etc.	5,000/-	---

09 | REFERENCES

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